

# ALIGNING IMPERILED SPECIES CONSERVATION AND PESTICIDE REGISTRATIONS

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## I. INTRODUCTION<sup>1</sup>

The effects of pesticides on wildlife have long been a conservation concern. *Silent Spring*, published by Rachel Carson over fifty years ago, shed light on the impacts of DDT (dichlorodiphenyltrichloroethane) on birds like the bald eagle, our nation’s iconic symbol.<sup>2</sup> DDT caused thinning in egg shells and other problems for birds, decreasing the productivity of nests and ultimately reducing some populations dramatically.<sup>3</sup>

The public outcry was clear and soon DDT was banned, helping set species like the bald eagle on the road to recovery. This outcome continues to be celebrated as a great conservation success story. We used science to identify a problem, took action to fix it, and the benefits to wildlife were clear in real time.

Fifty years ago, amidst dramatic economic growth in this country, there was an increasing public call to conserve wildlife, to find that

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<sup>2</sup> RACHEL CARSON, *SILENT SPRING* (1962).

<sup>3</sup> *Id.* at 103–113.

sometimes-elusive balance between development and conservation. At the same time, there was an important recognition that increasing agricultural productivity was technologically feasible and necessary to feed a growing population. In addition, environmental risk assessment was becoming more sophisticated, showing the promise to ensure that the use of pesticides would not compromise human health or the natural world. We needed a legal framework that would ensure pesticides could be registered efficiently, with a careful eye on the needs of human health and wildlife conservation.

The original Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) of 1947 was amended in 1973,<sup>4</sup> and several times since, and provides the overarching modern framework to safely register pesticides in a timely fashion. The framework provided registrants with regulatory predictability and therefore a greater incentive to invest in new technology. It also gave agricultural producers the expectation that productivity would remain strong and likely increase in the future. The Environmental Protection Agency (“EPA”) was entrusted with the responsibility of overseeing pesticide registrations.

In 1973, the Endangered Species Act (“ESA”) was passed into law<sup>5</sup> with nearly universal support. The statute provided a mechanism to list species as threatened or endangered, giving them important legal protections. The ESA, and the implementing regulations promulgated by the Fish and Wildlife Service and National Marine Fisheries Service, referred to as the Services, set forth a framework for developing and implementing recovery plans, working hand in hand with the states, and reviewing proposals for development and other activities that may affect listed species.

By reviewing proposals before they are implemented, the Services can recommend ways to minimize adverse effects on listed species and their designated critical habitat. They can also exempt impacts that are incidental to the action, provided they do not jeopardize survival and recovery, or undermine the ability of critical habitat to serve its role for the species. For actions that are funded, authorized, or otherwise carried out by a federal agency, this process is commonly called a section 7 consultation and results in a biological opinion from the Services when adverse effects are likely to occur from the proposed action.

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<sup>4</sup> Federal Insecticide, Fungicide, and Rodenticide Act of 1947, Pub. L. No. 92-516, 86 Stat. 975 (codified as amended at 7 U.S.C. § 136 (2012)).

<sup>5</sup> Endangered Species Act, Pub. L. No. 93-205, 87 Stat. 884 (codified as amended at 16 U.S.C. § 1531 (2012)).

The statutory scheme is logical, but the interplay between the ESA and FIFRA was challenging from the start. Because pesticide registrations constitute a federal action, a section 7 consultation is generally required unless EPA determines the pesticide will have no effect on an ESA listed species. As we discuss below, this is, to put it mildly, easier said than done. The issue abandons the relative luxury of a single agency administering a single statute—and instead we must contend with multiple agencies, mandates, and differing staff expertise, reconciling multiple statutory provisions, in the face of declining resources, a litigation-rich environment, and complex and sometimes uncertain science.

Despite the long and contentious history of ESA consultation under FIFRA, we are witnessing promising strides along a common path toward effective implementation of both of these important statutes. While challenges remain, hopefully the recent progress is a sign of greater achievements to come.

