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FIFRA, ESA, and Pesticide Consultation: Understanding and Addressing the Complexities

Introduction

Fifty years ago, Congress passed the Endangered Species Act of 1973 (ESA) with the intent to provide a means whereby rare and at-risk species and the ecosystem upon which they depend may be conserved (ESA 1973). Although half of a century has passed, few people in agriculture as well as in governmental or nongovernmental organizations understand the complexities and challenges associated with this Act regarding preserving the practical use of pesticides. Section 7 of the Act specifically requires each federal agency to consult with the U.S. Fish and Wildlife Services or the National Marine Fisheries Service (collectively "the Services") to ensure that any action the agencies authorize, fund, or carry out is not likely to jeopardize the continued existence of a threatened or endangered species (listed species) or result in the destruction or adverse modification of designated habitat. When the U.S. Environmental Protection Agency's Office of Pesticide Programs (EPA) approves a national pesticide registration (and its labeling), that is considered an action that requires an assessment under the ESA. When the Act was implemented, an "action" was expected to be point specific – but EPA's registration of a pesticide is national in scope. For this and other reasons, historically the EPA has tried but failed to fulfill that requirement except in very limited cases. At the same time, conservation groups and the public have become increasingly interested in pesticides and their potential impact on listed species.

Currently, as the EPA works diligently to bring pesticide registrations into compliance with the ESA, agriculture faces the potential loss of pesticides through ESA-related litigations and restrictions on pesticide labels prohibiting their application in sections of agricultural fields, entire counties, or even entire states. The cumulative outcome of these restrictions limits a farmer's ability to manage pests economically and effectively in a way that minimizes the development of pest resistance and maximizes the efficient use of fuels and other non-renewable resources.

Pesticide ESA consultation and risk management involving FIFRA registration actions is a complicated and to-date unresolved process. While under FIFRA a combination of integrated control methods, best management practices, education, and enforcement work together for effective pesticide use management, the national scope of variation when production and species needs are combined is difficult if not impossible to capture in a national evaluation. Photo from jokerpro/Shutterstock.

FIFRA and the Endangered Species Act: Finding a Balance between Agricultural Efficiency, Environmental Sustainability, and Regulatory Stability

Bernalyn McGaughey and
Stanley Culpepper

Crop systems and respective pests are dynamic and often unpredictable, highlighting the importance of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA 1947 and its amendments) process in allowing a flexible but protective label providing benefits and acceptable risk to humans or the environment. During the EPA's evaluation of a registration application, the agency considers unreasonable risk to humans or the environment while considering social, economic, and environmental costs and benefits of the pesticide use. Over the years, a combination of integrated control methods, best management practices, education, and enforcement have been developed through a multi-layered system of national pesticide registrations adopted and enforced by the state. However, for anyone unfamiliar with the context of pesticide registration and use, it may seem that an approved EPA pesticide label stands in isolation when

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implemented in the field, but this is far from the truth.

A national implementation network provides input from agricultural extension, crop consultants, local land and water protection agencies, retailers, state departments of agriculture, professional organizations, industry, and numerous U.S. Department of Agriculture (USDA) entities serving to educate, recommend, and enforce how the label is executed locally. This national effort supporting the implementation of a FIFRA pesticide label is in direct contrast with other types of site-specific actions and evaluations under the ESA. Actions within the ESA Section 7 process are most typically applied in a site-specific setting, ideally where results can be surveyed and evaluated with certainty. For pesticides, the consultation is national, with the insurmountable task of also considering all site-specific variables applicable to the local action.

Further confounding the ability to resolve the differences between FIFRA and ESA requirements is the fact that each Act defines an adverse outcome on non-target species differently and uses dissimilar definitions for conclusions about impacts and effects. This results in dissimilar conclusions about whether a species is "at risk." Arguably the greatest difference among the statutes when comparing Acts is that FIFRA requires risk-benefit balancing, while the ESA disallows any consideration of risk-benefit as ESA actions are based solely on species risk.

In this CAST series of six essays, authors seek to explore how and if FIFRA and the ESA can work together to overcome the challenges of historical dysfunction, logistical overload, and unmanageable burden.

Challenges in FIFRA/ESA Implementation

In deciding how, and if, to register or reregister a proposed pesticide use, FIFRA in part requires the EPA to determine that the use will not cause an unreasonable adverse effect to humans or the environment, while the ESA directs the action agency (in this case EPA) to determine if that registration action "may affect" a listed species. If a pesticide registration action is determined to have "no effect" on a species, then no further consultation with the Services is required by the EPA (the action agency). However, if an EPA determination of "may affect" is reached, then the agency must determine if the registration is Likely to Adversely Affect (LAA) or Not Likely to Adversely Affect (NLAA) those species. Species deemed NLAA can be addressed between EPA and Services by informal consultation, while LAA species require a formal consultation between EPA and the Services to determine whether the action can be permitted as proposed without jeopardy/adverse modification to the species or its designated critical habitat. The USDA has been informally involved in the consultation process as it is carried out between the EPA and the Services and is a formal participant in the FIFRA Interagency Working Group which was formed to address FIFRA/ESA consultation.

