Chapter 5

Improving the Endangered Species Act Pesticide Consultation Process

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To improve pesticide consultations under the Endangered Species Act (ESA), at least three key questions should be answered. First, under the ESA, what level of risk to ESA-listed species is acceptable from the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act? Second, how will the federal agencies that implement and comply with the ESA receive enough funding to meet their current and future pesticide consultation workload? Third, how can these agencies improve the process of consultation, so that it is more effective, efficient, transparent, and predictable? This chapter explains the importance of each question and provides a starting point for answers.

Introduction

When Rachel Carson published Silent Spring in 1962, she awakened Americans to the environmental costs of indiscriminate pesticide use. She contended that pesticides had been approved for use "with little or no advance investigation of their effect on soil, water, wildlife, and man himself." Fifty years later, what progress have we made in ensuring that pesticides are applied only after we adequately investigate their effects on wildlife?

Let us assess the numbers. Currently, the U.S. Environmental Protection Agency (EPA) has over 1,100 pesticide active ingredients registered for use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (*1*). How many of these ingredients have been adequately evaluated under the Endangered Species Act (ESA) for their potential impacts to imperiled wildlife? Under three dozen, or less than four percent (*2*). Combine these active ingredients with non-active

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ingredients and we have over 20,000 distinct pesticide formulations approved for use under FIFRA (*3*). FIFRA, as implemented over the past 65 years, does not safeguard ESA-listed species, because EPA has not properly considered impacts to these species.

Under FIFRA, EPA may register a pesticide if it does not cause "unreasonable adverse effects" on the environment (*4*). To determine whether this requirement is met, EPA conducts a cost-benefit analysis (*5*). Pesticides may be registered as long as their purported benefits outweigh their potential harms. In practice, a FIFRA registration often says little about a pesticide's effects on listed species, and even when it does, FIFRA does not give greater weight to ESA concerns. By contrast, the ESA establishes a far more protective standard: a pesticide must not likely "jeopardize" a listed species or "destroy or adversely modify" critical habitat for the species (*6*). Under this standard, the economic benefits of a pesticide cannot override its adverse impacts. Because most pesticides on the market today have not been evaluated under the ESA, presumably dozens, if not hundreds, of pesticides are applied daily without satisfactory measures to protect listed species. From this viewpoint, little has changed since 1962 to adequately protect listed species.

Meanwhile, the few attempts to regulate pesticides under the ESA have been mired in controversy. EPA disagrees with the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) on basic questions, such as the methods and assumptions for evaluating the risks to imperiled species from pesticide exposure. Sharp criticism from the pesticide industry has saddled every recent pesticide biological opinion issued by NMFS. And last year, U.S. Representative Ken Calvert introduced an amendment to the Interior and Environment Appropriations Act (H.R. 2584) that would prohibit EPA from implementing any recommendations in any pesticide biological opinion.

The current situation is nothing short of a crisis, but in every crisis is an opportunity to improve. This chapter focuses on three key challenges to improving pesticide consultations. By tackling these challenges, federal agencies can chart a path to a consultation process that is more effective at protecting wildlife, more efficient to implement, more transparent to the public, and more predictable to regulated entities. Without these fundamental reforms, a voluminous backlog of pesticide consultations will remain the norm.

The Current Pesticide Consultation Backlog

To improve the pesticide consultation process, we first need to understand the origins of the current backlog. For many years, EPA neglected its obligation to consult with USFWS and NMFS (collectively, the Services) when approving pesticides for registration under FIFRA. Once EPA began consulting, it and the Services disagreed on how to properly assess the risk to listed species from pesticide use. EPA's approach to risk assessment requires limited or no consideration of sublethal, cumulative, and synergistic effects of pesticides on listed species or ecosystem impacts (*7*, *8*). The Services, however, believe these effects must be adequately considered under the ESA. As a result of these disagreements and the backlog of pesticides that have never undergone

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consultation, most of the pesticides on the market today have not been properly evaluated to ensure that their use is not "likely to jeopardize" a listed species or "adversely modify" critical habitat under the ESA.

