



Petition to Withdraw a Guidance Document

November 19, 2020

Via U.S. Mail

To:

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I. Petitioner Information

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II. Guidance Documents Identification

The Center for Biological Diversity (Center) petitions the U.S. Environmental Protection Agency (EPA) to withdraw the guidance document: *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency—Endangered and Threatened Species Effects Determinations* (hereinafter “2004 Overview Guidance”)¹ to be withdrawn.

We request that EPA withdraw the related guidance document within the 2004 Overview Guidance “#70 Background on development of LOCs,” (Support Document #70) which cannot be found on any public-facing website, and all other “supporting documents” that are not valid guidance documents per EPA’s new final rule.

Furthermore, the Center also requests EPA withdraw the guidance document: *Guidelines for Ecological Risk Assessment-Risk Assessment Forum* (hereinafter “1998 Risk Assessment Guidance”).²

¹ U.S. ENVIRONMENTAL PROTECTION AGENCY, OVERVIEW OF THE ECOLOGICAL RISK ASSESSMENT PROCESS IN THE OFFICE OF PESTICIDE PROGRAMS-ENDANGERED AND THREATENED SPECIES EFFECTS DETERMINATIONS (Jan. 23, 2004) [hereinafter 2004 Overview Guidance] available at: <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>.

² U.S. ENVIRONMENTAL PROTECTION AGENCY, *Guidelines for Ecological Risk Assessment-Risk Assessment Forum*, EPA/630/R-95/002F (Apr. 1998) [hereinafter 1998 Risk Assessment Guidance] available at: https://www.epa.gov/sites/production/files/2014-11/documents/eco_risk_assessment1998.pdf.

First, the Center notes that EPA’s Final Rule: *Administrative Procedures for Issuance and Public Petitions Rule* (hereinafter “Final Rule”)³ does not explicitly require the petitioner to submit a separate petition for each guidance document that an entity seeks to withdraw. We believe that given the overlap and interrelated nature of the three guidance documents, and since the 2004 Overview Guidance incorporates by reference the 1998 Risk Assessment Guidance, it is appropriate to submit a single petition for the three guidance documents together. Because Support Document #70 is not available in an online format, we cannot confirm that such guidance document actually exists and believe it would be extremely inefficient to submit a separate petition for this document.

Second, the Center would like to note that neither the 2004 Overview Guidance nor the 1998 the Risk Assessment Guidance are included in the EPA Guidance Portal (last accessed November 16th) and do not have an EPA Identifier. By the plain text of the preamble of the proposed rule, EPA has therefore deemed that both of these documents have been rescinded and are no longer in force.⁴ As the EPA stated in its Response to Comments: “[t]his rule sets forth the procedures for posting active guidance documents and notes that guidance documents, as defined in this rule, not posted on the EPA Guidance Portal would be deemed rescinded.”⁵ Thus, the Center is only submitting this petition in an abundance of caution should EPA act inconsistently and arbitrarily in a *post-hoc* manner to resuscitate either guidance document. We only present this petition in the event EPA attempts to use the guidance documents now or in the future, and we seek to repeal them should EPA attempt an end-run around its own clearly articulated position regarding documents that cannot be found on the EPA portal. Should EPA agree that these have been deemed rescinded, the petition seeks to confirm that they are in fact permanently withdrawn and will never be utilized by EPA staff moving forward.

Additional Background on Guidance Documents:

The 1998 Risk Assessment Guidance set forth the ecological risk assessment process for reviewing the impacts of pesticides on the environment in general. It sets forth a framework that guided the EPA on analytical approaches to assess the effects of a pesticide on the soil, surface water, ground water, and on plants and animals, including endangered and threatened species.

The 2004 Overview Guidance set forth an ecological risk assessment process specifically for threatened and endangered species. The ecological risk assessment set forth several additional policies — specifically the use of “Levels of Concern” and “Risk Quotients” — that were announced for the first time in that guidance document. The document cites to Support Document #70 as the stated rationale for these policies, but this document does not appear to exist, and cannot be relied upon.