As the consultation process moves forward, if there is reason to expect that the action may cause jeopardy to a species or habitat, the Act then goes on to require mitigation (avoidance, minimization, and/or mitigation, including voluntary compensatory measures) of that potential effect without the ability to formally

consider the need for or benefits of the pesticide. The purpose of avoidance and/or minimization is of course to protect the species, which in ESA terms is to adjust the action to reduce or eliminate the harm or "take" to a species to a point where the species is not in jeopardy of extinction, or to a level where take is not likely to occur. An incidental take permit is needed if an action is "in an area where ESA-listed species are known to occur and where their activity or activities are reasonably certain to result in incidental take". The standard for determining if activities are likely to result in incidental take is whether that take is "reasonably certain to occur" (FWS/NMFS 1998). Compensatory measures or offsets are considered when unavoidable impacts remain after appropriate and practicable avoidance and minimization measures have been applied (US FWS 2023b).

In understanding that pesticide registrations and re-registrations are required to follow both the ESA and FIFRA requirements, each of the regulatory authorities have struggled with the complex consultation process. In fact, the two statues have not been able to function effectively together when each takes its traditional approach to evaluation of impact.

In addition to the risk assessment scientific process, it is important to highlight the influence that public perception has on policy. Christopher Bosso, in "Pesticides & Politics: The Life Cycle of a Public Issue," used FIFRA, enacted in 1947 well before strong attention turned to protecting the environment, as a showcase of how public sentiment gives energy to political change (Bosso 1990). Additionally, with the advent of Rachel Carson's Silent Spring, pesticides became the venue and subsequent poster child for our lack of awareness of the impacts the industrial age had on our environment (Carson 1962). Now, in a more environmentally aware age, the negative stigma remains. "Pesticides" or more broadly, agriculture, often have an undeserved finger of guilt pointed at them when regulation or assessments are undertaken. With this continuous volatility further complicating the process, the regulator and regulated community has struggled to complete national-level pesticide ESA/FIFRA consultations (see Appendix: "Events that Shifted FIFRA/ESA Policy"). This pressure in turn casts public doubt on the FIFRA scientific risk assessment process which has proven over time to be robust and credible. EPA's risk assessment process is risk- and evidence-based, and relative to other global systems, very transparent. However, the time this process takes when dealing with a national endangered species assessment, has proven problematic.

FIFRA and Regulatory Overhaul

Generally, and very loosely, there have been three eras of regulatory overhaul of FIFRA since its enactment. In each regulatory era during the life of FIFRA, there has been an induction period (incubation period of growing concern), an event reacting to the concerns (for example, a new study requirement and data call-in), and a result from a regulatory enactment point of view, mirroring Bosso's analysis of the "life cycle of a public issue" (Bosso 1990).

During the first "era," from 1947 to 1972, FIFRA focused on product labeling relating to content and human direct exposure concerns. That framework was based on the historical emergence of human pharmaceuticals (and pseudo-drugs having no curative properties or perhaps even being dangerous) and an increased understanding of the need to inform the public of the content and the safe and effective use of concoctions consumed for curative purposes. The focus was human health, with FIFRA being administered through the USDA Secretary of Agriculture until 1970, at which time the EPA was created and resulting in the modification of FIFRA by the Environmental Pesticide Control Act of 1972 (EPCA 1972).

With the advent of environmental awareness came a second era, from about 1972 to 1996, where FIFRA was amended multiple times as governmental agencies, industry, and the public grew increasingly aware of the need for more information to inform decisions and further strengthen pesticide labeling to better protect humans, wildlife, and the environment. Additionally, regulatory actions were extended to review older products (reregistration and eventually Registration Review) and further FIFRA amendments led to the closure of this second era with a new safety standard for food commodities, ensuring a "reasonable certainty of no harm" standard via the Food Quality Protection Act (FQPA 1996). With the advent of FQPA, many new testing requirements and evaluation procedures were implemented to define the toxicity and potential exposure of pesticides to non-target organisms and humans, especially children.

From 1996 with the development of FQPA to the present, the third "era" has played out through implementation of a cyclical regulatory review process repeating every 15 years and increasing focus on the implementation of protection mandates for listed species. During all of these "eras," the ESA and its applicability to pesticide regulatory decisions was not significantly amended, but EPA's lack of procedural compliance has been highlighted by litigation outcomes. Because the combined laws have proven to be exceedingly complex to co-implement, the assessment and protection of ESA listed species is one of the activities now dominating the resources and energies of the FIFRA regulator and regulated communities.