USFWS currently has over 170 pending requests for pesticide consultations. EPA, for its part, has identified over 1,100 pesticide active ingredients scheduled for Registration Review under FIFRA by October 2022, and plans to complete an endangered species risk assessment for each of these ingredients. Under the current pesticide consultation framework, USFWS will likely need over 30 additional biologists to handle these consultations. Assuming FWS allocates $125,000 annually for each biologist, it alone will need an additional $3.75 million annually for pesticide consultations. NMFS will also need additional funds. Where will these resources come from, especially when the Services have never received enough funding to keep pace with their pesticide consultation workload? As discussed in the next section, inadequate funding is one key challenge to improving the pesticide consultation process.

Key Challenges To Improving Pesticide Consultations

Many of the controversies surrounding pesticide consultations can be framed as challenges to improving the consultation process. To bring effective and lasting improvements, below are four key challenges posed as questions that the Services and EPA should address or seek answers to.

- Policy question – Under the ESA, what level of risk to listed species is acceptable from the registration of a pesticide under FIFRA?
- Science question – What is the proper method of assessing those risks?
- Funding question – How will the Services and EPA receive enough funding to meet their current and future pesticide consultation workload?
- Process question – How can the Services and EPA improve the process of consultation, so that it is more effective, efficient, transparent, and predictable?

EPA and the Services clearly understand the importance of the second question, as evident from the current National Research Council (NRC) study they have funded to address this issue (*9*). But far less attention has been given to the three other questions. The rest of this chapter articulates the importance of these other questions and provides general guideposts for answering them.

Policy Question: Scientific Uncertainty and Risk Tolerance

Scientific uncertainty is present in varying degrees in every ESA consultation, just as it is in almost all government decisions involving natural resources. Federal agencies and the Services never have complete and perfect information about how an activity will affect a listed species. As a result, the biological

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effects determinations in all section 7 consultations implicitly assume some likelihood of being wrong or inaccurate. How much risk of making a mistake is acceptable under the ESA, and who bears that risk? The answers to these questions are particularly important in pesticide consultations, because pesticide effects determinations involve exceptionally high levels of scientific uncertainty.

At first glance, the answers to these risk-tolerance questions may appear to lie entirely in the realm of science. After all, the root problem is *scientific* uncertainty. But closer scrutiny reveals that these questions hinge on non-scientific, policy judgments. Science can tell us *how* to calculate an acceptable level of risk, but it alone cannot tell us *what* that level should be. In our daily lives, for example, science can help us calculate the probability of developing cancer from smoking, but whether that level of risk is acceptable is based on our personal values. There is no empirically verifiable, objectively correct answer. The same is true of pesticide consultation questions that involve scientific uncertainty. For example, when evaluating the effects of chemicals on listed species, EPA relies on a combination of open literature data and test results on surrogate species (*10*). But no reliable data exists on whether these surrogate species are the most sensitive organisms to any particular pesticide, as sensitivity varies by pesticide. Given this irreducible uncertainty, should the Services and EPA assume a "safety factor" of zero-fold, ten-fold, or perhaps a hundred-fold when extrapolating results from a surrogate species to a listed species? The answer depends largely on how EPA interprets its responsibilities under section 7(a)(2) of the ESA and how much the Services and EPA seek to minimize the risk of harming the listed species by not regulating pesticide use enough (or, conversely, harming crop growers by over-regulating pesticide use beyond the levels needed to protect the species). Science alone cannot answer this question.

In its 1995 study titled "Science and Endangered Species Act," the National Academy of Sciences described this distinction between a science question and a non-science question when agencies confront scientific uncertainty (*11*). The NRC observed that "[e]ven though estimates of risk are grounded in scientific information, those implementing the [ESA] often make value judgments when making decisions about listing, jeopardy, etc" (*12*). Thus, the NRC explained, "science by itself is not sufficient input to policy decisions, apart from the objectives and values it serves" (*12*). Because the ESA's objective—its underlying value—is to protect and recover imperiled species, some courts have rightfully required the Services to resolve scientific uncertainty in favor of giving species the benefit of the doubt.