³ EPA Guidance; *Administrative Procedures for Issuance and Public Petitions*, 85 Fed. Reg. 66230 (Nov. 18, 2020) (to be codified at 40 C.F.R. pt. 2).

⁴ Rescinded guidance document means a document that would otherwise meet the definition of a guidance document or significant guidance document, but that the EPA may not cite, use, or rely upon except to establish historical facts.

⁵ U.S. EPA, *Summary of Public Comments and Responses for EPA Guidance; Administrative Procedures for Issuance and Public Petitions* at 27 (Aug. 2020) Docket EPA–HQ–OA–2020–0128 [hereinafter EPA Response to Comments].

By its own terms, both of these guidance documents clearly are “guidance documents.” Executive Order 13891 defines “guidance document” as “an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.”⁶ EPA follows this definition and defines “guidance document” as an “Agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.”⁷ As a historical fact, the EPA has used both of these guidance documents in its review and approval process during the registration of pesticide active ingredients and products. There are eleven exceptions to EPA’s definition of a “guidance document,” none of which apply to the 1998 Risk Assessment Guidance or the 2004 Overview Guidance.

EPA stated in its response to comments to EPA new final rule, “[t]o the extent that any particular document (regardless of what it is termed as or called) satisfies the definition of ‘guidance document’ in this regulation, the document would be subject to these procedures.”⁸ Further, “EPA does not intend to use this rule to parse the various nomenclatures and types of guidance that it uses.”⁹ The 2004 Overview Guidance fits within the definition of guidance document because the document is of general applicability, has affected and will continue to affect the behavior of regulated parties, and sets forth policy for EPA’s ecological risk assessment process. In particular, the 2004 Overview Guidance creates policy and guidance by establishing “Levels of Concern” (LOC) via “Risk Quotients” (RQ) for listed species.¹⁰ The 1998 Risk Assessment Guidance also meets this definition since it provided a foundation for the 2004 Overview Guidance and is cited throughout the 2004 document.

III. Relief Sought

The Center seeks the permanent withdrawal of the 2004 Overview Guidance in full. Additionally, the Center seeks the withdrawal of the 1998 Risk Assessment Guidance in full. To the extent that Support Document #70 still exists, the Center seeks the withdrawal of this guidance document.

IV. Interest of the Petitioner

The Center is a nonprofit environmental organization dedicated to the protection of species and their habitats through science, policy, and environmental law. The Center has more than 1.7 million members and online activists committed to the protection of endangered species. For thirty-one years, the Center has worked to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life for people and animals from toxic threats including pesticides.

⁶ Exec. Order No. 13891, 84 Fed. Reg. 199, 55235 (Oct. 9, 2019).

⁷ 85 Fed. Reg. 66230, 66237.

⁸ EPA Response to Comments.

⁹ 85 Fed. Reg. 66230.

¹⁰ See Section V(b) of this petition for elaboration.

The Center is significantly harmed by EPA’s continued reliance on the guidance because the guidance documents are underprotective of endangered species and have allowed EPA to skirt its legal obligations for decades. Accordingly, the withdrawal of the 2004 Overview Guidance and 1998 Risk Assessment Guidance would better help protect the environment and force EPA to abide by the rule of law set forth by Congress, because it could no longer rely on guidance that allows a pesticide product to negatively impact threatened and endangered species nationwide.

V. Rationale for the Withdrawal of the 2004 Overview Guidance and 1998 Risk Assessment Guidance

The purpose of the 2004 Overview Guidance was to set forth specific processes that EPA would use to evaluate potential risks to endangered and threatened species from exposure to pesticides.¹¹ These assessments were purported to be conducted at the screening level or at a more refined species-specific level, and would follow a consistent approach based on (1) the EPA’s 1998 Risk Assessment Guidelines, which the Center also petitions EPA to withdraw (2) the EPA’s 2000 Risk Characterization Handbook and (3) EPA’s Peer Review Handbook. For each assessment, EPA would purportedly first complete a “problem formulation” in which it defined the regulatory action, characterized the nature of the chemical stressor and pesticide use, identify assessment endpoints, and determine direct and indirect effects to listed species and their critical habitats. EPA would then conduct an “analysis phase” that would characterize the exposure to the pesticide, including the specific modeling needed for terrestrial and aquatic species, and assess the effects of the pesticide. At the final stage, EPA would purportedly complete a “risk characterization” that would integrate the exposure and effects data. This risk characterization would include several types of analysis, the limitations of which are discussed in greater detail below.