Although history has advanced the FIFRA regulation and policy, the joint FIFRA/ESA consultation cycle pattern has been different. The induction-event-result cycle seen in most regulatory arenas does not yet have a "result" for FIFRA/ESA resolution. The attempts to address consultation seem to be caught in the proverbial "do-loop," illustrated by Figure 1. Regulators and the regulated community have demonstrated their mutual desire to continue to protect listed species while resolving the procedural issues blocking successful ESA assessments, demonstrated as early as 1958 when the first uses of DDT were banned based on concerns about its effects on non-target organisms. However, an effective path out of the FIFRA/ESA do-loop is yet to be discovered, leaving us without a consistently functioning procedural consultation process.

Although the procedural process has failed historically, will there be a differ-

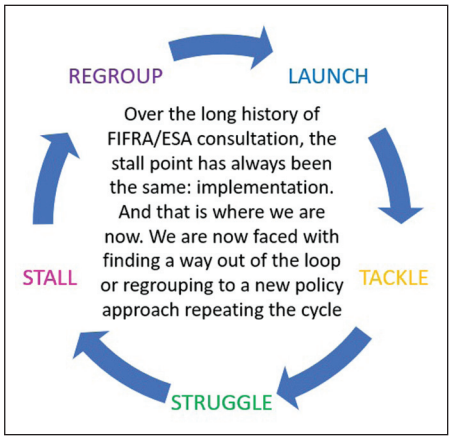


Figure 1. The repetitious cycle of FIFRA/ESA consultation can be loosely described as: launch (or reshape) policy, apply the policy by attempting to tackle complexities and demands on resources, face the struggle to implement a full program and a stall when implementation fails. At that point this loose "cycle" has been repeated over time.

ent outcome with the current cycle? The most recent "Regroup" has passed and the phases of "Launch" and "Tackle" are upon us. The efforts through the EPA OPP's 2022 Balancing Wildlife Protection and Responsible Pesticide Use (EPA 2022a), the 2022 ESA Workplan Update (EPA 2022d), the 2023 Vulnerable Listed Species Pilot Project (EPA 2023f), and the 2023 Herbicide Strategy (EPA 2023a) are all significant and, in unique ways, have some components of better science, improved mapping techniques for listed species and agricultural fields -- but for increased efficiencies, the sacrifice of other scientific components has caused some concern – actions not subject to examination and cooperation among organizations that has not been previously observed. However, implementation of this rapid set of new developments is still controversial with an unclear resolution. As we currently pass through the do-loop in Figure and struggle through proposed regulations, will science, cooperation, and innovation be able to lead us to a reasonable and adoptable outcome protecting agriculture and wildlife or is our fate to stall once again inevitable?

History Should Inform

As noted in the introduction, many have taken a short-term view of "EPA's failure to consult" and not appreciated that history has taught us, perhaps, that a round peg is being pounded into a square hole. It is not factual to portray "lack of consultation" as a "lack of trying" or lack of species protection. Neither the EPA nor the registrants have failed in struggling with the process; instead, the process has failed them. And perhaps there is untenable hope that FIFRA and ESA can work together without some serious out-of-the-box thinking in applying solutions that will fit both Acts.

Current regulatory efforts attempting to meet the requirements of both Acts, while understanding the importance of protecting wildlife and developing or maintaining the tools needed to manage pests safely, economically, and effectively in food, feed, and fiber crops, appear to have gained momentum. However, application and implementation of the FIFRA/ESA consultation process is not yet fully resolved. Reviewing the history of the FIFRA/ESA consultation developments may be instructional to seeking solutions at that point where the combination of the two acts always seems to get "stuck" – and that point is implementation.

The insecticide DDT arguably garnered our country's focus on the importance of pesticide environmental and wildlife safety. As early as 1958 uses of DDT were being canceled due to safety and wildlife concerns, with the insecticide being banned in 1972, only two years after the EPA was established. At this time, FIFRA was amended due to wildlife and other environmental concerns and ESA was adopted in 1973. Only eight years after EPA was established and five years after the enactment of ESA, in July of 1978, EPA made their first consultation request to the Services, before the Tennessee Valley Authority (TVA) decision mandated consultation as we know it today (TVA 1978). The FWS issued a responsive Biological Opinion (BiOp) on EPA's first FIFRA consultation nine months later. This relatively rapid response-time on the first consultation has never been repeated.

For an approximate 10–12-year period, beginning in 1982, pesticide consultation was attempted, but the outcome was still considered too slow, differential to new products versus old, and difficult or impossible to implement. Approaches to listed species risk assessment (and listed species per a Memorandum of Understanding between the EPA and the Services) were solidified (EPA 1986), and several consultations were reinitiated, but the backlog grew. The program faltered with enough concern that Congress stepped in to enact Section 1010 of Public Law 100–478 (PL 100–478 1988). The overriding themes of Section 1010 were given as the need to (1) educate agricultural producers, (2) include them in the development of ESA use restrictions on pesticides, and (3) to minimize the restrictions' impacts on producers. This law provided a clear sense that Congress desires that the EPA and the Services should fulfill obligations to conserve listed species, while at the same time considering the needs of agriculture and other pesticide users.

