

## **Final Guidance to Registrants on Activities to Improve the Efficiency of ESA Considerations for New Outdoor Use Registrations of Conventional Pesticides and Biopesticides**

The Pesticide Registration Improvement Act of 2022 (PRIA 5) requires the Environmental Protection Agency (EPA) to “develop, receive comments with respect to, and finalize guidance to registrants regarding analysis necessary to support the review of outdoor uses of pesticide products under the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1530 et seq.).” Accordingly, this document provides guidance on actions that applicants/registrants (hereafter “applicants”) can take to make more efficient EPA’s development of effects determinations for applications for new outdoor uses of active ingredient registrations decisions for conventional pesticides and biopesticides. The information in this guidance reflects lessons EPA has learned over the past several years as it continues to make progress towards meeting its ESA obligations.

PRIA 5 also required that the EPA develop ESA guidance to applicants for new active ingredients or registration review decisions of products with one or more outdoor uses for conventional pesticides and biopesticides that have outdoor exposures. While under PRIA 5, a new active ingredient application and a new outdoor use are different actions, the underlying ESA analyses for evaluating listed species are fundamentally similar. Therefore, the information contained in this guidance is largely the same as that contained in the PRIA 5 guidance for new active ingredients and registration review<sup>1</sup>. The only difference is a discussion of minor use crops in the section titled “Identify the Action Area.” EPA included this discussion in this final guidance because new use applications often contain minor crops.

This document does not create new requirements for applicants, and it is not meant to bind applicants or to convey additional data or analyses, as set forth in 40 CFR Parts 152 and 158, that applicants must submit to support pesticide registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This guidance is also not meant to define the process or tools EPA will use to conduct ESA analyses for new outdoor uses of active ingredients (sometimes referred to as AIs). The concepts laid out in this guidance can help applicants assist EPA in improving the efficiency of new outdoor uses of active ingredient registration determinations and are expected to better inform EPA’s ESA analyses. These recommendations are intended to help applicants address potential effects to listed species for new outdoor uses for active ingredients, including proposing mitigation measures as part of the application package.

This guidance is not meant to prompt applicants to conduct risk assessments or effects determinations for EPA. EPA would likely not consider such submissions while conducting its own analyses. EPA is responsible for conducting risk assessments and making effects determinations. Given the complexity of such analyses, EPA would have to divert substantial resources to review applicant-submitted assessments. Those resources would be better spent performing EPA’s own evaluation based on the best available data. Therefore, providing applicants with guidance on how to develop assessments to submit to EPA would be counterproductive. However, as described in this guidance, while EPA is not asking applicants to conduct or submit biological evaluations (BEs), some elements included in a BE, such as interpretation of intended use patterns, identification of taxa at risk and basic overlap analyses, may be helpful for applicants to better understand potential effects to listed species and address them

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<sup>1</sup> [PRIA 5 Guidance to Registrants on Activities to Improve Efficiency of ESA for new AIs and registration review](#)

early in the regulatory process. This guidance is meant to better inform applicants of potentially needed mitigation that they can commit to for a more efficient completion of effects determinations for new outdoor uses of active ingredients. This guidance also notes some opportunities within the regulatory processes for discussions with applicants to help inform such analyses. Currently, the process of conducting BEs and identifying and evaluating proposed mitigations for listed species has been time and resource intensive due in part to the iterative nature of discussions about the need for further mitigation with applicants. The need to consider several rounds of applicant-proposed mitigation options has led to EPA needing to conduct assessments multiple times for the same proposed use pattern(s). To the extent applicants include earlier in the process, clear, actionable, and appropriate mitigations that are consistent with the protection goals of the ESA the number of subsequent mitigation proposals that need to be evaluated can be minimized. Thus, EPA would not need to conduct its analyses multiple times, which would allow EPA to provide more timely decisions. Applicants are encouraged to review previous pesticide decisions that are relevant to their situation and that address ESA to help determine the extent of mitigations that may be warranted in their particular case.

