The Endangered Species Act and the Impacts to Pesticide Registration and Use

Washington State Department of Agriculture

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Acronyms and Definitions

CBD	Center for Biological Diversity: Based in Tucson, Arizona, CBD is a nonprofit membership organization dedicated to protecting endangered species.
EPA	U.S. Environmental Protection Agency.
ESA	Endangered Species Act of 1973 (7 U.S.C. § 136, 16 U.S.C. § 1531 *et seq.*).
ESPP	Endangered Species Protection Program: An EPA program designed to determine whether pesticide use in a certain geographic area may affect any listed species.
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. § 136 *et seq*.).
NGO	Non-governmental Organizations: A legally constituted organization created by natural or legal persons that operates independently from government.
NLAA	Not Likely to Adversely Affect.
NMFS	National Marine Fisheries Service: An agency of the U.S. Department of Commerce.
NOI	Notice of Intent: An official notification to an entity of the intention of another party to take legal action within a specified time frame.
SIP	State Initiated Plan: A plan developed by a state or tribe for protecting their resident ESA-listed species from exposure to pesticides.
RPAs	Reasonable and Prudent Alternatives: Alternative actions, identified during formal consultation, that (1) can be implemented in a manner consistent with the intended purpose of the action, (2) can be implemented consistent with the scope of the action agency's legal authority, (3) are economically and technologically feasible, and (4) would, avoid the likelihood of jeopardizing the continued existence of listed species and avert the destruction or adverse modification of critical habitat.
RPMs	Reasonable and Prudent Measures: Those measures the Services consider necessary or appropriate to minimize a take impact. RPMs are mandatory in that if any agency fails to implement them that agency runs the risk of violating ESA section 9. RPMs appear only in biological opinions that contain a “take” statement.
USFWS	U.S. Fish and Wildlife Service: An agency of the U.S. Department of the Interior.

WTC Washington Toxics Coalition: A 501(c)3 non-profit corporation.

Executive Summary

United States farmers now face an uncertain regulatory process that could severely restrict the use of hundreds of agricultural chemicals necessary to combat pests and plant diseases in nearly every major growing region in the nation.

This story dates back to 2002 when the U.S. Environmental Protection Agency (EPA) was sued by a coalition of environmental groups for failure to consult under the Federal Endangered Species Act (ESA) on 54 pesticides used for crop protection in the Pacific Northwest that could potentially affect threatened or endangered salmon. In June 2006 a federal court effectively rewrote the process for registration of pesticides used near salmon-bearing waters in the Pacific Northwest. The resulting "consultation process" that ensures EPA's compliance with the ESA laid the legal foundation for subsequent lawsuits related to assessment of the effects of pesticides on other listed species.

Under the ESA, EPA is required to work in concert with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) to ensure that pesticide registrations and use do not jeopardize endangered species. This requirement, managed through federal courts and confused by failed interagency collaboration, yielded a pesticide registration process that undermines the integrity of the ESA, limits the reasonable and safe registration of needed pesticides, and is likely to collapse under the pressures of new litigation. As a result, farmers in every major growing region in the nation face an uncertain regulatory process that could severely restrict the use of hundreds of agricultural chemicals necessary to combat pests and plant diseases. Significant and adverse impacts to agricultural production in at least 48 states will be unavoidable.

As part of a 2008 court order, NMFS authored two biological opinions that included several determinations identified by EPA, state agencies and pesticide registrants as potentially detrimental to agriculture producers. In its determinations regarding the impact of certain chemicals on salmon, NMFS did not consider the most current allowed uses for pesticides or the relationship of pesticide use to salmon habitat. The biological opinions also did not adequately consider current data collected on the presence of pesticides in surface waters. Correspondence between NMFS and EPA indicates there is little agreement on the data and the underlying assumptions used to assess effects on salmon in the consultation process. Also, lack of transparency in NMFS's development of proposed mitigation measures for protection of listed salmon remains a concern.

Despite these and other concerns voiced by the agriculture community and state pesticide regulatory agencies, EPA moved forward with implementing the mitigation prescribed in the NMFS biological opinions. These actions include no-spray buffers of up to 1000 feet near all conveyances of water, including ditches of any size and seasonal streams. In the State of Washington, NMFS mitigation measures would prevent the use of affected pesticides on up to 75 percent of the state's existing farmland. Despite the impact these mitigation measures could have on farm practices, NMFS failed to assess their economic feasibility. Further, the one-year implementation timeframe does not give sufficient time for the agricultural community to develop alternative practices and amplifies the economic burden of implementation.

While these initial biological opinions primarily impact the Pacific Northwest, a proposed lawsuit on ESA consultation for 394 pesticides and 887 species makes the functionality of pesticide consultation a nationwide concern. Court-directed consultation between EPA, USFWS and NMFS on such a scale is unsustainable given existing federal resources and processes. Moreover, specific court decisions to date have delivered unmanageable workloads for agencies and untenable timelines, but no workable solution to the problem of ESA consultation.

Agricultural and environmental interests alike see the need for a productive pathway forward that retains the ESA's effectiveness and prevents unnecessary impacts to U.S. agriculture. Washington State Department of Agriculture (WSDA) recommended actions it believes will be effective (available at http://agr.wa.gov/PestFert/NatResources/docs/WSDAESARec.pdf). Ultimately, solutions to pesticide registration/consultation challenges will come in a variety of forms and from a variety of sources. Resolution will be achieved only when states, policy makers and interested parties join the effort.