Section 1010 required agency reports to Congress and in 1991 EPA reported on their plans to identify reasonable and prudent means for an endangered species protection program as it relates to pesticide use. The goal was the implementation of effective protection practices, but the process proved unworkable once again, and litigation proliferated. Section 1010 was largely abandoned when, in 2013, the EPA announced that it did not intend to codify ESA implementation practices required by Section 1010 into regulations because it was not required to do so by law and EPA wished to retain "some measure of flexibility as it continues to implement the ESA". Henceforth, the involvement of agricultural producers would come through "public comment on draft Biological Opinions and on any proposed Service RPAs/RPMs ["reasonable or prudent alternatives"/ "reasonable or prudent measures"] in those draft Biological Opinions as soon as they are received" (US EPA 2013).

A partially parallel "reworking" of policy was through Counterpart Regulations proposed in 2003, accompanied by an EPA risk assessment restatement ("Overview Document, US EPA 2004), and enacted during 2005, but partially vacated by a court decision in 2006.

Separately, litigation on consultation for listed salmon resulted in a schedule to produce EPA Effects Determinations and Services BiOps. The first Salmon BiOps were finalized in 2006 and litigation over them began in the same year. Arguments materialized focusing on how the "science of assessment" was applied. So, the next iteration was an attempt to solve the controversy by seeking the "best available science" via an undertaking through the National Academy of Science National Research Council (NRC), whose report was published in 2013 (NRC 2013).

The NAS report, while useful, did not solve the challenges either, and the cycle began once again when applying the principles in the NAS report did not lead to implementation. Milestones along the way were a plan for "enhanced stakeholder input" (NRC 2013), a new consultation response strategy by the EPA—the Interim Method— (US EPA 2013), and a revamp of county bulletins as Bulletins Live 2 during 2014 (US EPA 2014). The first Bulletins Live had previously been applied but faded into history in a fashion similar to the disappearance of the original bulletin system established in 1988 (EPA 1988). But these latest iterations were not comprehensive enough to result in a working consultation process.

The cycle started again with a Revised Interim Method (US EPA 2019) and it was shortly realized to not have improved the situation. The latest iteration is the ESA Workplan update accompanied by EPA's "Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations" coupled with an "early mitigations policy" put into place the same year (US EPA 2022a).

Throughout the pesticide consultation history, and all its shifts in policy, it is not clear if we have often enough asked "Can the FIFRA-ESA consultation as historically envisioned really work?"—and then sought a way to make it work. The current updating of methods and implementation policy, as illustrated by the 2023 Vulnerable Listed Species Pilot Project (EPA 2023f) and the 2023 Herbicide Strategy (EPA 2023a), are far from being mature operationally, and shrink back from formerly more robust methods that were deemed "too slow" by the courts. But the question is, given the FIFRA/ESA national platform and current action-by-action consultation policy, will an abbreviated process work, and will the decisions from it be scientifically sound, defensible, and implementable? Or are we simply at the end of the cycle and on the verge of trying to find another way to "regroup?"

A Legal Discussion of the FIFRA/ESA Consultation Process Over Time

Brigit Rollins

Endangered Species Act

Adding species to the Federal List of Endangered and Threatened Wildlife and Plants (an action known as "listing") is a critical aspect of the ESA's framework. A species will only receive ESA protection if it is formally listed as either "threatened" or "endangered." A threatened species is defined as "any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range," while an endangered species is defined as "any species which is in danger of extinction throughout all or a significant portion of its range."

The ESA provides listed species with a variety of different legal protections. Perhaps the most well-known of these protections is the prohibition on "take" of any listed species. Under the ESA, "take" is defined as "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." 16 U.S.C. § 1532(19). The term "harass" is further defined as "an intentional or negligent act or omission which creates the likelihood of injury to wildlife by annoying to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding or sheltering."

Another protection offered to some listed species is the designation of critical habitat. The ESA describes critical habitat as:

> (i) the specific areas within the geographical area occupied by the species at the time it is listed […] on which are found those physical or biological features essential to the conservation of the species and which may require special management considerations or protection; and
>
> (ii) specific areas outside the geographical area occupied by the species at the time it is listed […] that are essential for the conservation of the species.

Simply put, critical habitats are areas located either within or outside of the geographic range of a listed species that contain features necessary for conserving the species. While the ESA does not provide a definition for "habitat," the United States Supreme Court has found that in order for an area to be designated as critical habitat for a species, the area must at the very least be capable of supporting the species (Wayerhaeser Co v. U.S. Fish and Wildlife Services 2018). The Services may designate critical habitat for either threatened or endangered species.

Finally, another crucial protection the ESA grants to listed species is a process known as Section 7 consultation. Under Section 7 of the ESA, federal agencies are required to ensure that the actions they carry out will not jeopardize the existence of any listed species or destroy designated critical habitat. If a federal agency determines that its action may jeopardize a listed species or destroy critical habitat, the agency is required to enter into Section 7 consultation with the Services to determine how the potential harm may be avoided.

