Mr. Andrew Wheeler  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Dear Administrator Wheeler,

We write to you today on behalf of the 1.8 million members and supporters of Defenders of Wildlife who seek to conserve wildlife and the habitats they depend on everywhere. The Environmental Protection Agency (EPA) recently released its Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides. This proposal updates the Interim Approaches to pesticide consultations under section 7 of the Endangered Species Act (ESA) that have been in place since 2015. This guidance covers both Step 1 (No Effect vs. May Effect determination) and Step 2 (Likely to Adversely Affect vs. Not Likely to Adversely Affect determination) of the analysis process.

While we appreciate the need to provide additional guidance and clarity, we find numerous problems with the EPA’s proposal. As written, this guidance is woefully inadequate to ensure the protection of federally listed threatened and endangered species. Our goal in these comments is to help EPA identify these problems and then provide recommendations on how to resolve them. We organize our comments in the order of the major analytical steps, but first note problems common to the whole document. To emphasize the importance of our concerns we tag each issue with one of three “severity” labels:

- **MAJOR** —The issue must be addressed by EPA if its duties are to be fulfilled;
- **INTERMEDIATE** —The issue should be addressed to improve the process;
- **MINOR** —The issue should be addressed to improve clarity;

### Overall issues

1. *FWS and NMFS were not included in the development of this proposal.* **MAJOR**  
We understand based on public comments and private conversations that the U.S. Fish and

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Wildlife Service and National Marine Fisheries Service ("the Services") were not included in EPA’s development of the proposed guidelines. As recent research shows, oversight by species experts at the agencies responsible for implementing the ESA are essential to protecting species. While the Services will be involved during consultation on any registrations, the proposed guidelines appear to create off-ramps that exclude species from even informal consultations when they should not be excluded (see extensive notes below). Fundamentally, EPA’s go-it-alone approach is shortsighted and ignores what has been long understood: the consultation process—the whole thing, including developing action agency guidance—works best through early engagement.

**Recommendation:** Before the final guidance is published, EPA should engage meaningfully with the Services. Many of the problems noted below would likely have been addressed through engagement.

2. **EPA references almost no literature.** A document of this consequence should be filled with supporting references. There are a few footnotes, but most are on minor issues. While the detailed operational issues at play may seem second-nature to the authors of the guidance, they are not to everyone who is involved. Even if many stakeholders are familiar, this is a basic issue of good scientific and administrative practice.

**Recommendation:** EPA should revise the entire document to carefully cite the literature that forms the scientific bases of its proposed approach.

3. **EPA attempts to pass responsibility to other agencies.** There are several places in Step 1 and Step 2 where EPA is passing responsibility to other agencies—such as land management agencies—for pesticide consultation. As we discuss in more detail below, this is not helpful and is fundamentally inappropriate.

**Recommendation:** EPA should accept its responsibility to consult fully on all pesticide registrations in the United States and revise the document accordingly.

4. **EPA does not mention unoccupied habitat.** The guidance does not mention unoccupied habitat, including areas of habitat that are necessary for recovery, in either step. To conduct the analyses without considering whether registration could preclude recovering species is to ignore a fundamental purpose of the ESA.

**Recommendation:** EPA should revise to guidance to explicitly describe how it will assess the effects on unoccupied habitat.

5. **EPA does not consider off-label use in risk assessment.** We have to assume there will be some off-label use of any particular pesticide, even if minor. No

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matter the degree or users’ intention, off-label use could be particularly harmful in sensitive areas. Both the use and likely misuse of pesticides should be considered...

*Recommendation:* EPA should discuss potential off-label use in every Biological Evaluation (BE). The possibility of off-label use should then be included as part of the environmental baseline in the biological opinion.

**Step 1: No Effect vs. May Effect**

The proposal for differentiating No Effect from May Effect determinations has several problems:

1. **Step 1a, asking whether the exposure pathway is incomplete for all use, is unclear.**  
   *MINOR* There is no definition or discussion of exposure pathways, how they are determined, or the amount or types of data that are needed to make the determination. Furthermore, the completeness of a pathway will usually contain a probabilistic element. What is the threshold for determining a pathway is likely complete? Any non-zero probability?  
   *Recommendation:* EPA should define undefined terms, clarify what thresholds might be used (even if qualitative guidance), etc., to improve the document.