Aside from this general instruction to act cautiously, however, the Services have tremendous flexibility in deciding precisely how to resolve scientific uncertainty in ESA consultations. The ESA requires federal agencies to use only the "best scientific and commercial data available," not the best data possible (*6*). Because the best available science rarely plugs all knowledge gaps, the Services' Section 7 Consultation Handbook offers two options for addressing substantial scientific uncertainties: delay issuing a biological opinion until more information is gathered, or issue the biological opinion with the available information but give "the benefit of the doubt" to the species (*13*). Under this framework, Services biologists rely on their best professional judgment to resolve scientific uncertainty

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on a case-by-case basis. If the decision is challenged in court, the standard of review is whether the decision was "arbitrary and capricious" under the Administrative Procedure Act (*14*), a test that is highly deferential to the agency. The Services' decisions are further buttressed by the fact that under section 7(a)(2) of the ESA, the burden of proof is on the EPA, not the Services, to "insure" that its actions will not likely jeopardize listed species or destroy or adversely modify their critical habitat. Thus, the burden of insufficient knowledge must be carried by EPA, not the Services, in satisfying the requirements of section 7(a)(2).

The Services' considerable discretion and flexibility in making section 7 effects determinations is a double-edge sword. Discretion and flexibility—exercised in the absence of a transparent framework—often lead to regulatory uncertainty and inconsistent application. In particular, exactly when do the Services give species the benefit of the doubt? And how much benefit is given to any particular species? Because there are no clear answers to these questions as applied to pesticide consultations, frustration and disagreement can ensue.

By creating a general risk-tolerance framework that the Services and EPA can use to address these questions, the Services may relinquish some flexibility in decision-making but realize several compensatory benefits. One is to provide the public with greater predictability and transparency about how the Services will address scientific uncertainty in pesticide consultations. Indeed, the NRC made a similar recommendation in its 1995 study, stating that "[a]rticulating an explicit framework [for making the connection between values, objectives, and scientific evidence] can help link science and values and lead to better and more defensible decisions" and "disarm criticisms that the government is capricious or partisan in implementing the act" (*15*). A related benefit is that the Services will reduce their litigation risk by ensuring that all pesticide risk-tolerance decisions follow a consistent framework, one that should undergo public notice and comment. Another benefit is to ensure that the Services conduct pesticide consultations in a manner sufficiently protective of listed species by establishing a minimum level of precaution that every Service biologist must apply. Even with the best of intentions, decisions on setting acceptable error rates when resolving scientific uncertainty "are complicated and consequential enough that unaided intuition cannot always be trusted to do a good job" (*16*).

Some people assume that the current NRC study can answer these risk-tolerance questions and that it is premature for the Services to begin developing a risk-tolerance framework. The NRC, however, has been charged with answering science and technical questions relating to pesticides, including how to interpret scientific uncertainty. It has not been asked to opine on policy questions about what level of risk is acceptable under the ESA. Thus, the NRC study is necessary but not sufficient to determining how the Services and EPA should address scientific uncertainty in pesticide consultations.

Some people might also assume that risk-tolerance issues will be solved on their own, perhaps through the Services issuing additional biological opinions that help define the "benefit of the doubt" standard or through future court decisions that address the issue. But there are several reasons why this reliance is misplaced. First, it hardly provides the level of regulatory certainty needed to avoid litigation on future biological opinions. Future consultations must evaluate the effects of

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hundreds of pesticides on perhaps hundreds of species, resulting in thousands of pesticide-species combinations. Each combination will raise substantial issues of scientific uncertainty. Second, many of the current NMFS pesticide biological opinions have focused on salmonids, which have been well-studied relative to many other imperiled species. Future consultations must address effects on species, such as the Salt Creek tiger beetle (*Cicindela nevadica lincolniana*), for which scientists have far less information. Scientific uncertainty may become an even more vexing issue in those consultations. Third, ongoing controversy and litigation on pesticide consultations increase the ESA's political baggage and provide fodder for a wholesale legislative "fix" to the current debacle. The problem, however, is not the ESA itself but the differing perspectives and values of the Services and EPA. If the Services and EPA can resolve their differences through administrative action, they are more likely to retain control over the fate of the pesticide consultation program and defuse volatile controversies.