Prior to initiating Section 7 consultation, a federal agency must first determine if the process is even necessary. According to the ESA, Section 7 consultation is only required for actions an agency has "authorized, funded, or carried out[.]"Examples of agency actions include, but are not limited to: promulgation of regulations; granting a license, contract, lease, or permit; or actions directly or indirectly causing modification to the environment. If an agency is planning to carry out an activity that qualifies as an agency action, it must engage in Section 7 consultation. While there are a handful of exceptions to the ESA's consultation requirements, the United States Supreme Court affirmed in

Nat'l Ass'n of Home Builders v. Defenders of Wildlife (2007), that all "actions in which there is discretionary Federal involvement or control" are subject to Section 7 consultation.

Once an agency has determined that it is taking an action subject to Section 7 consultation, it can reach out to either FWS or NMFS to begin informal ESA consultation. During informal consultation, the agency taking the proposed agency action (referred to as the "action agency") will work with the Services to determine which listed species are present in the proposed action area, and the possible impacts the proposed action may have on those species (US FWS and NMFS 1998). It is during this phase of the consultation process that the action agency will determine whether its proposed action "may affect" any listed species or critical habitat. A "may affect" finding can include actions that are either "likely to adversely affect" or "not likely to adversely affect" listed species or critical habitat (USFWS 2022). If the action agency finds that its proposed action will have no effect on listed species or critical habitat, and the Service agrees, then consultation is at an end and no further action is needed. Similarly, if the action agency makes a "may affect" determination, but concludes that the proposed action is not likely to adversely affect species or habitat and the Service agrees, then no further action is needed. However, if the action agency finds that its proposed action is likely to adversely affect listed species or critical habitat, then it is required to proceed with formal consultation.

The overall goal of formal consultation is to ensure that the proposed agency action will avoid either jeopardizing the continued existence of a listed species or destroying or otherwise adversely modifying designated critical habitat. Formal consultation begins when the action agency submits a written request to either FWS or NMFS and ends when the Service issues a Biological Opinion ("BiOp"). The BiOp is a detailed document that contains a discussion of the current status of the listed species or critical habitat at issue, and an analysis of the effects the proposed agency action will have on the species or habitat.

Ultimately, the BiOp will result in either a "jeopardy" or "no jeopardy" / "adverse modification" or "no adverse modification" conclusion. The Services will issue a "jeopardy" finding if they determine that the action agency's proposed action is expected to "reduce appreciably the likelihood of both the survival and recovery of a listed species[.]"Similarly, an "adverse modification" finding is issued if the Services conclude that the proposed action will result in "a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species." If a BiOp contains a jeopardy/adverse modification finding (often referred to as a "J/AM" finding), then the document will also include a selection of reasonable and prudent alternatives.

Reasonable and prudent alternatives refer to alternative ways of carrying out the proposed agency action that would avoid, minimize, or offset the likelihood of jeopardy or adverse modification. Reasonable and prudent alternatives are limited to: (1) alternatives the Service believes will avoid the likelihood of jeopardy or adverse modification; (2) alternatives that can be implemented in a manner consistent with the intended purpose of the action; (3) alternatives that can be implemented within the scope of the action agency's legal authority and jurisdiction; and (4) alternatives that are economically and technologically feasible. The Service and action agency will work together to develop any reasonable and prudent alternatives included in the BiOp.

Once the BiOp is issued, Section 7 consultation is at an end. If the BiOp determines that the agency action will not result in jeopardy or adverse modification, then the agency may proceed as initially planned. However, if the BiOp contains a finding of jeopardy or adverse modification, then the action agency may choose to adopt the reasonable and prudent measures proposed in the BiOp, decide not to carry out the proposed action, reinitiate consultation with the Services, or take some other action that the agency believes would satisfy its ESA requirements. Importantly, whatever the action agency chooses to do, it must still ensure that its action is not likely to jeopardize any listed species or result in the adverse modification of critical habitat.

Federal Insecticide, Rodenticide, and Fungicide Act

One of the primary FIFRA actions that EPA carries out is the registration of new pesticide products. According to FIFRA, no pesticide product may be legally sold or used in the United States until the EPA has registered a label for that product. The registration process requires the pesticide manufacturer to submit the complete formula of the pesticide, a copy of the label that will accompany the pesticide, and a significant amount of scientific data for EPA to review as part of the registration application. FIFRA instructs EPA to register a pesticide for use if the agency determines that the product, when used as intended, will "perform its intended function without unreasonable adverse effects on the environment[.]"

FIFRA defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide[.]"The "unreasonable adverse effects" standard has been described as a risk-benefit analysis that requires EPA to balance the known risks and benefits to using the pesticide according to its proposed label.