2. **Step 1b, extinct and extirpated species threshold missing.**  
   *INTERMEDIATE* Step 1b does not include a step-down for the extirpation case, e.g., “If extirpated, is there a substantial chance that the species will be reintroduced to an exposure area, either through natural or assisted means?” Substantial or another term should be interpreted to mean a threshold lower than likely (50%), but not so low as to dramatically increase the burden of analysis (say, >20%).  
   *Recommendation:* EPA should recognize extirpated species in its stepdown, including an evaluation of the likelihood that a species is actually extirpated as well as the likelihood of reintroduction or recolonization of an area.

3. **In Step 1c, the 1% overlap criterion is arbitrary, useless, dangerous to species, and illegal.**  
   *MAJOR* Simply using a percentage of the area of overlap could mean exposure and take of many, many individuals, yet the ESA does not allow for take of all species within 1% of its range, without a permit. The Act forbids “takes” of endangered animals wherever they reside. 16 U.S.C. § 1538(a)(1)(B). “The term ‘take’ means to harass, harm, . . . wound, [or] kill” protected species. *Id.* § 1532(19). “Harm” includes “significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding or sheltering.” 50 C.F.R. § 17.3(c). In addition, because of heterogeneity of populations in time and space, even 1% of a range could include many individuals (e.g., in prime
There is simply no exception for any de minimis take, especially where, as here, the proposed take may be limited in geography but far from de minimis in impact on a species’ population. See also Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or., 515 U.S. 687, 704 (1995) (“Congress intended ‘take’ to apply broadly to cover indirect as well as purposeful actions.”). This is not a good, science-based criterion, and using this filter is illegal.

Recommendation: EPA should remove the proposed filter using 1% overlap.

4. **Step 1d, federal lands overlap is simply a bad criterion.** This is a bad criterion for several reasons:

   a. Federal land management agencies rarely consult on Pesticide Use Proposals (PUPs), though they probably should do so more. That is, EPA’s assumption that this is being done already is inaccurate.

   b. Even if land management agencies are consulting on PUPs more regularly, those are questions of specific application, not the major issue of registration. Unless every registration excludes federal lands from application, as well as any surrounding land where drift, other transport, or indirect effects are possible, then federal lands cannot be excluded.

   c. The EPA’s argument that it is more efficient to have the land management agencies consult on the pesticides is, frankly, absurd. Maybe it would cost EPA slightly less, but (a) that’s not the same as the efficiency of registering a pesticide—the action in question—which involves many parties beyond EPA, and (b) it does not account for the technical expertise of EPA plus the FWS and NMFS biologists who are focused on evaluating the pesticides.

Recommendation: EPA should not shirk its responsibility by trying to pawn off technical analyses, which it is required to do, on agencies and personnel who are not responsible and who lack the necessary expertise.

5. **Direct and indirect effects definitions are inconsistent.** The proposal uses the terms “direct effects” and “indirect effects” throughout, but then goes on to say “These terms do not refer to the regulatory definitions of the terms under ESA, which describe the direct and indirect effects of the action.” It is unclear why a document about consultation would not use the regulatory definitions of the ESA.

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5 To get an idea of the PUP consultation rate, we searched among some 6,000 biological opinions using the ESAdocs Search tool ([https://esadocs.defenders-cci.org](https://esadocs.defenders-cci.org)). We find very few PUPs—just 31 BOs listed—and certainly not the thousands one might expect (say, one per refuge, one per BLM office, one per national forest) under EPA’s assumption.
**Recommendation:** We recommend that EPA use different terminology for the ecotoxicological references of the terms and use the ESA definitions in this ESA-focused document.

6. **Do more for refined range maps.**  **MAJOR** The EPA indicates its analysis will be based on the species ranges presented by the Services. What if a registrant has done refined range maps for key species that may be exposed to a pesticide but FWS has not yet completed those refined maps? The BA/BE should use best available scientific and commercial data (and available must be emphasized) and the onus should be on FWS or NMFS to argue why it would use less-than-best resources, like county-resolution maps.

   **Recommendation:** The EPA should use the best available science for refined range maps, which will help FWS adopt better maps, faster.