### **1. What is EPA required to do under the ESA for its pesticide actions?**

The ESA requires that federal agencies ensure the actions they authorize are not likely to jeopardize federally threatened or endangered (listed) species or adversely modify designated critical habitat for listed species. Species are listed as endangered or threatened by the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (jointly, the Services). To meet its obligations under the ESA and its implementing regulations,<sup>2</sup> EPA must first conduct effects determinations for certain pesticide regulatory actions and, if EPA determines that the proposed action may affect an individual member of a listed species or critical habitat, initiate consultation with the appropriate Service(s). If EPA determines that the proposed action is not likely to adversely affect (NLAA) a listed species or critical habitat, EPA initiates informal consultation with the appropriate Service(s). If EPA determines the proposed action is likely to adversely affect (LAA) listed species or critical habitat, the Agency initiates formal consultation with the appropriate Service(s).<sup>3</sup> EPA then implements protections identified during the consultation, as specified in biological opinions (BiOps) issued by the Service(s), which may include addressing reasonable and prudent alternatives (RPAs) intended to avoid jeopardy and reasonable and prudent measures (RPMs) intended to minimize take.

EPA is not required to predict if a pesticide may jeopardize a species or adversely modify critical habitat (jeopardy and adverse modification are referred to as J/AM). Making these determinations is under the purview of the Services. However, the ESA's implementing regulations (known as the counterpart regulations at 50 CFR Part 402, Subpart D) provide authority for EPA to predict the likelihood that a proposed action may result in J/AM. EPA is making such predictions more routinely and taking measures to avoid J/AM when it predicts there is a likelihood of J/AM to help expedite consultations and to protect listed species that may be at risk of a J/AM determination sooner in the registration and consultation processes. Where EPA takes on this analysis, it would predict a future jeopardy determination if an action is reasonably expected to (1) appreciably reduce the survival and recovery of

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<sup>2</sup> 50 CFR Part 402; specifically, 50 CFR Part 402, Subpart D, includes counterpart regulations for pesticide consultations under FIFRA.

<sup>3</sup> EPA uses the counterpart regulations for formal consultation. 50 CFR Part 402, Subpart D.

a listed species in the wild by reducing the reproduction, numbers, or distribution of a species or (2) destroy or adversely modify designated critical habitat.<sup>4</sup>

## 2. What is the Role of the Services?

As a result of the consultation process, the Service(s) may issue a BiOp, which evaluates the potential for J/AM of listed species. If the Service(s) find that the proposed action is likely to result in J/AM, the Service(s) include RPAs in their BiOp. Additionally, BiOps include RPMs to minimize the potential for incidental take<sup>5</sup> of listed species, irrespective of any determination of likely J/AM. Take as defined under the ESA means "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct."<sup>6</sup>

As described in EPA's Pesticides ESA Workplan, "Balancing Wildlife Protection and Responsible Pesticide Use (April 2022)<sup>7</sup> and its ESA Workplan Update (November 2022),<sup>8</sup> one of EPA's main goals is to improve approaches to identifying and requiring ESA protections to address the likelihood of J/AM and "take" during registration rather than waiting for consultation with the Services to conclude, which can take years. We expect that these early mitigations will improve the efficiency of the consultations.

## 3. Activities the Applicant/Registrant Can Elect to Take to Inform Mitigations

The following are recommended actions applicants can take to better inform potential mitigation measures that can be submitted with their application for a new outdoor use of an active ingredient registration for conventional and biopesticides. In turn, this would enable EPA to conduct effects determinations and address potential J/AM more efficiently. Recommended actions for applicants to consider are described below and include:

**Identify the action area** to ensure that the proposed action is consistent with the intended use pattern supported by the applicant. This step may include a careful review of proposed or existing labels to determine whether to continue to support uses that might impact listed species without changing use directions on labels to reduce potential exposures to those species.

**Identify routes of exposure** that may affect listed species to help identify relevant pesticide exposure and transport pathways for mitigation.

**Perform initial spatial overlap** of the species' range and pesticide use area to identify and modify, if necessary, the scope of the ESA evaluation required to support the pesticide new use registration application.

**Identify mitigation measures** informed by the three previous elements and by other strategies that are under development. Applicants are encouraged to include in their application packages

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<sup>4</sup> Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

<sup>5</sup> Unintentional harm or death of even one individual of a listed species

<sup>6</sup> <https://www.fisheries.noaa.gov/laws-and-policies/glossary-endangered-species-act>

<sup>7</sup> <https://www.fisheries.noaa.gov/laws-and-policies/glossary-endangered-species-act>

<sup>8</sup> <https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf>

mitigation measures that are a result of the various strategies that are under development as they are finalized (e.g., herbicide strategy) and include a reference to the Bulletins Live! Two (BLT) system using the most recent language per the Interim Ecological Mitigations (IEMs). These should be discussed before submission of the new use for active ingredients and integrated into submitted labels, when feasible.