Introduction

This paper provides background on how pesticides are registered and the impact the ESA has on this process. Additionally, this paper outlines major hurdles faced by EPA and NMFS/USFWS (the Services) in the pesticide registration process. After describing the need for an improved consultation process, the paper encourages states, policy makers and interested parties to join the call for resolution to the significant challenges of incorporating ESA compliance into the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) registration process.

Enacted in 1973, the ESA is intended to protect animals and plants determined to be threatened with extinction. These threats may come from habitat destruction, exposure to pollutants, climate change, over-harvesting or other natural or man-made causes. In order to reduce the potential for extinction, the Services are tasked with administering the ESA. All federal agencies are required to ensure their actions will not jeopardize the continued existence of any species with "listed" status. As a result, EPA must enter into a process with the Services known as "consultation" to ensure that agency actions will not adversely impact a listed species.

Pesticide registration is one of the actions subject to the ESA: in compliance with Section 7 of the ESA, EPA must ensure that use of the pesticides it registers under FIFRA will not harm these species[1]. The ESA may impact the registration of more than 900 active ingredients used in more than 19,000 formulated products registered under FIFRA. Each product may be used at many sites, each of which may require individual instructions for use in order to protect one or more of the 1,200 listed species throughout the country.

The process of registering a pesticide for use is complex and time intensive. During the registration process, EPA must determine that any use ultimately approved by the agency will not have unintended environmental impacts.

To adequately address the requirements of the ESA, EPA must evaluate the potential for a pesticide to impact a listed species. If necessary, EPA works with the Services to develop limitations on use that will ultimately appear on the pesticide label. This requirement presents administrative challenges as a result of the differing standards of FIFRA and ESA. Under FIFRA, EPA can only register a pesticide if its intended use will not cause "any unreasonable adverse effects to the environment"[2]. The determination of a potential for unreasonable adverse effects is made during the risk assessment process used by EPA. In this process, EPA evaluates the effect of an active ingredient in relation to an effect's threshold or "trigger level".

EPA has authority to place restrictions on pesticide use in order to avoid unreasonable adverse effects. Under Section 9 of the ESA, an action must not result in "take" of a listed species. The definition of "take" is to ``harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." "Harm" means an action which actually kills or injures fish or wildlife, such as significant habitat modification or degradation which significantly impairs essential behavioral patterns, including, breeding, spawning, rearing, migrating, feeding, and sheltering (50 CFR, Part 217, Sec. 217.12). The Services assess the level of harm caused by registered pesticide use and determine

whether or not the recovery of a listed species is appreciably reduced. This determination is known as a "jeopardy" decision.

The broad definition of take under ESA is more stringent than the "unreasonable adverse effects" standard in FIFRA. As a result pesticide registration must meet two different regulatory standards.

The conflict between the requirements of FIFRA and the ESA is demonstrated in the Pacific Northwest where litigation and subsequent NMFS biological opinions for the protection of salmon and their habitat are impacting registered pesticides necessary for agricultural production. More recent litigation is expected to have impacts across the country by requiring effects determinations for dozens of listed species (aquatic and terrestrial) in every state. Figure 1, a map showing agricultural lands in the United States and the existence to known listed species[3], illustrates that none of the lower 48 states are immune from the impacts of intended court challenges.