Critically, at this risk characterization phase, EPA would purportedly integrate its exposure and effects data to derive a “risk quotient” or “RQ” and then EPA would evaluate — as a policy matter — what action to take based on whether or not the RQ exceeded its “level of concern” or “LOC” or “LOCs.” The 2004 Overview Guidance states the LOC is in fact “the policy tool for interpreting risk quotients” and states that these LOCs were derived based on Support Document #70 “Background on development of LOCs.”¹² As explained by the EPA:

Risk characterization integrates the results of exposure and toxicity data to evaluate the likelihood of adverse ecological effects on non-target species. For most chemicals, the effects characterization is based on a deterministic approach using one point on a concentration-response curve... In this approach, OPP uses the risk quotient (RQ) method to compare exposure over toxicity. After risk quotients are calculated, they are compared to the Agency’s LOCs. *These LOCs are the Agency’s interpretative policy* and are used to analyze potential risk to non-target organisms and the need to consider regulatory action.¹³

¹¹ 2004 Overview Guidance at 7.

¹² See generally, *Id.*

¹³ *Id.* (Emphasis added).

As discussed later in this petition, LOCs are nothing more than arbitrary policy constructs that were created at some point after the publication of the 1998 Risk Assessment Guidance — perhaps in Support Document #70 — and simply announced to the public in the 2004 Overview Guidance. How, why, and specifically which LOCs the EPA chose to adopt at that time was simply a matter of executive fiat, the decision did not involve public comment, and as also discussed later, did not involve the two expert agencies on endangered species — the U.S. Fish and Wildlife Service and the National Marine Fisheries Service. Because there was no explanation for the basis for threshold determinations for LOCs and RQs in the 2004 Overview Guidance nor the 1998 Risk Assessment Guidance, the LOCs and RQs are nothing more than arbitrary and capricious policy choices, and are woefully inadequate in protecting endangered species from pesticides.

Section 7(a)(2) of the Endangered Species Act (ESA) requires the EPA to consult with the United States Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively the “Services”) prior to registering any pesticide active ingredient or product to insure that such pesticide will not jeopardize the existence of any threatened or endangered species, or destroy or adversely modify the species’ critical habitat.¹⁴ Importantly, this requirement also applies to programmatic agency actions, including the promulgation of regulations and other policy guidance that harms listed species. The reason is simple — extinction is forever. Accordingly, “the strict substantive provisions of the ESA justify more stringent enforcement of its procedural requirements.”¹⁵

It is simply a matter of historical fact that the EPA failed to consult on its development of the 2004 Overview Guidance or the 1998 Risk Assessment Guidance. And because neither of these policy guidance documents required EPA to abide by the clear requirements of the ESA, many endangered species nationwide continue to be exposed to dangerous levels of pesticide contamination. Other than being compelled by court orders, over the past twenty-plus years, neither the 2004 Overview Guidance nor the 1998 Risk Assessment Guidance resulted in any on-the-ground conservation measures for listed species.¹⁶

The failure to consult with the Services had real-world consequences, namely that it allowed EPA to illegally conduct its pesticide evaluation processes using underprotective, analytically deficient methods and procedures for years. Many of these deficiencies are outlined in *Washington Toxics Coalition v. Department of Interior*,¹⁷ and include among other things, the failure to evaluate cumulative effects, synergistic impacts, “inert” ingredients, tank mixtures, and sublethal effects beyond growth and reproduction, such as olfactory communication and immune system health.¹⁸

As has been noted in hundreds of comment letters by the Center over the years, EPA’s pesticide exposure pathways models do not address *any* of the real-world complexities listed above.

¹⁴ 16 U.S.C. § 1536(a)(2).