7. **Future pesticide use is not considered.**  **MAJOR** The issue of past-current-future use is noted in the discussion of use sites and use data, but not really addressed. This is as important as—if not more important than—past or present use or crop data. EPA should explicitly discuss how future expected uses are considered, especially when the permitting will run for 15 years. How big a problem could this be? Total net cropland area increased by 2.98 million acres nationwide from 2008 to 2012\(^6\). If we assume the area increases at this rate, which is a three- or four-fold increase over the next 15 years, that may total nine to 12 million new acres over which an agricultural pesticide might be used. Importantly, both the retrospective analysis and prospective analyses\(^7\) show that agricultural change is spatially structured, often by crop. Other pesticides, such as those used in mosquito control, have similar future-use considerations that must be evaluated. For example, research indicates a three- to ten-fold increase in the area occupiable by the Asian tiger mosquito in the Northeastern U.S. by the end of the century because of climate change\(^8\) which may also mean a substantial expansion of pesticide application. EPA and the Services must consider potential for increased (and decreased) usage going forward. This is a huge gap in the guidance and any sort of analysis that should go into the BEs.

   **Recommendation:** The EPA must attempt to model and account for future areas of application to afford species the protections they will need so long as a registration is still active.

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8. **Off-site transport “conservatism” is poorly supported.** The discussion of off-site transport states that the buffer around areas of application is limited to 2,600 feet, and mentions (but does not cite) studies from the 1990s that supposedly suggest this is “conservative.” This does not sound conservative to us. Is this an empirical result or a model result, the latter of which may make invalid assumptions? Is it the same assumption used in other jurisdictions with more protective regulations? The precise studies relied upon for this conclusion should be cited and the premise reconsidered.

   **Recommendation:** In line with the general recommendation to add references to the literature, EPA should ensure that this particular line of argument is well-supported in the guidance.

9. **Sublethal effects consideration.** The EPA states “Additional sublethal effects will be considered if they can be quantitatively linked to survival, growth or reproduction.” If the agency will be requiring registrants to collect the quantitative data needed to make these links then this may be fine. However, if the agency plans to simply skip these analyses because the quantitative data are lacking—which is how we read this—and lean on the potentially lower bar of “best available science” while not affording species the benefit of the doubt, then this is inadequate.

   **Recommendation:** EPA should clarify in the guidance what data are required and how it will proceed with data that are insufficient to quantify the effects on survival, growth, or reproduction, when the ESA requires that species be given the benefit of the doubt.

10. **1% range overlap is arbitrary and dangerous.** As discussed above, the May Affect threshold of 1% range overlap with application area is invalid. EPA even goes on to state, “Use of 1% as a cutoff is conservative given the assumptions related to the Action Area and drift discussed previously that lead to an overestimate of potential use areas.” This makes no sense. EPA may be thinking it is conservative for jeopardy, which is also highly questionable, but that is not the threshold for a may affect determination.

   **Recommendation:** Drop any reference and decision points based on the arbitrary 1% criterion.

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**Step 2: Discriminating Between Likely to Adversely Affect (LAA) vs. Not Likely to Adversely Affect (NLAA)**

1. Just to be clear, EPA may never get to this phase of the analysis from Step 1 if some of the bad filters at that stage are not fixed. This is a fundamental flaw in the guidance as proposed.

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2. **Species range overlap details matter.** **MAJOR** As written, the proposal appears to indicate that use areas not directly overlapping a species range will be removed from further analysis. If that were to occur as early in the assessment process as the document indicates, many species could be inappropriately excluded from analysis because they are filtered too soon. However, if the “range data provided by the Services” includes the area of influence, such as the upstream portions of a watershed above an aquatic species’ range, then this early filter may not be an issue. If this is the case, then the proposed approach should say so, clearly. Latter portions of this section hint at this, but it remains unclear.

   **Recommendation:** Carefully clarify how and when non-overlapping areas will be removed from consideration to ensure that species are not prematurely excluded from analysis.

3. “...a composite factor is applied...” **MINOR** In calculating spray drift overlap with a species’ range, EPA states “Basing drift on each individual use layer greatly overestimates the drift overlap...composite factor will be applied to the drift area...to scale the number of acres impacted by off-site drift and subsequently lower the total predicted overlap with a species range due to drift”. The composite factor is not explained further nor are any worked examples shown to understand the implications of this decision.

   **Recommendation:** EPA should provide more detail about the composite factor and provide one or more worked examples (e.g., set aside in a text box) to make it clear what is done.