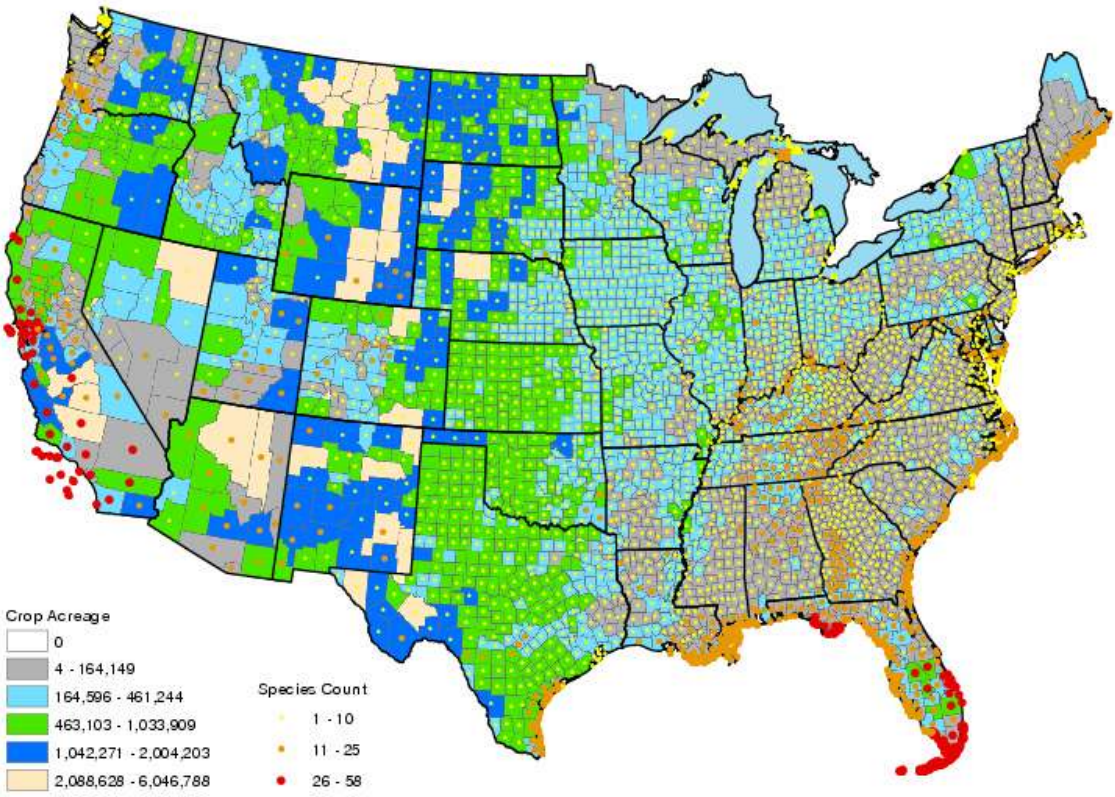

Figure 1. Listed species with respect to crop acreage per county.

Consultation with the Services

Informal Consultation

Under Section 7 of the ESA, EPA must consult with the Services when pesticide registration activities *may affect* a listed threatened or endangered species. In 2004 the Ninth Circuit Court of Appeals affirmed pesticide registration is a federal action subject to consultation under the ESA[4]. In most cases, only one of the Services will be involved during this process. NMFS conducts consultation related to marine species, while USFWS conducts consultations related to freshwater aquatic and terrestrial species.

Before requesting consultation, EPA determines whether or not registration of a pesticide for use may affect a listed species or critical habitat. To insure the initial determination meets the requirements of the ESA, EPA establishes a dialogue with the Services in the early stages of the registration process. This activity is generally referred to as "informal consultation" under section 7 of the ESA.

As part of the initial determination, EPA must provide six types of information identified in the ESA (50 CFR §402.14(c)):

- A description of the action to be considered.
- A description of the specific area that may be affected by the action.
- A description of any listed species or critical habitat that may be affected by the action.
- A description of the manner in which the action may affect any listed species of critical habitat and an analysis of any cumulative effects.
- Relevant reports, including any environmental impact statements, environmental assessments, or biological assessment prepared.
- Any other relevant available information on the action, the affected listed species or critical habitat.

If, after discussions with the Services, EPA determines the proposed action is not likely to affect any listed species in the project area and, if the Services concur, the informal consultation is complete and registration moves forward. If it appears that registration may affect a listed species, EPA may then prepare an ecological risk assessment to assist in determination of the likelihood of adverse effect on a species.

Formal Consultation

If EPA determines that registration is likely to adversely affect a listed species or critical habitat, then formal consultation is required, and EPA submits a written request for formal consultation to the Services. During formal consultation, the Services and EPA share information regarding the potential effects of the proposed registration and likelihood for listed species to be affected. Formal consultation may last up to 90 days, after which the Services prepare a biological opinion addressing whether the registration of a pesticide or group of pesticides will not likely jeopardize the continued existence of a listed species. The Services have 45 days after completion of formal consultation to write the opinion.

In making a jeopardy decision, the Services first assess the current "baseline" of the species. Added to the baseline are the various effects of the proposed registration, including direct (e.g., mortality) and indirect (e.g., reduction in food supply) effects that may impact the listed species. The Services also examine the cumulative effects of other non-Federal actions, including state, tribal, local or private activities that are reasonably certain to occur in the action area.

If a proposed registration is likely to jeopardize the listed species or destroy or adversely modify critical habitat, then the Services work closely with EPA to identify reasonable and prudent alternatives (RPAs) to avoid such effects. RPAs are those alternatives that can be implemented by EPA in a manner consistent with the intended purpose of the registration and that the Services believe avoid jeopardy to listed species or destruction or adverse modification of critical habitat. Reasonable and prudent measures (RPMs) are those actions necessary and appropriate to minimize the impacts of the registration and use of a pesticide or group of pesticides and are not negotiated. If implementation of an RPA or a Federal action results in take, an incidental take statement must be developed to exempt such take from ESA section 9 prohibitions[5]. EPA may implement alternative RPAs to those specified in the biological opinion. However, any alternative RPA must meet the standard of not likely to jeopardize a listed species or destroy or adversely modify its critical habitat. The consultation process is illustrated in figure 2.