¹⁵ *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

¹⁶ *Washington Toxics Coalition v. EPA*, 413 F.3d 1024 (9th Cir. 2005); *Northwest Coalition/or Alternatives to Pesticides v. Lyng*, 844 F.2d 588 (9th Cir. 1988).

¹⁷ *Washington Toxics Coal. v. U.S. Dep’t of Interior, Fish & Wildlife Serv.*, 457 F. Supp. 2d 1158, 1163 (W.D. Wash. 2006).

¹⁸ *Id.*

Instead, EPA evaluates a pesticide active ingredient in the abstract only, relying almost exclusively on industry-generated laboratory testing, and an inadequately populated database that fails to capture most of the scientific literature regarding the impacts of pesticides. Based on the questionable use of surrogate species¹⁹ — all of which are far less sensitive to pesticides compared to virtually any listed species — and dubious models like the “model farm pond” EPA has swept the impacts of pesticides under the rug for decades.

When EPA was forced to consult due to litigation losses, the deficiencies of the 2004 Overview Guidance become that much more apparent. As the Center has stated before, in the recent past, the NMFS completed approximately 676 effects determinations regarding the registration of a subset of pesticides that are used in the Pacific Northwest on listed salmonid species (counting each pesticide product’s effects on a separate listed species/ESU as a unique effects determination). Over the course of several biological opinions, the NMFS concluded that jeopardy and/or adverse modification of critical habitat to listed salmon and steelhead species would occur in 293 of those effects determinations. Of those 293 jeopardy/adverse modification findings, EPA concluded in 49 of those effects determinations that the pesticide would have “no effect” on a listed species and concluded 40 times that the pesticide was “not likely to adversely affect” a listed species.

In other words, over 30 percent of the time, EPA reached the opposite (and less protective) result — based on the analytical methods of the 2004 Overview Guidance and the 1998 Risk Assessment Guidance — compared to the NMFS regarding the effects a pesticide would have on a listed salmon and steelhead species. And of course, even more disturbingly, of the 293 jeopardy determinations made by NMFS since 2001, EPA has refused to implement a single RPA for any listed species under any circumstance for any pesticide.

The 2004 Overview Guidance and the 1998 Risk Assessment Guidance also completely ignore both the statutory requirement and real-world necessity of assessing impacts to critical habitat from pesticides. The destruction and the degradation of habitat remain the primary threat to the vast majority of listed species, a fact that Congress expressly noted when it passed the ESA in 1973.²⁰ Accordingly, the *recovery* of threatened and endangered species depends on sufficient habitat being protected and restored to ensure a species’ long term viability. One of the clearest areas where the EPA’s 2004 Overview Guidance fails to account for the needs of threatened and endangered species is the failure to address adverse modification of critical habitat *separately* as an independent analysis from the jeopardy one.

Section 7(a)(2) of the ESA requires all agencies to consult with the Services in order to (1) insure that their actions will not jeopardize any listed species and (2) insure against the destruction or adverse modification of a listed species’ critical habitat. While these two statutory mandates do partially overlap, some agency actions can adversely modify critical habitat *without* causing jeopardy.²¹ In fact, many federal actions, including the use of pesticides may adversely modify habitat but not cause enough harm to create a likelihood of jeopardy.

¹⁹ *Id.*

²⁰ D.S. Wilcove et al., 1988. *Quantifying Threats to Imperiled Species in the United States: Assessing the Relative Importance of Habitat Destruction, Alien Species, Pollution, Overexploitation, and Disease*, 48 *BIOSCIENCE* 607.

²¹ Dave Owen, *Critical Habitat and the Challenge of Regulating Small Harms*, 64 *FLA. L. REV.* 141 (2012).

It is quite common that an agency action will occur in an area that is designated as critical habitat but is unoccupied by the species at the time the activity occurs. For example, a pesticide could be applied to the environment at a time of year when a listed species is not present, such as scenarios where listed salmon and steelhead are only present within freshwater portions of their critical habitat at certain times of the year, yet a pesticide application could impact critical habitat for that species at any time of year by killing prey that they will depend upon later in the year.