## II. THE PROBLEM OF SCIENTIFIC UNCERTAINTY IN MEASURING PESTICIDE RISK TO SPECIES

In many cases today, the impacts from certain pesticides on wildlife are less obvious than they were with DDT, at least at first glance. Pesticides may not cause mortality, for example, but can cause sub-lethal effects and may interact with other chemicals in the environment—including other pesticides—and have negative impacts on wildlife populations.

Measuring these effects can be challenging. We often do not have a great deal of data on the effects from an individual pesticide on imperiled species, let alone the synergistic effects of many different ones coupled with other stressors in the environment like habitat loss and invasive species. In addition, we often do not have a great deal of detailed information about imperiled species. Their ranges have regularly been reduced and comprehensive surveys are not always available. Basic information for some species like population size and occupied range is sometimes unknown.

A review of basic facts and figures illustrates the problem the government and the agricultural and conservation communities face: there are more than 1,100 active ingredients in nearly 20,000 registered pesticide products already on the market.<sup>6</sup> These are applied across the

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<sup>6</sup> There currently are about 740 registration review “cases” that include approximately 1,140 pesticide active ingredients. Pesticide cases may be related by chemical class or structure,

country, in differing amounts, for different purposes, by applicators who by law are subject to differing sets of requirements. And there are roughly 900 million acres of farmland nationwide.<sup>7</sup> At the same time, there are around 1,500 species that are listed as either endangered or threatened under the ESA.<sup>8</sup> Critical habitat has also been designated under the ESA for many of these species.<sup>9</sup>

Under FIFRA, the EPA has a responsibility, in part, to balance certain risks and benefits.<sup>10</sup> EPA's mandate is to regulate and register the use of pesticides and to ensure that the use of pesticides will not cause *unreasonable* adverse effects on human health or the environment. EPA also shares a responsibility with all federal agencies to consult with the Services under section 7 of the ESA: to "insure that any action authorized, funded, or carried out by [federal agencies] is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined . . . to be critical . . . ."<sup>11</sup>

Addressing these two important mandates is not simple. FIFRA registration actions by EPA are by their nature nationwide in scope, but the analysis with respect to endangered species is inherently very local. The risk assessments that EPA does for pesticides have been difficult to translate into species-level effects in a particular region.

In doing these risk assessments, we not only consider the effect of just one pesticide on a species, but where data exist, the effect of the interaction of multiple pesticides, and possibly other factors that may be affecting a species or its habitat. For example, the level of rainfall can be an important factor in determining whether and how much of an applied pesticide makes it into contact with a species of concern or its habitat. The national nature of many assessments creates very complex analyses involving hundreds of species spread across an enormous geographical area.

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mode of action, use, or for other reasons. *Registration Review Process*, ENVTL. PROTECTION AGENCY, <http://www2.epa.gov/pesticide-reevaluation/registration-review-process> (last visited April 9, 2015). As of March 24, 2015, the database of registration information maintained by EPA's Office of Pesticide Programs reflected a total of 19,234 registered pesticide products.

<sup>7</sup> NAT'L AGRIC. STATISTICS SERV., U.S. DEP'T OF AGRIC., 2012 CENSUS OF AGRICULTURE 7 (2014).

<sup>8</sup> U.S. FISH & WILDLIFE SERV., CRITICAL HABITAT: WHAT IS IT? (2015).

<sup>9</sup> *Id.* ("critical habitat has been designated for 704 of the 1,570 U.S. species . . . listed as endangered or threatened.")

<sup>10</sup> *See, e.g.*, 7 U.S.C. § 136a(a) (2012) ("To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered.")

<sup>11</sup> 16 U.S.C. § 1536(a)(2) (2012).

For reasons that should be self-evident from the simple multiplication of these factors, our scientists have struggled for decades to devise an effective, efficient, reliable, and transparent method for conducting these assessments. At the heart of this was a disagreement over the amount of information and the relative degree of certainty needed to make determinations about the risks of pesticides on species populations. Both the Services and EPA are mission-oriented organizations. Both are committed to the faithful implementation of the applicable laws and use of sound science. But faced with differing mandates and different pressures, the agencies often find themselves at an impasse.