The Services and EPA should begin constructing a general framework for evaluating, under the ESA, what level of biological risk to listed species is unacceptable from the registration of pesticides. An initial step to creating this framework is to clearly articulate the distinction between a science question and a non-science question in the context of scientific uncertainty in pesticide consultations. To date, there has been a disproportionate emphasis on addressing the former and far less attention paid to the latter.

Any risk-tolerance framework under the ESA should be based on the precautionary principle and the concept of giving species the "benefit of the doubt." The ESA is not a value-neutral statute. It is animated by the idea that preventing extinction and recovering imperiled species is a good thing. As the Supreme Court held, "Congress has spoken in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as 'institutionalized caution'" (*17*). A clear and robust "benefit of the doubt" standard would align squarely with the ESA's normative leanings. On this issue, the NRC has observed that for "a variety of statistical reasons, including those pertaining to availability of data, protection would be more likely if the burden of proof were to show that a proposed action would not harm a listed species rather than to show that it would" (*18*).

To begin developing a risk-tolerance framework, the Services should consider evaluating how scientific uncertainty is addressed under other environmental laws, especially those protecting human health. Ultimately, the Services should begin developing sidebars on how they will address major pesticide risk-tolerance issues, such as the use of safety factors when extrapolating from surrogate to listed species, the treatment of synergistic and additive effects, the effects of pesticides on the ecosystem of listed species, and the assumptions about the timing and extent of pesticide application. The Services should also consider how the level of precaution exercised might vary based on the expected consequences of making an erroneous decision. The 1995 NRC study explains this issue extensively and provides an excellent springboard for developing a risk-tolerance framework.

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Funding Challenge: Eliminating the Backlog

Even if all science, policy, and legal issues relating to pesticide consultations are addressed, the consultation backlog remains because the Services lack the resources to address more than a fraction of all pesticide consultation requests. As noted earlier, EPA plans to complete an endangered species risk assessment for each of the over 1,110 active ingredients scheduled for FIFRA registration review by October 2022. It seems unlikely that the Services can keep pace with this schedule by relying on Congressional appropriations alone. After all, EPA can assume this ambitious pace largely because of user fees it receives through the Pesticide Registration Improvement Renewal Act. If the Services do not receive comparable funding, how can they possibly track EPA's progress?

As a path forward, the U.S. Government Accountability Office or another institution should determine the amount of resources required for the Services to complete its current and projected future pesticide consultation workload. Because there has been no clear figure to date, it has been difficult to make a compelling case for support for increased funding to the Services. Next, the Services, EPA, and pesticide stakeholders should start a dialogue on solutions to help fund pesticide consultations for both the Services and EPA. One option is a pesticide user fee devoted specifically to funding consultations. It may currently be difficult for registrants to support this option, particularly because there is profound disagreement about how to conduct pesticide consultations. But if these disagreements can be resolved in a manner that is acceptable to reasonable stakeholders who are truly interested in solutions, then registrants and Congress should seriously consider how they can help fund pesticide consultations, so that pesticides currently on the market are brought into compliance with the ESA.

Process Challenge: Improving the Process of Consultation

The process question is about how the Services and EPA can design and implement a workable pesticide consultation program, one that addresses scientific disagreements, risk-tolerance issues, and funding constraints. As a result, it is perhaps the last question to answer in efforts to improve consultations, although it should always inform attempts to answer the science, risk-tolerance, and funding questions.