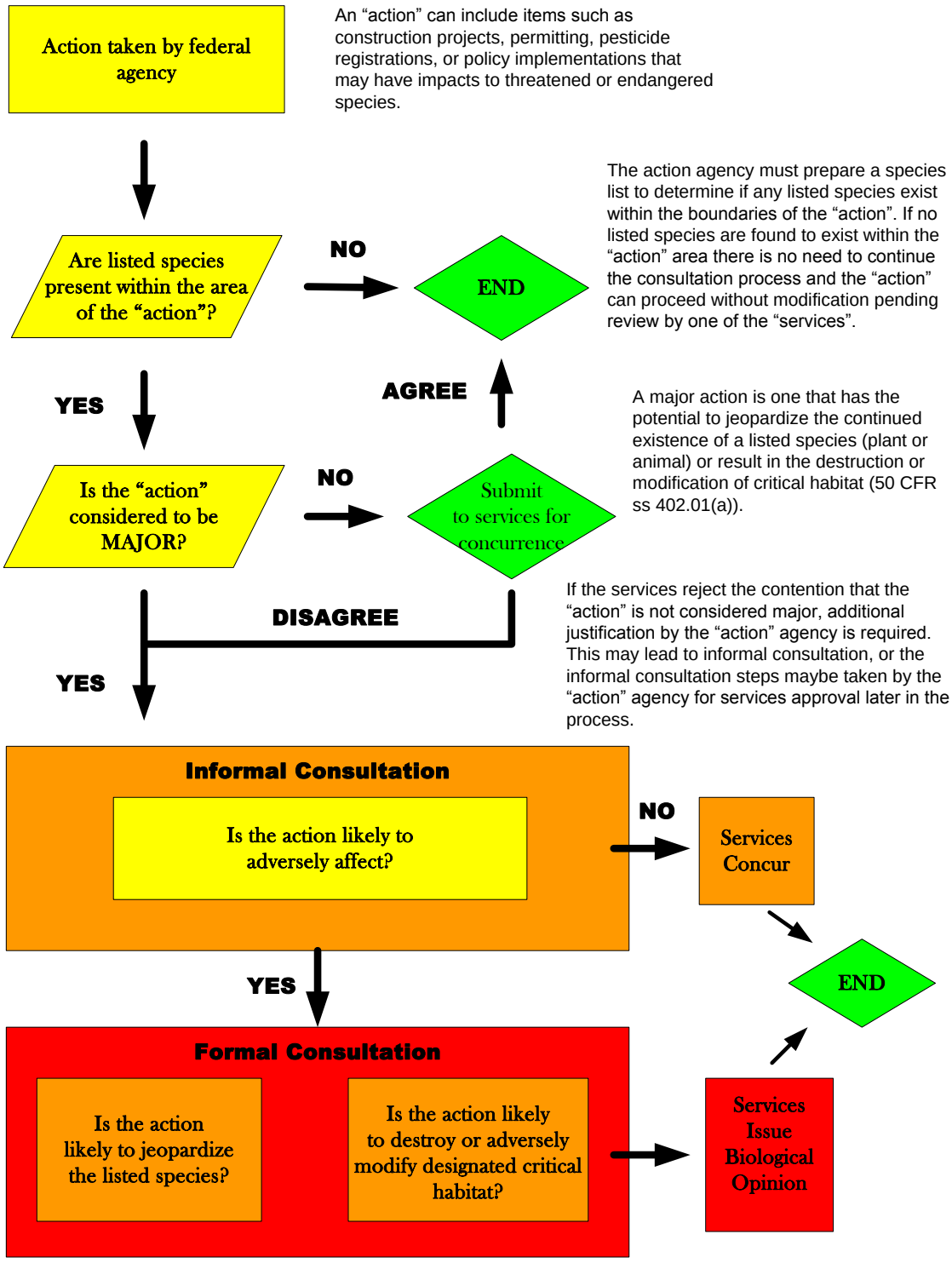

Figure 2. Generalized endangered species Section 7 consultation process (See Chapters 3 & 4 of the ESA Consultation Handbook[17] for more detail).

EPA Pesticide Registration Process and the ESA

EPA's strategy for ESA compliance is to address listed species concerns within the context of the pesticide Registration and Registration Review process. Registration refers to new pesticides and Registration Review refers to pesticides previously registered by EPA.

EPA conducts ecological risk assessments to support a registration decision as part of the Registration and Registration Review process. In order to address the ESA during the pesticide Registration and Registration Review process, EPA developed the *Endangered Species Protection Program (ESPP)*[6]. This program intends to provide appropriate protection to listed species and their critical habitat from potential harm due to pesticide use while avoiding unnecessary burden on pesticide users and agriculture. In order to address ESA concerns, the ESPP requires refinements to geographic and biological components of the ecological risk assessment as they apply to listed species.

As risks to listed species are identified through either EPA registration process or consultation with the Services, EPA issues Endangered Species Protection Bulletins (Bulletins) that specify mitigation or protective measures. Bulletins describe specific geographic areas within individual U.S. counties where use limitations exist. When needed, Bulletins are referenced in pesticide label statements that inform users the product may harm a threatened or endangered species or their critical habitat. The use limitations specified in Bulletins are supplemental label language enforceable for the county specified. The EPA may use Bulletins to mitigate risk to listed species either prior to initiation of consultation or as a mechanism to implement RPAs and RPMs identified through consultation with the Services.

Typically, the Registration and Registration Review process consists of dialog between the pesticide registrant and EPA with minimal opportunity for third parties to participate. In an attempt to provide process transparency, EPA has established an internet web page known as a docket[i] that contains a preliminary work plan and the initial problem formulation for assessing ecological risk for each pesticide to be reviewed. These documents detail EPA's knowledge base as well as any anticipated data needs for review of the pesticide. During the comment period any interested party may submit data or information for EPA's consideration. The public comment period in the early stages of the Registration Review process allows stakeholders, such as grower groups, environmental NGOs or state agencies, to evaluate EPA's assumptions and determine their relevance to local conditions. Public review allows all interested parties to determine whether additional data that may affect initial assumptions of perceived risk is available for submission to EPA. External review also supports refinement of the risk assessment to reflect local conditions that are substantially different from conditions assumed for a national level assessment.