### III. THE FORMULATION OF A WORKABLE STRATEGY

In the last decade, there has been an increase in lawsuits targeting EPA for failure to consult, and the Services for unreasonable delay in completing consultations, brought by those concerned that the needs for species were not being adequately addressed. The Courts were beginning to impose new deadlines and interim measures such as buffer zones around habitat until consultations could be completed.<sup>12</sup> The registrants and pesticide users felt regulatory predictability had been lost and that they did not have a voice in the process. They in turn appealed court decisions, causing protracted legal battles. In short, the effective implementation of FIFRA and the ESA was enmeshed in scientific disagreements, concerns about transparency, workload challenges, and legal disputes.

The agencies understood the problems and began to develop a four-part strategy for improving registration reviews and ESA consultations. First, assistance was sought from the National Research Council ("NRC") of the National Academy of Sciences ("NAS") for an independent scientific review to help resolve disagreements. Second, working with EPA and the Services, the U.S. Department of Agriculture ("USDA") increased and focused its engagement with pesticide users and registrants on issues surrounding pesticide usage and endangered species. Third, EPA and the Services worked to make constructive progress with the environmental community to resolve legal disputes where possible and create a work plan that the federal agencies could manage. Fourth, the agencies developed a collaborative scientific

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<sup>12</sup> *E.g.*, *Wash. Toxics Coal. v. Env'tl. Prot. Agency*, No. C01-0132C, 2004 U.S. Dist. LEXIS 29886 (W.D. Wash. Jan. 22, 2004).

dialogue to make both FIFRA registration review and ESA consultation work more effectively and efficiently in the future.

*A. Aligning Scientific Methods—The NAS Report*

In March of 2011, former EPA Administrator Lisa Jackson, with the support of the Secretaries of Agriculture, Commerce, and the Interior, wrote a letter to the president of the NAS. In it, she asked the NAS, on behalf of EPA, USDA, and the Services, to convene a committee of independent experts to review the scientific and technical issues of meeting the agencies' and departments' respective responsibilities under the ESA and FIFRA.

Specifically, the committee was asked to identify best available scientific data and information; consider sub-lethal, indirect, and cumulative effects; evaluate the effects of inert ingredients and chemical mixtures; advise on the use of models to assist in analyzing the effects of pesticide use; incorporate uncertainty into evaluations effectively; and describe the best use of geospatial information and datasets in assessing the risk.

On April 30, 2013, the NAS provided their recommendations to the agencies in the form of a report entitled "Assessing Risks to Endangered and Threatened Species from Pesticides."<sup>13</sup> The NAS report has had a powerful and positive effect. There is more and better collaboration between EPA and the Services.

Upon receipt of the report, the agencies began a joint review and developed a plan for implementation. The agencies determined a set of interim approaches for use in risk assessments and described them in a white paper. The interim approaches were provided to the public with a request for feedback, and then presented during a public workshop on November 15, 2013. On April 22, 2014, at the request of stakeholders, the agencies held another public workshop allowing the stakeholders to present their input. In response, the agencies refined the interim approaches further, continued to welcome feedback, and are fully committed to improving the methods over time.

In order to have a manageable process for consultations, the government must be able to prioritize the most risky pesticides for evaluation first. With pesticides, there are strong, credible reasons to believe that the riskiest pesticides, for humans and for endangered species, are the existing pesticides already on the market. These

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<sup>13</sup> NAT'L RESEARCH COUNCIL, ASSESSING RISKS TO ENDANGERED AND THREATENED SPECIES FROM PESTICIDES (2013), *available at* [http://www.nap.edu/catalog.php?record\\_id=18344](http://www.nap.edu/catalog.php?record_id=18344)

pesticides, in general, have older, simpler, and more toxic chemistries with a broader mode of action. In other words, in general, they affect a larger number of species in more profound ways than the newer pesticides, which are designed to be more targeted, less lethal to non-target organisms, and to have lower side-effects in the larger ecology.