If EPA determines that a pesticide product meets the "unreasonable adverse effects" standard, it will proceed with registration. When EPA registers a pesticide, it will specify the uses the pesticide is approved for, and the conditions of such use including safe methods of storage and disposal (CRS 2012). Such information will be included on the pesticide label, and it is considered a violation of FIFRA to use a pesticide contrary to its labeling requirements (US EPA 2023c).

Registering a pesticide under FIFRA is considered an agency action subject to ESA Section 7 consultation, but it is not the only agency action EPA carries out under FIFRA. After a pesticide product is first registered, FIFRA directs EPA to review its registration every fifteen years to ensure that the pesticide continues to meet the "unreasonable adverse effects" standard. The process requires EPA to collect and review data, develop

additional risk assessments, and hold focus meetings to address any areas of uncertainty or concern. Registration review concludes with EPA issuing a final registration review decision.

In some cases, EPA may issue an interim registration review decision during the review process. An interim decision may be issued when EPA would like to add new risk mitigation measures to the pesticide's label or ask for additional data prior to completing registration review. Although such interim decisions are part of the overall registration review process, courts have found that they constitute agency actions under the ESA and are subject to Section 7 consultation (Nat. Res. Def. Council v. U.S. Env't Prot. Agency 2022). Therefore, in some circumstances, a pesticide's registration review decision may be subject to two rounds of Section 7 consultation.

Finally, courts have also found that registering a new use for an already registered pesticide is an agency action that requires Section 7 consultation (Farmworker Ass'n of FL v. Envtl. Protection Agency 2021). Much like registering a pesticide or conducting registration review, FIFRA instructs EPA to approve a proposed new use if it finds that doing so would not cause "unreasonable adverse effects" to the environment.

Previous Efforts to Comply with ESA & FIFRA

Prior to 1989, EPA did not have an organized approach to meet its ESA responsibilities when carrying out agency actions under FIFRA. During the early 1980s, EPA would review individual pesticide registrations, and consult with the Services on a case-by-case basis (Kolm 1991). However, the process was time-consuming, and due to how many new registrations EPA issued each year, there was little time left to evaluate already registered pesticides. In an attempt to make the consultation process more efficient, EPA moved to a new "cluster approach" in 1982. Under the cluster approach, EPA would group together pesticides with the same use pattern (pesticides used on corn, on forests, or to target mosquitoes, for example) would be considered at the same time. While the cluster approach seemed to speed up the Section 7 consultation process, it still proved inefficient and had a tendency to prioritize restrictions for major uses pesticides while failing to review the impacts of minor uses. An independent review of EPA's pesticide program revealed that the agency was not meeting its ESA requirements in roughly one third of all pesticide decisions (Kolm 1991; Angelo 2008). In response to that review, EPA announced that it would work to come into compliance with the ESA by 1988.

To reach full compliance, EPA intended to address the restrictions that had so far been recommended by the Services during the case-by-case consultations and the cluster consultations carried out during the 1980s. The plan was to print restrictions on pesticide product labels and provide additional information bulletins that contained use instructions. However, the program failed to get off the ground, and by 1989, EPA had gone back to the drawing board.

In July 1989, EPA published a Notice of Proposed Program in the Federal Register announcing the development of the Endangered Species Protection Program ("ESPP") (US EPA 1989). The program had two objectives: first, to achieve the best protection for listed species, and second, to be responsive to the needs of agricultural production by not placing unnecessary burden on pesticide users. To accomplish those objectives, EPA proposed taking a species-based approach to ESA consultation wherein EPA would identify the listed species most vulnerable to pesticides, work with FWS to identify the counties were such species are located, and develop geographic-specific restrictions. Once again, EPA proposed adding language to the pesticide labels that would direct users to county-specific bulletins which would provide specific information on use limitations. Ultimately, this initial version of the ESPP had a variety of shortcomings. The program was voluntary and unfinalized, which made it unenforceable. Additionally, prior to widespread internet use it was difficult for users to access the county bulletins (Angelo 2008).

In 2005, EPA released an updated version of the ESPP (US EPA 2005). Under the updated program, EPA would address concerns to listed species while carrying out pesticide registration, reregistration, and registration review. This shows a shift away from the species-first approach to the ESPP that EPA had proposed in 1989 and a return to evaluating risks to listed species on pesticide-by-pesticide basis. Under the new ESPP, EPA would develop an endangered species assessment when reviewing a pesticide registration. The assessment would result in one of three conclusions: that the pesticide would have "no effect" on listed species; that the pesticide "may affect but is not likely to adversely affect" listed species; or that the pesticide is "likely to adversely affect" listed species. According to EPA, each determination could relate to a specific use of a particular pesticide and a particular listed species. If EPA reached either a "may affect but is not likely to adversely affect" conclusion or a "likely to adversely affect" conclusion, the agency would reach out to the Services to initiate Section 7 consultation. As with previous iterations of the ESPP, any necessary pesticide use restrictions would be geographically specific. Pesticide labels would contain language directing users to consult county bulletins that would contain species maps and information on any relevant restrictions. While EPA noted that the ESPP itself is not a legally binding regulation and could be amended at any time, the agency noted that any bulletins issued pursuant to the ESPP would be "effective and enforceable upon reference to them on a product label." The EPA created a website to website to host the bulletins, which the agency still uses today (US EPA 2024b).