4. **Method to calculate likelihood that >=1 individual exposed is flawed.** **INTERMEDIATE** The EPA proposal uses a convoluted way to calculate the proportion of a species’ range that overlaps usage area, then multiplies that by “the best available population size estimate” to determine if ≥1 individual is likely to be exposed. For example, the threshold would be tripped if 2% of a species’ range overlaps the usage area and there are 100 individuals. There are (at least) two problems with this:

   a. First, the best available population size estimate for most listed species is not going to be a very precise estimate. (Very likely true even after removing from consideration listed Hawaiian species, whose population numbers and biology are particularly understudied.) At a minimum, the proposal should state that the population size at the upper confidence limit will be used; this approach would make the calculation as protective for the species as possible.

   b. Second, this approach ignores natural patterns of heterogeneity in the distribution of individuals throughout a range. If the gross approach proposed here is even used, it should be the fallback that is applied when nothing about distribution within a range is known or can be inferred.
**Recommendation:** The proposal should be modified to first create a stepdown to require that EPA attempt to find spatially explicit data on a species’ distribution before assuming it is homogenous across a range. Second, the proposal should specify that this calculation use the upper confidence limit (whether range, 95% CI, or some other reasonable measure of uncertainty) of population size to be as protective as possible.

5. **Incomplete consideration of use data.** There are several issues that EPA does not—but should—address with respect to data and data gaps:
   a. First, the proposal states “EPA intends to collect data from a variety of sources…” Intention does not matter; this should be a requirement.
   b. Non-crop uses of pesticides presumably have fewer / spottier data available than crop data, regardless of whether such data are proprietary. There is no mention of evaluating and reporting on the completeness of non-crop use data to be used in the analysis. What about variation in spatial availability of data, or completeness of data within use categories? What are some best-case examples that may serve as a baseline? How will EPA itself evaluate data gaps that could fundamentally change the conclusions of the analysis? How will FWS and the public know?
   c. In discussing rangeland and forestry applications, EPA claims “assuming that all lands are treated (in the absence of usage data) potentially represents a gross overestimate of overlap.” But the agency fails to mention that it also potentially represents a completely accurate estimate. EPA states that it may use USDA census data for classes of pesticides, e.g., reporting for all insecticides.

**Recommendations:** First, describe which data are available and then lay out how EPA will close those gaps. While this comment is mostly focused on non-crop usage data, the same holds true for crop data. This should be a very carefully considered matter. Second, because the ESA and courts have required that the benefit of the doubt be given to the species, the assumption of all lands in range and forestry applications should be the default. Less expansive areas should only be used—or argued for—when there are sufficient data.

6. **Adjust for impervious surface with care.** In discussing turf, ornamental, and similar areas, the proposal states that EPA is investigating a way to adjust area by removing impervious surface. We urge caution with this approach. First, EPA must carefully consider whether excluding impervious surface is warranted: some

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herbicides are used specifically on impervious surface to remove unwanted vegetation. Second, the EPA should consider both existing data and new classifiers from remotely sensed data.

**Recommendation:** Specify clearly in the guidance how EPA will determine how much impervious surface to exclude for different active ingredients. Second, the new National Land Cover Database\(^{11}\) is available and offers an impervious surface layer that may be useful. Otherwise, new classifiers are relatively easy to develop given modern computing tools and data, and EPA should consider whether such development is warranted.

7. **Mortality or decreased growth or reproduction in a given year.** \(^{\text{INTERMEDIATE and MAJOR}}\) EPA combines 2b and 2c in a single step for discussion. There are several significant shortcomings:

a. **Time-of-year analysis** for direct effects makes sense, however, there is no discussion of time-of-year indirect effects. For example, what if pesticide application has no direct impact because the species is not present at the time of application, but harms habitat or other ecological interactions that manifest once the species is present? This seems highly likely for many pesticides. Further, because indirect effects are expected to manifest later than direct effects\(^{12}\), special care should be taken to account for harm that may not be immediately apparent.

**Recommendation:** EPA needs to update the guidance to specifically address temporal indirect effects.

b. **Migration analysis** has the same major shortcoming as the time-of-year analysis: there is no discussion of carry-over indirect effects. The general issue of both time-of-year and migration are covered in the section 7 handbook in terms of permanent versus transient effects\(^{13}\). As presented, the proposed approach only considers whether the off-season application has a temporary effect.

**Recommendations:** As with the temporal indirect effects analysis, EPA needs to update the guidance to fully address indirect effects on migratory species.

c. **Precision of species range** is a well-known issue among ESA practitioners and some parts of the proposal (e.g., referencing ESA-related documents to refine a species’ range) are sensible. However, there are some significant problems:


i. The federal lands filter is just as inappropriate here as it is in Step 1. The EPA should not propose and the Services should not allow pushing pesticide consultation off on federal land management agencies. That makes no sense. In addition to basic questions of efficiency, registration is upstream of any consideration of use by the agencies (or anyone) and falls under EPA’s duty to evaluate and decide whether to register a pesticide.