**Address risks associated with all active ingredients** included in pesticide product(s).

Each of these elements are described further in the following sections of this document. EPA also reminds applicants to submit robust application packages that satisfy all applicable data requirements under 40 CFR Part 158. Also, if applicants generate data to support pesticide applications to other regulatory bodies such as toxicity data on beneficial insects, alternative bird or mammal species, and data on environmental degradates, then those data may also help EPA conduct or refine its BEs.

**a) *Identify the Action Area***<sup>9</sup>

The action area represents the geographic footprint of the proposed or approved uses. In general, more uses or proposed uses results in larger geographic footprints, which increases the chances that the pesticide use may overlap with listed species ranges and/or their critical habitat and increase the extent of that overlap. Moreover, certain uses tend to potentially overlap with greater numbers of listed species than others. Therefore, EPA suggests applicants propose use patterns that they intend to support and market in the United States. EPA is **not** discouraging applicants from submitting application packages that address important pest control needs. EPA does not, however, want to delay registration decisions because it is evaluating uses that are not intended to be marketed or may not be useful to growers. EPA also encourages applicants to identify the intended use sites with as much precision as possible. For example, the difference between ‘trees’ and ‘managed Christmas trees’ from a spatial context is substantial. However, if flexibility is important for a particular use pattern, then a broader description of use sites may be appropriate.

The action area also incorporates areas where offsite transport is reasonably likely to occur. For example, if there is a potential for off-target pesticide movement with air (drift/volatility), soil erosion, or water (runoff or movement downstream), without proposing an adequate buffer or other mitigation to address issues associated with pesticide movement from these mechanisms, the action area will likely be substantially larger due to a larger spatial footprint that could overlap with listed species and critical habitats (these routes of exposure are discussed further in the following section of this document). Therefore, proposing mitigations early in the registration process to address off-target movement can potentially reduce the geographic extent of the action area thereby reducing the number of species within the action area.

Minor uses or other specialty crops may have a more limited spatial footprint which will influence the extent of potential exposure and the likelihood of potential impacts to listed species. While not required, additional information on the spatial extent of these crops or uses could be useful to better understand and potentially refine the overlap between the actual use site and a listed species range

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<sup>9</sup> The action area includes all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action [50 CFR §402.02]

and/or critical habitat. Voluntary submission of such information should include sufficient detail to allow EPA to perform an independent analysis of data quality and utility in that it can be easily incorporated into the current processes used by the agency.

***b) Identify What Routes of Exposure Potentially Affect Listed Species***

As described above, the action area can be influenced by the fate properties of a pesticide, the proposed product formulation, and the directions for use (e.g., what application methods are allowed or prohibited). A pesticide may leave a treated field and enter off-site habitats during application with wind (spray drift) or after application with moving water (runoff), soil (erosion), or air (volatility). Applicants should take note of the physical and chemical properties, such as mobility, bioaccumulation, vapor pressure, solubility in water, and degradation rate (persistence) because these factors influence how and to what extent a pesticide may leave a treated area. Proposed application equipment such as air, ground, or backpack, and formulation type such as granule, treated seed, or soluble spray are important as they influence potential exposure routes and potential for spray drift and runoff, as well as off-site movement of pollen and/or plant tissue for plant incorporated protectants (PIPs) for biopesticides. If the pesticide will move beyond the targeted site for the uses in question, these factors may increase or decrease the action area. This information can assist applicants in identifying primary routes of off-site exposure to a habitat of a listed species so that applicants can identify mitigation measures to keep the pesticide on the field to the extent feasible. Note that for some species, on-field exposure may also be an important source of pesticide exposure that may also need to be addressed.

Applicants should also consider the toxicity of the pesticide to various taxa. The more toxic a pesticide is to a particular taxon, the more potential for direct effects to that taxon when exposure occurs, which may also lead to indirect effects to a species (impacts to prey, pollination, habitat and/or dispersal).