### *B. Increasing Transparency and Engaging the Public*

The second part of the strategy for improving registration reviews and ESA consultations included enhancing public transparency and engagement. This aspect of the overall approach must account for the evolving development and use of environmental data, not just by federal scientists, but also by stakeholders and interested parties.

We are in the midst of an information revolution. Throughout the federal government we are constantly working on improving our geospatial data. In the ESA-FIFRA context, this can help us and pesticide users learn where species are or could be located in relation to crop production in order to target controls and best practices for pesticide application. The pesticides industry has a stake in this too and companies have an interest in contributing to this work. USDA and its partners, likewise, are generating improved data on cropped areas where pesticides are used most heavily.

One of the most important ways EPA delivers useful data for ESA purposes is through the use of county-wide bulletins as part of the FIFRA enforceable labeling program. These bulletins give pesticide users local information on pesticide use restrictions. The bulletins are online, accessed through EPA's web application "Bulletins Live!"<sup>14</sup> Farmers and other applicators can simply go online, enter their state and county information, and the time of year they are applying pesticides, and they will see if any relevant restrictions are in place.

EPA has another new online tool that is available to the public called the "Salmon Mapper" that helps to implement the stream buffers called for in the recent Northwest Coalition Against Pesticides ("NCAP") settlement (discussed below).<sup>15</sup> This tool allows applicators to see where the streams are located and where buffer zones have been put in place to protect salmon habitats.

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<sup>14</sup> *Endangered Species Protection Bulletins*, ENVTL. PROTECTION AGENCY, <http://www.epa.gov/espp/bulletins.htm> (last updated Dec. 19, 2014).

<sup>15</sup> *Salmon Mapper*, ENVTL. PROTECTION AGENCY, <http://www2.epa.gov/endangered-species/salmon-mapper> (last updated Nov. 18, 2014).

But this kind of data is a small fraction of what is soon to be upon us in the environmental field. The world of environmental law—and the science and information that supports it—is susceptible to rapid change because of this explosion in data. It was not all that long ago that a company's discharge monitoring reports were the best, if not sole, source of information about pollution in waterways. And our air quality was measured by costly and dispersed monitors, whose readings were infrequent and often inaccessible. If information is power, we lived and practiced in a kind of environmental oligarchy—where data was guarded by its owners, and the transmission lines ran from the company fence line to the regulator's files, with no intermediate stops.

But anyone with a child, or a grandchild—or a smart phone in their pocket—knows firsthand how little relationship that quaint order bears to the complexities presented by today's—and tomorrow's—technologies. More people can gather data, more people can disseminate data, and more people can find and interpret data than ever before. We cannot overestimate the game changing nature of technological advances that put more information in the hands of more people. But this proliferation of information and data sources requires a degree of scrutiny to help ensure both its validity and its utility. For example:

- How do we identify and differentiate between the sources of data?
- How do we assure its quality and understand its limitations?
- How do we interpret it and translate it?
- How do we share new information, and how do we describe what we understand to be the limitations of any given set of data?
- How does new information relate to the framework of laws and regulations we are accustomed to operating under?
- How will the government change the way it approaches the gathering and analysis of data?
- How will the government receive, verify, and share new sources of environmental information?

Returning to the ESA-FIFRA context itself, a new stakeholder process implemented by the agencies has increased public engagement and transparency. Since 2011, the agencies have organized meetings and workshops with stakeholders interested in pesticide consultations. For example, the agencies used EPA's Pesticide Program Dialogue Committee ("PPDC") to collect feedback on multiple occasions. Members of the PPDC represent a variety of stakeholders including pesticide registrants, growers, states, and non-governmental organizations.