[i] The EPA docket is a website (http://www.regulations.gov/search/Regs/home.html#home) that provides the public with access to agency information in a wide variety of rulemaking and non-rulemaking areas. The docket serves as a source of current and historical information on agency activities, including comments received from the public to inform agency decisions.

Pesticides and the ESA Litigation

Interested parties can file federal lawsuits to force compliance with the ESA if they believe either EPA or the Services has not met their statutory obligations under ESA. To date, litigation has resulted in at least two court-ordered findings and several settlement agreements between plaintiffs and either EPA or the Services.

Litigation on pesticide registration has focused on EPA's obligation to consult with the Services after determining potential effects to listed species may occur. Historically, when the levels of concern for endangered species were exceeded in the risk assessment for registration, EPA included language indicating further assessment would be needed to determine the extent of potential effects to listed species and that consultation with the Services may be needed. However, these consultations have not occurred in a timely manner which led the federal courts to issue summary judgments against EPA for failure to consult. The first case of this type occurred in the Pacific Northwest regarding salmon listed for protection.

Salmon in the Pacific Northwest

Utilizing the citizen suit provision of the ESA, a coalition of environmental organizations and fishing groups (Washington Toxics Coalition (WTC) *et al.*)[7] filed suit against EPA alleging the agency failed to consult with NMFS on the effects of 54[ii] pesticides on listed salmon in the Pacific Northwest. On July 2, 2002, the U.S. District Court for the Western District of Washington found EPA failed to consult with NMFS on the effects to salmon of the 54 pesticides. The court order mandated EPA to make effects determination for all pesticides in question by August 1, 2003.

EPAs initial assessment determined 37 of the 54 pesticides "may effect" listed salmonid species. These 37 pesticides were submitted to NMFS for formal consultation under the ESA, Section 7(a)(2). NMFS did not initiate consultation after receiving EPA's effect determinations. As a result, in November 2007 the Northwest Coalition for Alternatives to Pesticides *et al*., sued NMFS for failure to complete the consultation on the 37 pesticides. On August 1, 2008, NMFS and plaintiffs negotiated a stipulated agreement that requires completed biological opinions by February 2012, nearly 10 years after the original court ruling against EPA.

In November of 2008, NMFS issued the first biological opinion for three insecticides (chlorpyrifos, diazinon and malathion). The Services issued a second biological opinion in April 2009 for three additional insecticides (carbaryl, carbofuran and methomyl). The registrants of chlorpyrifos (Dow and MANA), diazinon (MANA) and malathion (Cheminova) challenged the findings of the biological opinion for these pesticides in court on August 21, 2009. This case is unresolved at this time.

California Red-legged Frog in California

The Center for Biological Diversity (CBD) filed suit April 2, 2002 alleging that EPA failed to comply with ESA Section 7(a)(2) by not ensuring that registration of 66 pesticides will not affect the California red-

[ii] Originally 55 pesticides were specified in the court order; however, lindane was identified by two different names.

legged frog, a federally-listed threatened species. CBD, EPA and defendant-interveners CropLife America *et al*., negotiated a stipulated agreement resolving the lawsuit. The key provisions of the agreement are: a schedule for effects determination, interim injunctive relief, and development and distribution of a bilingual brochure. Further details on this lawsuit, litigation relating to the Barton Springs Salamander in Texas, and similar lawsuits can be found on EPA's website[8,9,10,11].

Although stipulated agreements resolved the initial lawsuits, the actions proved to be administratively burdensome and disadvantageous to pesticide users. For example, the stipulated agreement for the California red-legged frog precludes the use of 66 pesticides in parts of 33 counties in California until either EPA determines the pesticides have no effect on the red-legged frog or USFWS consultation is completed. This agreement, in effect, causes the immediate ban on use of these 66 pesticides. Further, although EPA agreed to the stipulated consultation schedule, USFWS has yet to act upon the consultation packages submitted by EPA, setting the stage for further litigation or court-ordered consultations.

Center for Biological Diversity NOI for 394 pesticides and 887 species

On January 28, 2010, the CBD filed a notice of intent (NOI) to sue EPA for inadequate evaluation and regulation of 394 pesticides harmful to hundreds of endangered species throughout the nation[12]. The notice contends that EPA violated the ESA by failing to consult with the Services regarding the impacts of pesticides on 887 threatened species. The CBD also contends EPA violated the Migratory Bird Treaty Act by registering pesticides known to kill and harm migratory birds. Short of a settlement agreement that rolls the pesticides and species of concern into EPA's Registration Review process, it is unclear how EPA, much less the Services, will address this lawsuit with existing resources.

To date, litigation against EPA regarding consultation on pesticides has been limited to the narrow geographic scope of a listed species and a specific subset of pesticides. The limited scope of the court-ordered consultations and stipulated settlement agreements allowed EPA to absorb the added consultation workload within its existing resources. The Services have less ability to manage added consultation workload, as demonstrated by NMFS's completion of only two biological opinions for the WTC litigation. USFWS has yet to complete any of the biological opinions requested by EPA. If successful in court, the CBD litigation would stretch available resources at EPA and the Services to the breaking point.

Ultimately, the result of the various settlement agreements for ESA-related lawsuits is that EPA and the Services are forced to conduct consultation in a piecemeal process. This diverts resources away from the systematic review process established for pesticides registration.