   Recommendation: Remove the federal lands filter.

ii. EPA states “The 2600 ft limit is based on the limits of the spray drift models available; beyond this limit potential effects cannot be determined.” That is different from the argument presented earlier in the guidance document—and highlighted above—that available data indicate a 2600 ft buffer is appropriate.

   Recommendation: Carefully review whether current data and science indicate that 2600 ft is a sufficient buffer and document carefully in the guidance. If the data are not sufficient, then drop this limit and do more detailed analyses.

iii. In several places, EPA’s diagrams suggest arriving at NLAA long before it can appropriately reach that conclusion, for example:

   ![Figure 9. Consideration of a Species Dietary Preferences.](image)

   Recommendation: These should be changed to something like “Go to next stage of analysis.”

iv. EPA states “…AgDRIFT would be expected to overestimate drift exposure to species that dwell in the interior of forest” based on the argument it is based on a conceptual model of flat, unimpeded terrain.

   Recommendation: EPA must include scientific support for such a statement, which on its face seems so oversimplified as to be dangerous.

v. The “dichotomous key” in the guidance (e.g., for the Precision of Species Range Data evaluation) is very poorly done relative to how dichotomous keys are supposed to be written. For example, each question should be crisp and concise with discrete “Yes” or “No” answers. As another
example there should be no dead ends where a question is asked but only one outcome is provided (e.g., “Yes” with no “No” option).

**Recommendation:** Please review how to write a dichotomous key and revise extensively.

d. **Confidence in toxicity data (surrogacy)** is a valid issue but EPA simply states, “we found in our preliminary analyses with several pesticides...for data-rich species that allowed for such an analysis (e.g., salmonids)...even species within the same genus were often found throughout the species-sensitivity distribution for a broader taxonomic group.” The very next paragraph states, “it is not possible at this time to quantify the uncertainty associated with this surrogacy approach for each listed species.” While it may be high variation, that does not mean the agency cannot quantify it.

**Recommendation:** EPA should specify that the most sensitive species in a taxonomic group should be considered as surrogates, which is the appropriate approach.

8. **Probabilistic analyses and data limits.** The National Research Council analysis of pesticide consultations included the recommendation to use probabilistic evaluations rather than only deterministic analyses. Where possible, EPA should use probabilistic evaluations or state clearly when data is insufficient for the probabilistic approach to work. EPA’s discussion, however, is off-base because it does not discuss potential or known limitations of the data or methods. This proposal is “based on” a simplified version of the Terrestrial Investigation Model (TIM) and other relevant documents, but EPA doesn’t discuss how those foundational approaches were developed. For example, the TIM model is based on birds, but the proposed guidance never discusses this potential limitation with respect to other taxa.

**Recommendations:** First, we encourage EPA to use probabilistic analyses where ever possible, but the agency to guard against any temptation to place probabilities above species protections. Second, and to that end, EPA should provide considerably more detail on (a) the details of the methods it will use and (b) how the agency will handle analyses with insufficient data.

9. **Step 2d, indirect effects.** EPA states that “For habitat requirements or for species with plants included in their diets, a 50% decline in growth of aquatic plants or a 25% decline in growth of plants (based on most sensitive tested species) is assumed to result in decreased cover / availability of food and decreased likelihood of survival/growth of a listed individual.” Those seem like absurdly high losses before considering a species to be adversely affected. What is the scientific basis for this? If that has been the standard used in the past, then have the past thresholds been deemed sufficiently protective?
Recommendation: If EPA has research to support why the thresholds noted above and in the guidelines are sufficient, then it should cite that research and explain the basis in the text.

Conclusion

Section 7 consultations on the effects of pesticides on listed species are one of the most important aspects of ESA implementation, and one of the biggest challenges facing implementation. EPA must fulfill its duties under the ESA, which means improving the guidance it has proposed for risk assessment. We identified 12 major and numerous less-severe problems with the proposed guidance, all of which need to be addressed. Only by addressing these issues can EPA fulfill the mandate of the ESA as well as the mandates of FIFRA.

Please feel free to let us know if you have any questions, comments, or concerns. We can be reached at 202-772-3262, or via email at jmalcom@defenders.org.

Sincerely,

Jacob Malcom, PhD
Director
Center for Conservation Innovation

Jason Rylander
Senior Endangered Species Counsel