In the past decade, the only serious attempt to address the regulatory process question was through a 2004 ESA-FIFRA counterpart rule that created an alternative pesticide consultation process. There were several legal and policy flaws with that rule, including EPA's lack of accountability to the Services for making "not likely to adversely affect" determinations under section 7 of the ESA. Policymakers can learn from those mistakes if they were to design a new collaborative process, which should achieve the general goals of greater effectiveness, efficiency, transparency, and predictability discussed earlier, as well as the following specific goals:

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- Improve the Services' ability to help EPA satisfy its duty under the ESA to ensure that the registration and re-registration of pesticides under FIFRA is not likely to jeopardize any listed species or destroy or adversely modify critical habitat.
- Focus on creating enough inter-agency accountability, reliability, and trust within the consultation process, so that the workload between EPA and the Services can be distributed in a way that provides the required level of protection for wildlife, yet enables the agencies to efficiently process hundreds, if not thousands, of pesticide consultations within the next decade. A truly effective framework will allow the agencies to focus less on who completes the first draft of a biological analysis that underlies a section 7 effects determination, provided that the Services' final review and approval authority is clearly maintained (*19*). A key component to realizing this vision is to craft a risk-tolerance framework with a clearly articulated and constrained decision-making process, such that capable agency biologists—whether sitting at EPA or the Services—can easily agree on and draft a biological effects determination that is transparent and defensible.

The Need for Transformation and Bold Leadership

In every crisis is an opportunity to improve. We should all commend the Services and EPA for taking an important step to improving the pesticide consultation process by seeking recommendations from the NRC on key science questions. As argued in this chapter, however, science plays an important but limited role in resolving the pesticide crisis. Other pieces of the solution include articulating a framework for addressing scientific uncertainty in pesticide consultations, securing enough funding to complete current and future consultation requests, and designing an improved consultation process that is more effective at conserving wildlife, more efficient to implement, more transparent to the public, and more predictable for stakeholders. The Services and EPA should lead this transformation by crafting a multifaceted plan that addresses all the key challenges to improving pesticide consultations. Without this comprehensive vision for a better future, the current conflicts between pesticide use and wildlife conservation will languish unresolved.

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References

1. Owens, S. A. U.S. Environmental Protection Agency Letter to Edward J. Markey. April 28, 2011.
2. Pesticide Consultations with EPA. 2011. NOAA Fisheries. http://www.nmfs.noaa.gov/pr/consultation/pesticides.htm. March 28, 2012.
3. Esworthy, S. *Pesticide Registration and Tolerance Fees: An Overview*; Congressional Research Service: Washington, DC, 2010; p 23.
4. 7 U.S.C. § 136a(c)(5)(C).
5. 7 U.S.C. § 136(bb).
6. 16 U.S.C. § 1536(a)(2).
7. U.S. Environmental Protection Agency. *Overview of the Ecological Risk Assessment Processin the Office of Pesticide Programs*; Office of Pesticide Programs: Washington, DC, 2004.
8. *Washington Toxics Coalition v. Dept. of Interior*; 457 F. Supp.2d 1158 (W.D. Wash. 2006).
9. The National Academies. Ecological Risk Assessment Under FIFRA and ESA. http://www8.nationalacademies.org/cp/projectview.aspx?key=49396 (last accessed July 10, 2012).
10. U.S. Environmental Protection Agency. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*; 2004; p 32.
11. National Research Council. *Science and the Endangered Species Act*; National Academy Press: Washington, DC, 1995.
12. National Research Council 159.
13. U.S. Fish & Wildlife Service & National Marine Fisheries Service. *Endangered Species Consultation Handbook*;1998; pp 1−7.
14. 5 U.S.C. § 706(2)(a).
15. National Research Council. *Science and the Endangered Species Act*; National Academy Press: Washington, DC, 1995; p 159.
16. National Research Council 166.
17. *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978).
18. National Research Council. *Science and the Endangered Species Act*; National Academy Press: Washington, DC, 1995; p 175.
19. *Washington Toxics Coalition v. Dept. of Interior*, 457 F. Supp.2d 1158 (W.D. Wash. 2006).