Until recently, the 2005 ESPP has remained EPA's method for handling Section 7 consultation when registering pesticides or conducting registration review. However, like previous attempts, the method has not been perfect. The agency has continued to struggle with fulfilling its ESA responsibilities leading to mounting lawsuits, court orders, and settlement agreements that have caused EPA to once again revisit its process for Section 7 consultation when carrying out FIFRA actions.

Recent Lawsuits

Over the last several years, EPA has

been faced with various lawsuits filed by different environmental organizations alleging that EPA has violated the ESA by failing to engage in ESA consultation when taking agency actions under FIFRA. In some cases, plaintiffs have challenged the registration of a pesticide without prior ESA consultation (Ctr. for Food Safety v. U.S. Envt'l Protection Agency 2023). In other cases, the plaintiffs challenged registration review decisions that were issued without consultation (Nat. Res. Def. Council v. U.S. Envt'l Prot. Agency 2022). In yet more cases, plaintiffs have challenged EPA actions that amend a registered pesticide label by adding a new use without fulfilling Section 7 requirements (Farmworker Ass'n of FL v. Envtl. Protection Agency 2021).

Many of these cases have ended either in court decisions favorable to the plaintiffs, or in settlement agreements with EPA committing to complete Section 7 consultation by a particular deadline (US EPA 20022a). For example, in Farmworker Ass'n of FL v. Envtl. Protection Agency, the court found that EPA had failed to undergo ESA consultation when it amended the label for the pesticide aldicarb to allow for use on orange and grapefruit trees in Florida to combat citrus greening disease. In a two-page order, the court vacated the label and sent it back to EPA for further ESA review. Without the label amendment in place, aldicarb could not be used on citrus trees. In Ctr. for Food Safety v. Regan (2022), the court found that EPA had unlawfully registered the pesticide sulfoxaflor without undergoing ESA consultation. While in that instance the court chose to leave the registration in place, it remanded the decision to EPA with a court-ordered timeline to complete consultation.

Between court orders and settlements, EPA estimates that it has court-enforceable deadlines to complete Section 7 consultation for eighteen pesticides (US EPA 2022a). Together with additional settlement discussions the agency was in at the time, EPA determined that completing the consultations would take until beyond 2030. Acknowledging the uncertainty this creates for farmers, and the burden it presents to the agency, EPA began to develop a new approach to Section 7 consultation.

Current Developments

In April 2022, EPA published a document titled "Balancing Wildlife Protection and Responsible Pesticide Use: How EPA's Pesticide Program Will Meet its Endangered Species Act Obligations". That document, together with an update published the following November (US EPA 2022a), announced two primary strategies that EPA planned to pursue to bring its FIFRA actions into full ESA compliance. Both strategies share some similarities with methods EPA has tried in the past, but with several marked differences. The primary difference between EPA's past approaches and its latest attempt is a focus on "early mitigation" (US EPA 2022a) While the 1980s attempts and ESPP methods relied on the traditional Section 7 consultation process of evaluating pesticide registrations, making effects determinations, and consulting with the Services to develop BiOps when appropriate, the new method EPA is focused on adopting early mitigation methods for pesticides that are predicted to be at risk of jeopardy or adverse modification findings during future consultations. By adopting early mitigation measures, EPA hopes to avoid future findings of jeopardy/adverse modification and keep use restrictions to a minimum.

The first strategy identified in EPA's work plan is similar to the cluster approach that EPA took in the 1980s. Under this strategy, EPA would group together pesticides with similar chemicals and then focus on identifying and incorporating early ESA mitigation measures across those groups (US EPA 2022d). At the moment, EPA appears to be sorting registered pesticides into three broad groups – herbicides, rodenticides, and insecticides (US EPA 2023a). The agency has chosen to address the herbicides group first, and released a document titled "Draft Herbicide Strategy Framework to Reduce Exposure of Federally Listed Endangered and Threatened Species and Designated Critical Habitats from the Use of Conventional Agricultural Herbicides" ("Draft Herbicide Strategy") for public comment in July 2023. The comment period closed in October, and a finalized version of the Strategy is expected sometime in early 2024 (US EPA 2024b).

Within the Draft Herbicide Strategy, EPA has identified two primary categories of mitigation measures that it expects to incorporate into existing herbicide labels. The first category of mitigation is focused on reducing pesticide spray drift, while the second category is aimed at reducing pesticide runoff and erosion. According to EPA, those are the most common ways that listed species are exposed to herbicides. To reduce spray drift, the Draft Herbicide Strategy proposes adding additional buffer requirements to herbicide labels in areas where the risk to listed species exceeds a certain threshold. Depending on the expected level of risk, EPA may also require windbreaks, hedgerows, hooded sprayers, and application rate reductions.