Impact of Biological Opinions on Pesticide Use

The Services have released several biological opinions related to the use of pesticides and their impacts to listed species. Generally, these opinions require buffers ranging from 20 to 1000 feet adjacent to habitat. To date, the most sweeping biological opinions related to pesticide use have been those in the Pacific Northwest for the protection of listed salmonids (figure 3). To reduce the chance for jeopardy occurring as a result of application of the pesticides of concern, NMFS specified RPAs and RPMs to protect listed salmon. These measures are expected to affect an extensive amount of agricultural land in California, Oregon, and Washington with less impact estimated for Idaho.

Figure 3. Counties Affected by 2008 Pesticide Biological Opinion (U.S. Environmental Protection Agency, August, 2007).

The RPAs outlined in the biological opinions for protecting salmon include:

- Drift and runoff buffers.
- Application limitations when wind speed exceeds 10 mph.
- Application prohibitions when soil moisture is at field capacity or a storm event is likely in 48 hours following the application.
- Reporting of all incidents of fish mortality.
- Effectiveness monitoring.

The RPMs attempt to minimize the amount and extent of an incidental take by:

- Reducing the risk of chemicals reaching the water.
- Monitoring any incidental take or surrogate measure of take that occurs from the action.
- Reporting annually to NMFS on the monitoring results from the previous season.

Three specific elements of the RPAs garnered substantial attention:

1. The definition of water bodies to which the RPAs apply.

   According to NMFS, "salmonid habitats are defined as freshwaters, estuarine habitats, and nearshore marine habitats including bays within the evolutionary significant unit ranges including migratory corridors. The freshwater habitats include intermittent streams and other temporally connected habitats to salmonid-bearing waters. Freshwater habitats also include all known types of off-channel habitats as well as drainages, ditches, and other manmade conveyances to salmonid habitats that lack salmonid exclusion devices"[13]. Based on NMFS

requirements, EPA developed buffers that range from 100 to 1000 feet around identified water bodies. The extent to which the buffers are required is potentially devastating for commodities reliant upon the impacted pesticides for crop protection.

2. The size of the buffers specified.

Figure 4 illustrates the potential impact of buffers specified in the biological opinion for three organophosphate insecticides by highlighting areas where their application would be prohibited in the Skagit Delta in Western Washington State. The figure assumes a 500-foot buffer applied to known streams and canals. Table 1 quantifies the agricultural acres affected by buffers of 100, 500 and 1000 feet. Notably, buffers were not calculated for all ditches and intermittent streams because their locations are not known with specificity. The actual agricultural acres affected are likely greater than estimated due to the presence of ditches and intermittent streams and because farmers typically do not partially treat a field.

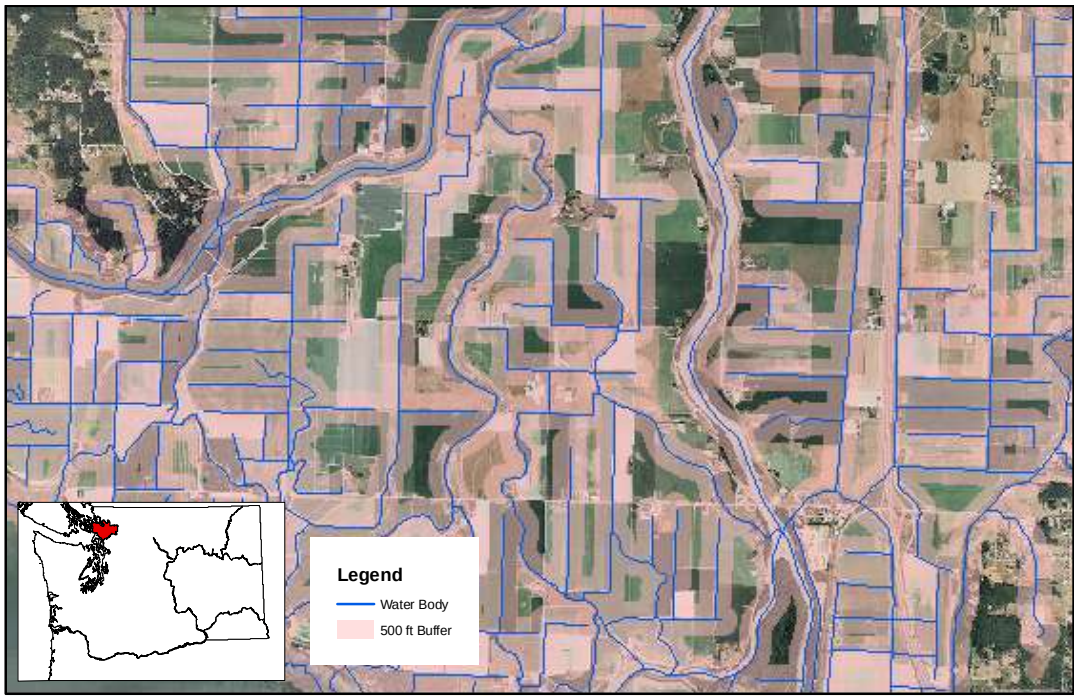

Figure 4. 500 ft pesticide no application buffer (Fir Island Skagit County).

Table 1. Summary of agricultural land impacted by ESA buffers in the Skagit Basin, WA (Total agricultural acres: 54,083).