EPA's 2004 Overview Guidance risk assessment process focuses on direct harm to living organisms and at best contemplate a screening-level analysis of indirect effects. Thus, EPA made a policy choice as to whether it will provide listed species the benefit of the doubt when it conducts its risk assessment with respect to critical habitat. And unfortunately, EPA has chosen to not give listed species the benefit of the doubt when it comes to critical habitat.

The most significant way that EPA fails to give the benefit of the doubt to listed species is its arbitrary use of LOCs themselves. By its own description, EPA purportedly integrates the results of pesticide exposure and toxicity data to develop an "RQ" for each pesticide. Once the RQ has been established for a particular pesticide, EPA then evaluates it to its pre-established LOCs for different types of organisms. This policy-tool then determines if the use of a pesticide crosses some threshold of acceptable risk.

Unfortunately, the EPA's policy tool — the LOCs — are just ludicrously absurd.

The LOC that triggers additional restrictions for impacts to any non-target organisms is set at 0.5 (RQ>0.5). For any threatened or endangered *aquatic* wildlife species, the LOC for acute impacts is set at 0.05 (RQ>0.05). For any terrestrial mammal or bird, the LOC for acute impacts is set at 0.1 (RQ>0.1). Why were these numbers chosen? EPA's approach in the 2004 Overview Guidance does not align even with the most basic principles of conservation biology, let alone the ESA's broad mandate to provide the benefit of doubt to threatened and endangered species.

Why should a threatened aquatic species be given a greater degree of protection than an endangered terrestrial species? Why should threatened aquatic species be given the same degree of protection as endangered aquatic species? EPA doesn't even have specific LOCs for amphibians and reptiles, so what is EPA to do when it assesses a species that is aquatic for part of its lifecycle and terrestrial for another part of it? Threatened species, by definition, are at far less risk of extinction than endangered species. In the Pacific Northwest, there are dozens of endangered and threatened salmon and steelhead species. The threatened Oregon Coast Coho population numbers are in the hundreds of thousands, while the endangered Snake River sockeye salmon population numbers are in the tens to hundreds.²² Yet, both of these species would be considered "aquatic endangered species" under 2004 Overview Guidance's ecological risk assessment procedures. Why is it logical that the LOC should be the same for both species?

There is no scientific reason why aquatic species should have a lower LOC than terrestrial species if one considered the conservation status of any particular species. Just as there may be

²² *Northwest Environmental Advocates v. U.S. Environmental Protection Agency*, No. 05-cv-01876-AC (D. Or. Feb. 28, 2012).

two aquatic species facing different degrees of imperilment, there are many threatened aquatic species that are far more secure than terrestrial endangered species. A bird or mammal down to its last few hundred individuals can be exposed to far greater risks from pesticides for no other reason than it happens to be a bird or mammal.

There is no reason why the LOC for *all* threatened and endangered species couldn't just be set at the same very low and uniform level. If EPA wanted to be truly precautionary in its approach to pesticides, it could easily set the LOC for all threatened and endangered species at 0.01 or even 0.001. Even better, the EPA could adopt the approach of the European Union on pesticides and require all pesticide registrants to prove that their products are 100% safe, rather than requiring EPA to prove that the pesticide is harmful to listed species.²³ In other words, if EPA wanted to, it could follow the law and “give the benefit of the doubt to the species.”²⁴

At its core, LOCs are arbitrary policy choices of EPA, supported by a document that may or may not exist, contained within a guidance document that had no public comment process in 2004 and which EPA has deemed rescinded, loosely based on another guidance document from 1998 that is outdated and has also been deemed rescinded.

Accordingly, we request the guidance documents be permanently withdrawn.

Respectfully Submitted,



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²³ European Commission Regulation EC 1107/2009 & Directive 91/414/EEC. Available at: http://ec.europa.eu/food/plant/plant_protection_products/legislation/index_en.htm.

²⁴ *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988) (quoting H.R. Conf. Rep. No. 96-697, 96th Cong., 1st Sess. 12, *reprinted in* 1979 U.S. Code Cong. & Admin. News 2572, 2576).