To gain an understanding of these factors and to inform measures to be included or proposed as labeling in new use of an active ingredient packages to address ESA, applicants may elect to carry out their own assessment using EPA's methodology and tools. To be clear, and as noted earlier in this document, EPA is not asking applicants to conduct and submit assessments. However, if applicants conduct assessments to help them identify mitigations (or proposed mitigations), the evaluation would include: selecting appropriate toxicity (or pathogenicity for biopesticides) and fate endpoints when reviewing studies and assessing the data, selecting appropriate model input parameters, calculating off site transport distances for drift and runoff using AgDRIFT, PWC, T-REX, and other tools, where applicable, and identifying taxa of concern. EPA intends to keep up-to-date versions of its models and input guidance available on its web site as they are developed or changed. Applicants may be able to describe the taxa that may experience direct effects and the relevant routes of exposure and indirect effects from prey, pollination, habitat and/or dispersal. This information can be used by applicants to inform mitigations that are included in the initial registration application package. These analyses may also help to inform any pre-submission discussions with EPA regarding appropriate mitigations that may address ESA concerns. EPA acknowledges that relating chemical properties and application directions to predominant offsite exposure pathways takes expertise, and not all applicants have ecological risk assessors on staff, and that during the registration process applicants may need to engage with the EPA to discuss appropriate data and label directions.

***c) Perform Initial Spatial Overlap Analysis***

To better understand the potential overlap of a pesticide's uses or proposed uses with listed species and critical habitat, EPA recommends that, prior to filing an application for a new use for an active ingredient, applicants conduct an overlap analysis of their proposed uses against listed species ranges and critical habitats. This will help applicants identify the number and type of listed species that may be exposed and potentially affected in the intended action area as described in section 3 of this document, above. The overlap analysis would also help inform applicants regarding the extent of necessary mitigations and help them identify and describe proposed use sites for a new use of an active ingredient. It is critical that applicants use the information on listed species ranges and any critical habitat as determined or agreed on by the Services as this is the best scientifically available source of information. EPA expects that this information will evolve over time and will strive to make the most recent data it uses to describe species ranges, critical habitats, and mitigation areas available.

One tool to help applicants conduct such an analysis is a use data layer (UDL) overlap dashboard that EPA released in June 2023<sup>10</sup>. This dashboard provides pre-processed overlap for EPA's standard agricultural and non-agricultural UDLs with several off-site distances. After selecting the UDLs associated with the proposed uses and exploratory off-site distances, lists of species and critical habitats found within the action area can be downloaded. These lists will provide the overlap results for each selected UDL and off-site distance to help evaluate options for refining the action or proposing mitigations. Available GIS data for species, critical habitat, and UDLs can also be explored using this tool. EPA expects to continue to expand the capabilities of these tools as the Agency receives feedback from users.

EPA also has several tools available on its website<sup>11</sup> that it uses to perform overlap analyses in its BEs that applicants can use including a UDL overlap tool and Census of Agriculture (CoA) overlap tool. These tools provide conservative overlaps with pre-processed elements to efficiently assess listed species. These tools may be used in tandem, as they may both provide refinement of the overlap based on different principles. Additional information on these tools is available on EPA's website referenced earlier in this paragraph. EPA will continue to periodically update these tools when it updates the underlying data sources and make updated versions of these tools available to the public. EPA plans to make updates available at <https://www.epa.gov/endangered-species/provisional-models-and-tools-used-epas-pesticide-endangered-species-biological> and will alert stakeholders if the location of these updated tools changes.

By conducting these overlap analyses, applicants can readily see where the proposed uses and off-site areas overlap with listed species and critical habitat. While EPA generally has reliable information on agricultural uses, information on many non-agricultural uses is less readily available. Non-agricultural application sites are often represented with more broadly defined spatial layers. For example, the UDL layer for forests and turf covers extensive areas of the country, and to address these extensive UDL layers and increase efficiency, applicants should ensure that proposed labeling is as clear as possible and reflects the intended use sites with as much specificity as possible. For example, turf could include residential areas, sod farms, golf courses, and commercial/recreational sites among other possible use sites. Applications to trees could include Christmas tree plantations, managed forests, residential trees, or any other trees that are active or dormant. Therefore, specifying the intended use site when it is a

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<sup>10</sup> [Advancing Transparency of Endangered Species Act Evaluations Through Publicly Available Data | US EPA](https://www.epa.gov/advancing-transparency-of-endangered-species-act-evaluations-through-publicly-available-data)

<sup>11</sup> <https://www.epa.gov/endangered-species/provisional-models-and-tools-used-epas-pesticide-endangered-species-biological>

subset of a broader description category may substantially reduce the scope of the ESA evaluation. EPA is not discouraging applicants from proposing or supporting any particular use site but is asking applicants to the extent feasible to describe the intended use pattern with as much detail as appropriate so that EPA does not have to interpret ambiguous language.