Buffer Width (ft)	Acres of agricultural lands affected	Percent of agricultural lands affected
100	4,845	9%
500	25,992	48%
1,000	40,578	75%

3. One-year implementation time for the RPAs.

   The one-year time line specified in the biological opinion may allow EPA time to implement the specified RPAs and RPMs. However, one year is not adequate to allow for exploration of alternative pest control strategies for farmers. Minor crops[iii] may not have a viable replacement pesticide registered for use or an alternative pesticide may not work well with integrative pest management (IPM) programs that balance pest control with beneficial insect populations and use of specific pesticides. Another concern for minor crops is whether a Maximum Residue Level (MRL) has been established for replacement chemistries in export markets. If a MRL is not established for a replacement pesticide the ability to export a commodity is limited.

A Path Forward

Improved Relationships between EPA and the Services

Due to conflicting statutory requirements and litigation-driven consultation, the working relationship between EPA and the Services can be described as fractured at best and, at its worst, openly antagonistic[iv,14,15,16]. As a result, there is little give and take between EPA and the Services as envisioned within the ESA consultation handbook for conducting section 7 activities[17]. Further, lack of negotiated RPAs between EPA and the Services yields unrealistic implementation timelines and mitigation measures.

The Services and EPA can resolve procedural issues related to Section 7 consultations for pesticide registrations through policy modifications. With sufficient will among policy-makers, agencies could develop a coordinated, interagency system that preserves the integrity of the ESA while allowing for the reasonable, safe and timely registration of pesticides as required under FIFRA.

Federal Rules

Joint Counterpart Regulations

The application of section 7(a)(2) of the ESA to pesticide registration presents numerous obstacles to both the registration of safe, effective pesticides in agricultural production and the implementation of measures to protect threatened and endangered species. In an attempt to address these obstacles, the Services and EPA developed Joint Counterpart Regulations in 2004. These regulations were intended to allow EPA to make a "not likely to adversely affect" (NLAA) determination for pesticides during the Registration and Registration Review process, streamlining the consultation process.

Joint Counterpart Regulations between the Services and EPA were established under the allowance for an optional alternative to the procedures found in § 402.13 and § 402.14(b) of the ESA. This approach

[iii] Minor crops refer to nearly all crops except cotton, corn, soybeans, and grain crops such as wheat, oats, and rice.
[iv] See referenced EPA letters of September 15, 2008 and April 10, 2009 regarding the biological opinions for three organophosphate and carbamate insecticides respectively and NMFS response on September 30, 2009 to EPA regarding implementation of the biological opinion for the organophosphate insecticides.

has precedent: U.S. Bureau of Land Management used the concept of counterpart regulations to make NLAA determinations in lieu of the Services[18,19].

In August 2006, the U.S. District Court for the Western District of Washington set aside two critical provisions of the 2004 Joint Counterpart Regulations[20]. This court ruling significantly constrains the degree to which modification (outside of legislative changes to the ESA) can be implemented. In part, the court ruled:

1. EPA can make a NLAA determination. However, a NLAA determination is not statutorily equal to the ESA section 7(a)(2) language of "not likely to jeopardize". Therefore, unilateral NLAA determinations cannot be converted into a section 7(a)(2) "not likely to jeopardize" finding without consulting with the Services.

2. EPA and the Services may implement what is known as "optional formal consultations" whereby an EPA effects determination can be converted into the relevant Services biological opinion and incidental take statement as required by the ESA. If the relevant Service disagrees with the conclusion(s), it may modify EPA's effects determination or write its own biological opinion.

Proponents of a streamlined pesticide registration/ESA consultation process consider this ruling a setback because the Services can overrule EPA's determination of effects to listed species.

Federal Legislation

If the Services and EPA agree Joint Counterpart Regulations are mutually beneficial for conducting consultation for pesticide registration, it may be necessary to amend either FIFRA or ESA to address the provisions struck down by the U.S. District Court in 2006. This amendment would address EPAs ability to make NLAA decisions. In order to significantly streamline the consultation process, the NLAA determination must be equivalent to a section 7(a)(2) finding of not likely to jeopardize, thus negating the need to consult with the relevant Service on a subset of pesticides. This alteration of FIFRA or ESA would focus the consultation process with the Services on those pesticides EPA found likely to adversely affect a listed species.

State Initiated Plans

On November 2, 2005, EPA published a Federal Register Notice, "Endangered Species Protection Program Field Implementation"[21]. The Notice included EPA's goal for ESPP to fulfill responsibilities under FIFRA in compliance with the ESA. The EPA also acknowledged that local, state and tribal circumstances may influence the effectiveness of different approaches to listed species protection. Under the "Endangered Species Program Field Implementation," states and tribes may develop and propose State Initiated Plans (SIP) for their specific involvement in protecting listed species.

These plans, while not specifically allowing states or tribes a "seat at the table" during the consultation process, provide a complementary mechanism to address concerns related to process and consideration of best available data. Elements of SIPs, including development of more focused pesticide use profiles, crop mapping information and surface water monitoring data for pesticides, can reduce uncertainty in the pesticide risk assessment process and help risk managers make sound science-based decisions.

Figure 5 illustrates the FIFRA and ESA consultation process and opportunities for use of state specific data to reduce uncertainty about pesticide exposure and risk to listed species.