In response to the stakeholder feedback, the agencies prepared and proposed for public comment a process described in a white paper entitled, “*Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives*” (“Stakeholder Paper”). The agencies finalized the Stakeholder Paper in March 2013.<sup>16</sup>

The Stakeholder Paper begins by emphasizing the value of improved coordination across the agencies, a key recommendation of the NRC report.<sup>17</sup> Early engagement with stakeholders is an underpinning of effective consultation. Registrants and pesticide users had criticized the mitigation requirements included in some past biological opinions as unscientific, economically unsound, and simply impractical. Registrants and the agricultural community were especially concerned by a perceived lack of adequate engagement between the government, pesticide companies, and pesticide users before the mitigation was required.

By working with registrants, pesticide users, and the environmental community early in the review process, the agencies can help avoid potential eleventh hour surprises and foster a better atmosphere where all parties may find mutually agreeable solutions. The early coordination with registrants facilitates a dialogue that may result in certain types of mitigating actions, such as an agreement to voluntarily limit pesticide applications in some particularly sensitive areas or at specific times that are important for species. In these cases, it may be possible to eliminate the need for formal consultations, or at a minimum make them much less complex.

The Stakeholder Paper describes “Focus” meetings, which are now being held at the start of registration review for pesticide active ingredients.<sup>18</sup> This change brings the affected stakeholders into EPA’s review process at the earliest point of a pesticide’s registration review cycle. It allows the mitigation conversation to start at the very beginning. In addition, the Stakeholder Paper recognizes USDA’s valuable relationships with the agricultural community that provide a

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<sup>16</sup> ENVTL. PROT. AGENCY, EPA-HQ-OPP-2012-0442, ENHANCING STAKEHOLDER INPUT IN THE PESTICIDE REGISTRATION REVIEW AND ESA CONSULTATION PROCESSES AND DEVELOPMENT OF ECONOMICALLY AND TECHNOLOGICALLY FEASIBLE REASONABLE AND PRUDENT ALTERNATIVES (2012), available at <http://www.epa.gov/oppfead1/endanger/2012/regreview-esa.pdf>.

<sup>17</sup> *Id.* at 2.

<sup>18</sup> *Id.* at 4.

critical link between EPA's expertise on pesticides and the Services' expertise on listed species' locations, status and biology.<sup>19</sup>

Another important element of the Stakeholder Paper involves providing the public with the opportunity to offer comments on draft documents, including draft biological evaluations and opinions, before the agencies make final decisions.<sup>20</sup> This provides yet another point for engagement by stakeholders. In the case of a biological opinion, for example, EPA has committed to collecting any comments on the draft biological opinions and providing them to the Services. The Services then prepare a document to be included in the administrative record of the consultation explaining how comments were considered, and if appropriate, how the final biological opinion was modified to address the comments. These changes, the agencies believe, will help to provide clarity and transparency, strengthen relationships with all stakeholders, and result in stronger decisions.

### *C. Resolving Legal Disputes and Creating a Shared Work Plan*

The third key aspect of the strategy to improve registration reviews and ESA consultations involved resolving legal disputes and creating a shared work plan for the agencies. This approach will allow all of the agencies' scientists to implement the NAS recommendations within the context of specific registrations and answer the questions that inevitably will arise during this process.

Three recent settlements of lawsuits involving EPA and the Services (*Northwest Center for Alternatives to Pesticides v. Environmental Protection Agency*<sup>21</sup>; *Northwest Coalition for Alternatives to Pesticides v. National Marine Fisheries Service*<sup>22</sup>; and *Center for Biological Diversity v. Fish and Wildlife Service*<sup>23</sup>)—unopposed by industry—have contributed to a coordinated workplan. The cases from which these settlements arose dealt with the continuing need to complete five

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<sup>19</sup> *Id.* at 9.

<sup>20</sup> *Id.* at 1–2.

<sup>21</sup> Stipulated Settlement Agreement and Proposed Order of Dismissal, at 3, 6–7, *Nw. Ctr. for Alts. to Pesticides v. Env'tl. Prot. Agency*, (2:10-cv-01919-TSZ) (W.D. Wash. Aug. 15, 2014) (amended complaint challenged failure to complete organophosphate ("OP") and other BiOps ordered in WTC; stipulation reinstated salmon buffers).