#### ***d) Identify Mitigations***

Equipped with the information from the analyses described above intended to identify what species may be affected and what exposure routes are relevant to those species, applicants may then elect to identify mitigations to address non-target exposures to listed (and non-listed species). In the context of mitigation strategies to protect listed species, the Services prefer first avoiding pesticide exposure and minimizing impacts by reducing exposure. When avoidance and minimization are not feasible or adequate to protect species/habitat, then offsets can be considered by EPA and the Services. In this guidance, EPA is focusing on avoidance and minimization only.

As described in EPA's November 2022 ESA Workplan Update, EPA is developing various strategies to inform mitigations across types of pesticides (herbicides, rodenticides, insecticides, fungicides), for certain regions (e.g., Hawaii), and potentially for certain uses (e.g., mosquito adulticides). Once EPA issues a final strategy that applies to a proposed active ingredient, use site, or species, the Agency expects applicants would apply the applicable strategy and include mitigations, as appropriate. Until such time as EPA completes these strategies, the following are some considerations for applicants to identify early mitigations.

As explained in the ESA Workplan Update, EPA has been considering three general geographic scopes of ESA mitigations, including (1) national level mitigation implemented on pesticide product labeling; (2) sub-national/regional mitigations implemented on labeling; and (3) localized (or geographically specific) mitigations implemented using labeling with details available in EPA's BLT system.<sup>12</sup> In practice, EPA has seen actions where ESA mitigations may fall into just one of these categories or can fall into all three. EPA's experience has shown that when the pesticide's effects are far ranging spatially and may affect multiple taxa such as plants, birds, mammals, and fish, national level mitigation on pesticide product labeling is likely to be needed. On the other hand, where the action area overlaps with limited listed species that have a limited footprint, geographically specific mitigations may be more appropriate. EPA recommends applicants consider incorporating common practices to mitigate effects to listed species, including using the minimum effective application rate as the maximum labeled application rates on labels for a given use site and pest, increasing droplet sizes for spray applications, incorporating field management practices for runoff reduction, and utilizing various types of buffers to reduce pesticide exposures off-field from spray drift, runoff, and erosion. EPA is not suggesting that application rates should be lower than those needed for efficacious pest control. EPA also notes that mitigations should be feasible and practical for growers.

Applicants should consider potential effects to listed species located on the field and to listed species that are near/adjacent to fields with habitats that may be exposed via runoff, soil erosion, off-target spray drift, and/or exposure to habitats from volatility. EPA's experience is that mitigating on-field

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<sup>12</sup> Mitigations in BLT are referred to as Bulletins and are legally enforceable when pesticide product labeling requires users to access and follow them. See <https://www.epa.gov/endangered-species/bulletins-live-two-viewbulletins> for additional information on Bulletins and BLT.

effects can result in the most substantial mitigations. Lowering use rates and number of applications can be useful mitigations where effects to a species/taxon are not extremely high. For example, in cases where a relatively small reduction in exposure would address effects to one or more listed species, then a reduction in the maximum labeled application rate (or a combination of different mitigations that reduce the amount of pesticide applied to a site) could address such concerns.

In cases where effects to a species or taxon are more extreme, such that simple changes to label directions would not be sufficient to address concerns and remain efficacious for pest control, then use prohibitions, spatial prohibitions, or timing restrictions (e.g., crop stage, time of year) may be more appropriate. Such restrictions are typically intended to address exposure to one or more species of concern and are geographically specific. Alternatively, a combination of multiple effective mitigations may also be needed to address risk concerns. EPA's current thinking on the extent and efficacy of various mitigation options will be described as part of the various strategies as described in the ESA Workplan Update that are under development. EPA intends to communicate the location of such information to the applicants and the public as it is made available or updated.

If applicants find that spray drift reduction mitigations may be needed, EPA has found that some of the most impactful mitigations for reducing off-site exposure include using the largest droplet size that is still efficacious and/or limiting aerial applications only to where they are most needed. In other cases, applicants may determine that a buffer distance between the application site(s) and species habitats are a more fitting approach. For additional information on potential mitigations to minimize spray drift, see the ESA Workplan Update and the technical document describing potential runoff and spray drift mitigations, currently available at [EPA-HQ-OPP-2023-0365](https://www.regulations.gov/document/EPA-HQ-OPP-2023-0365).<sup>13</sup> EPA will continue to make updates to the technical document as new data become available and plans to make updates available to the public on a periodic basis.