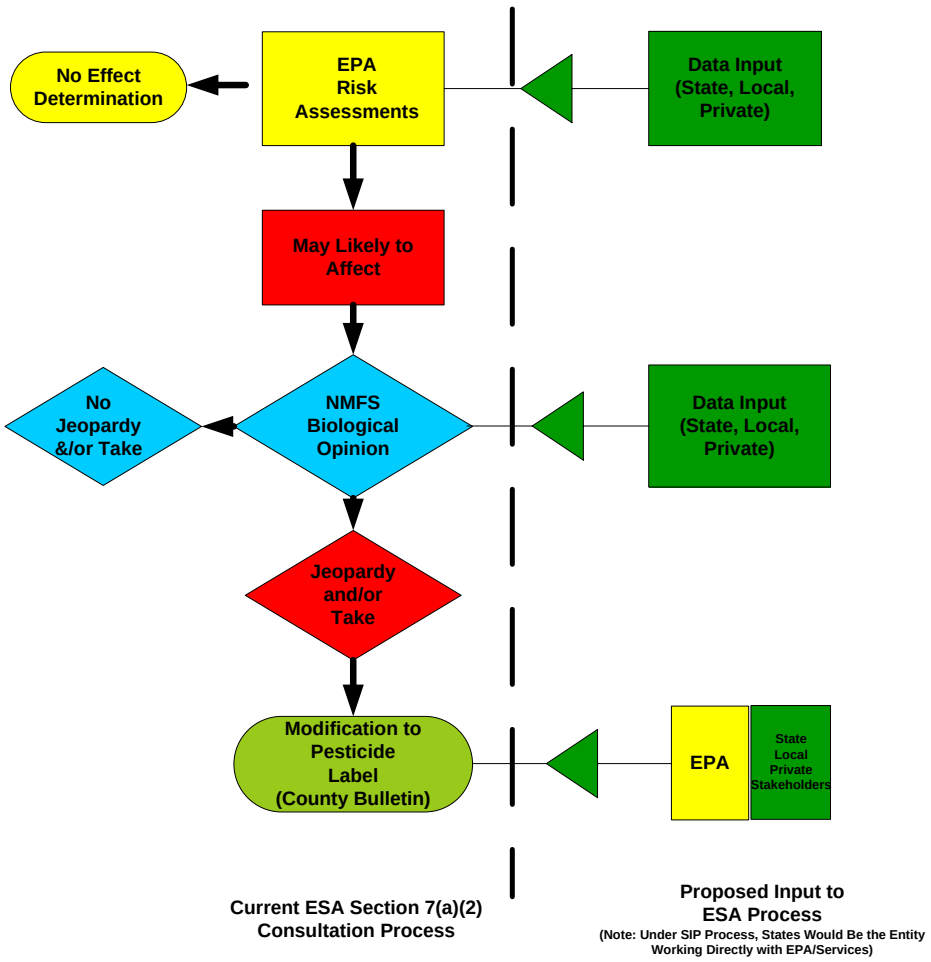

Figure 5. Illustration of FIFRA and ESA consultation process.

The SIP program compliments EPA's registration review public comment process and provides structure to data acquisition and analysis efforts. SIPs can detail the quality assurance procedures needed to meet the requirements of the Data Quality/Information Quality Act of 2000[22]. SIP-established quality assurance criteria can also streamline integration of third-party data in federal regulatory decisions, including water quality information not included in national datasets, and land use information detailing the relationship between pesticides applications and habitat occupied by listed species. However, as of June 2010, EPA has not issued final approval to any submitted SIP, so there is no baseline by which to measure the effectiveness of SIP implementation.

There are several limitations in the SIP and Registration and Registration Review processes as currently implemented. First, the notification process for pesticides posted to the Pesticides Public Regulatory Docket for comment and submission of data is not transparent. Currently, an interested party must constantly check the docket to see which pesticides are open for comment. Second, registration review applies to previously registered pesticides only, and does not address new product assessment. Last, the

SIP is an agreement with EPA and is not binding on the Services. Currently, there is no mechanism to establish local, state or tribal partnerships with the Services.

Summary

The current pesticide registration/consultation process limits the ESA's effectiveness at protecting listed species by delaying development and implementation of rational, effective measures for pesticide use. Because of numerous procedural barriers and minimal opportunity for states and stakeholders to engage decision-makers, the process also fails to provide reasonable registration of pesticides. Solutions to these challenges are available. For example, mediation of the strained relationship between the Services and EPA can establish a collaborative and transparent consultation process for pesticide registration. Also, past and future biological opinions will benefit from incorporation of both current available data and assessment of the economic feasibility of proposed RPAs and RPMs. Similar benefits can be achieved through clear integration of consultation into EPA's registration process. Integration can prevent future litigation based on the "failure to consult" premise and improve opportunity for public participation.

The facts are clear: the consultation process is poised to collapse under the weight of proposed litigation, further limiting effective species protection and adversely impacting the nation's agricultural community. Washington State Department of Agriculture (WSDA) recommended actions it believes will be effective (available at http://agr.wa.gov/PestFert/NatResources/docs/WSDAESARec.pdf). Ultimately, solutions to pesticide registration/consultation challenges will come in a variety of forms and from a variety of sources. Resolution will be achieved only when states, policy makers and interested parties join the call to improve the pesticide consultation process.

REFERENCES

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