<sup>22</sup> Stipulated Settlement Agreement and [Proposed] Order of Dismissal, *Nw. Coal. for Alts. to Pesticides v. Nat'l Marine Fisheries Servs.*, (No. 07-1791-RSL) (W.D. Wash. July 30, 2008) (agreement to complete Biological Opinions for Propargite, Fenbutatin-oxide, Diflubenzuron, OPs, Bromoxynil, Prometryn, 1, 2-D, and racemic metolachlor).

<sup>23</sup> Stipulation Amending Original Stipulated Settlement and Order, *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Servs.*, (No. 3:11-cv-5108-JSW) (N.D. Cal. July 28, 2014) (agreeing to complete consultations on five pesticides for the California Red-legged Frog).

biological opinions on a number of organophosphate and other pesticides identified in the *Washington Toxics* case.<sup>24</sup> The agencies committed to completing nationwide consultations for five pesticides, including carbaryl, chlorpyrifos, diazinon, malathion, and methomyl.<sup>25</sup> The consultations for chlorpyrifos, diazinon, and malathion will be completed by December 2017.<sup>26</sup> Consultations for carbaryl and methomyl will be done one year later.<sup>27</sup> These settlements also reinstated stream buffers to protect salmon in the Northwest.<sup>28</sup>

The agencies believe that we must effectively complete the existing work plan. Given limited staff and resources, it is important to prioritize these risk assessments and consultations, which will allow the NRC recommendations to be adopted and refined further. The goal is to establish a standard approach for consultations that can be applied routinely under FIFRA as the registration review process for existing pesticides is applied.<sup>29</sup>

#### *D. Collaboration for Efficient and Effective Consultations*

With the NRC's assistance, the agencies have come a long way in resolving the scientific disputes of the last forty years. They are now working diligently on the five chemicals described in the settlement agreements. By investing this time together now, the agencies expect to increase effectiveness and efficiency in the future. Collaboration among the agencies is absolutely essential to this work. An efficient and effective registration and consultation process requires a high degree of coordination and shared scientific principles.

The five consultations above are expected to produce lessons learned and more detailed guidance for future consultations, allowing EPA and registrants to develop assessments that more easily translate into consultations by the Services. This is a classic case of going slow at first to go fast later. The agencies believe the increase in effectiveness and efficiency will be an essential element of managing the broader registration workload that EPA and the Services will handle in the future.

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<sup>24</sup> *Wash. Toxics Coal. v. Env'tl. Prot. Agency*, No. C01-0132C, 2004 U.S. Dist. LEXIS 29886 (W.D. Wash. Jan. 22, 2004).

<sup>25</sup> *Id.* at 3.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> Stipulated Settlement Agreement and Proposed Order of Dismissal, at 6–7, *Nw. Ctr. for Alts. to Pesticides v. Env'tl. Prot. Agency*, (2:10-cv-01919-TSZ) (W.D. Wash. Aug. 15, 2014).

<sup>29</sup> Under section 3 of FIFRA, each pesticide registration under FIFRA is reviewed every fifteen years. 7 U.S.C. § 136a(g) (2012).

Collaboration with registrants, farmers, and environmental groups is equally important. As previously described, the early coordination facilitates a dialogue that may result in voluntary mitigation to avoid sensitive areas for species. These relationships also open the door to other creative mechanisms for addressing adverse effects that have been used effectively for other types of consultations.

#### IV. CONCLUSION

After decades of struggling to resolve imperiled species consultation and pesticide registration questions, the agencies have developed a promising path forward. This journey is far from over, and vigilance and continued focus is needed as it continues. The resolution of the five consultations in 2017 and 2018 will be a chance to gauge progress and build upon it. There undoubtedly will be unexpected turns along the way. With that said, the NRC's independent scientific review, the important new mechanism to engage stakeholders and increase transparency, and the shared work plan are important elements of our strategy to address important agricultural and imperiled species needs simultaneously.