If applicants find runoff reduction mitigations may be needed, EPA recommends considering a host of potential runoff mitigations that the Agency has identified based on the physical chemical properties of the pesticide. Applicants should consider whether a pesticide that tends to run off the treated area is adsorbed to eroding soil particles or dissolved in the runoff water. Some examples of potential mitigations to address runoff include vegetative filter strips and riparian buffer strips, cover crops, no or reduced tillage, residue tillage management, strip tillage, mulching or compost addition, contour farming, terrace farming/field terracing, and strip or alley cropping. See the ESA Workplan Update for additional information on potential runoff and soil erosion mitigation. In practice, EPA finds that multiple runoff mitigations are often needed to address situations where EPA predicts there is a likelihood of J/AM in its effects determinations. EPA's current analyses regarding the efficacy of runoff and drift mitigations are described in the technical document referenced in the previous paragraph.

If the proposed registrations or mitigations include agents that reduce pesticide movement such as drift reduction or soil binding agents, then submitting data that describes the efficacy of these agents would help EPA determine how these agents impact the need for and extent of mitigations. Submission of such information should include sufficient detail to allow EPA to perform an independent analysis of data quality and utility.

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<sup>13</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2023-0365-0007>



If applicants propose mitigation measures that allow EPA to register the new outdoor use(s)/pesticide product(s) while meeting its ESA obligations, then the regulatory process will likely be much faster. However, it is EPA's and the Services' purview to make J/AM determinations. In cases where proposed mitigations are not sufficient to meet ESA obligations, then efficiencies in the regulatory process will not be realized and EPA would need to continue to work with the applicant(s) to identify mitigations that address ESA. EPA acknowledges that its ESA evaluation processes continue to evolve and that up-to-date evaluation processes will be documented in detail in BEs as they are completed and made publicly available to assist applicants. As noted earlier in this guidance, there are opportunities during the regulatory processes to discuss mitigations and other aspects of registration.

**e) Activities Applicants Can Take when Submitting Applications for a New Outdoor Use for a Product(s) with More than One Active Ingredient**

When an applicant applies for a new use registration where the pesticide product contains multiple active ingredients, EPA must assess effects to listed species as they relate to all the active ingredients in the proposed product. Therefore, the analysis needed for such combination registrations may be substantially more complicated and identify additional taxa where additional mitigations may be needed. Such reviews are likely to require significantly more resources on EPA's part. EPA acknowledges there can be benefits of combining more than one AI into a single product, but also notes that active ingredient co-formulants may present separate risk scenarios. Therefore, prior to submitting a new outdoor use for an active ingredient application that contains a product(s) with more than one active ingredient, EPA suggests that applicants consider if EPA has made effects determinations and is in consultation with the Services for the other registered active ingredient(s) in the co-formulation or if EPA has completed consultation with the Services. If so, these analyses may be a basis for a path forward for EPA to proceed to a decision on the combination product and meet its ESA obligation for each active ingredient in the combination product. The most protective set of mitigations identified across the active ingredients included in multi-active ingredient products would likely be needed to protect listed species. If ESA considerations have not yet occurred for the additional active ingredients, EPA suggests applicants compose a table of the fate properties (e.g., environmental half-lives, mobility constants), acute and chronic toxicity endpoints, label rates, and risk quotients from previous risk assessments as determined in EPA's risk assessment for the registered active ingredient(s) and submit this information as part of the submission package. The intent of providing this information to support new use applications is to enable applicants and EPA to more easily evaluate the extent of mitigations that may be needed to be protective of all active ingredients in the product. To the extent that these analyses have not been conducted or completed for each pesticide active ingredient in the proposed new outdoor use formulation, applicants should consider the ESA analysis as discussed above and whether additional mitigation measures may be needed to address listed species protections for each active ingredient.

**4. Conclusion**

In closing, this guidance is intended to provide applicants with some steps that could be taken prior to the submission of a new outdoor use package for conventional and biopesticides. These steps should lead to a more efficient process for conducting an ESA analysis. These steps are also intended to help applicants identify appropriate mitigation measures that can avoid or minimize effects to species (both

listed and non-listed) early in regulatory and consultation processes, which should better inform EPA's ESA analyses for registration processes of new outdoor uses.