To reduce herbicide runoff with water or bound to soil (erosion), the Draft Herbicide Strategy has identified a variety of mitigation measures and organized them into what EPA calls a mitigation menu. Those measures include restrictions on applications when rain is in the forecast; restrictions based on field characteristics like soil type and field slope; methods of application; in-field management activities designed to reduce runoff such as terrace farming or mulch amendment; management activities adjacent to sprayed fields like establishing buffer strips; and other activities intended to increase water retention. Importantly, EPA is proposing what appears to be a completely novel approach for implementing the runoff/erosion reduction measures. According to the Draft Herbicide Strategy, EPA is proposing a point-based system that the agency says would give farmers more control over which measures to implements. The system would work by assigning a point value for each of the identified runoff/erosion mitigation measures based on the measure's efficacy. Herbicide labels would identify how many mitigation points are needed for each of the product's intended uses. From there, pesticide applicators can review the mitigation menu and choose the methods that would work best to achieve the necessary number of points. The Draft Herbicide Strategy notes that activities farmers are already taking to reduce runoff or erosion may be used to

satisfy the point system. Currently, EPA does not appear to be recommending a similar system for implementing spray drift mitigation measures.

According to the Draft Herbicide Strategy, EPA will incorporate the proposed mitigation measures into pesticide labels in two primary ways. For those mitigation measures that EPA finds are necessary across the entire pesticide use area, the agency would add the restrictions to the product's general label. However, for the mitigation measures that EPA identifies as necessary only in specific geographic areas, the agency would continue to rely on county bulletins which would be posted on its website Bulletins Live! Two ("BLT") (US EPA 2024a). Pesticides with geographically specific restrictions would include language on their product labels directing users to check BLT for any relevant mitigation requirements.

Finally, EPA notes that for impacts that cannot be avoided or minimized, the agency will work on identifying offsets to "compensate for remaining unavoidable impacts." While the Draft Herbicide Strategy states that offsets "can include actions such as habitat preservation or restoration, invasive species control, and species reintroduction," no further information is currently available as to what, if any, offsets may be included in the final strategy.

The Draft Herbicide Strategy is only the first of the three pesticide groups EPA will address under the new policy. While a draft strategy for insecticides is not expected until 2024, the Draft Herbicide Strategy gives some indication of how EPA will develop the insecticide strategy.

The second strategy identified in EPA's 2022 work plan is similar to the species-based approach that EPA developed in 1989. Under this second strategy, EPA would introduce early mitigation measures targeted at "vulnerable species," or species that EPA has identified as being at the greatest risk of pesticide exposure (US EPA 2022a). Following the publication of EPA's April 2022 work plan, the agency launched the Vulnerable Species Pilot Program ("VSPP"), which involved identifying mitigation measures for twenty-seven species with limited ranges (EPA 2022f). The species included in the VSPP were selected based on a combination of factors that EPA has determined make the species particularly vulnerable to pesticides, including limited geographic range, small population size, and general susceptibility to environmental stressors (US EPA 2023f). To reduce pesticide exposure for these species, EPA has identified mitigations that would apply broadly to conventional pesticide active ingredients that are applied outdoors. The mitigation measures fall into two general categories, avoidance and minimization.

As its name suggests, avoidance mitigations refer to areas where the proposed mitigation measures involve prohibiting pesticide applications. Such areas would be limited to places where the species is most likely to occur, and would be based on "specific and refined" information from FWS. For areas where avoidance mitigations are required, EPA would direct pesticide applicators to coordinate with FWS at least three months prior to making a pesticide application in order to "determine appropriate measures to ensure the proposed application is likely to have no more than minor effects on the species."

The minimization mitigations proposed in the VSPP are focused on measures that would reduce spray drift, runoff, and erosion during and following application. Proposed mitigations for reducing spray drift include spray drift buffers, and the prohibition of certain application methods or droplet sizes. Proposed measures for reducing runoff and erosion include prohibitions on applications when soil in the area is saturated, prohibition on applications when rain is in the forecast, and requiring applicators to adopt land use practices designed to reduce runoff or erosion such as contour farming, planting a cover crop, or mulching. While the VSPP does not appear to employ the same point-based system for runoff/erosion mitigations presented in the Draft Herbicide Strategy, EPA would still allow farmers to select which of the land management mitigation measures work best on their fields.

EPA notes that while most of the proposed mitigations identified in the VSPP would apply year-round, some would only be required during certain times of the year. For example, EPA proposes only requiring avoidance and mitigation measures for the American burying beetle when temperatures are forecasted to be above 60 degrees Fahrenheit for three or more nights in a row.

Because all of the mitigations proposed in the VSPP are geographically specific, EPA will rely on BLT to inform applicators of any required restrictions. Pesticide labels would contain language directing users to check BLT prior to application. EPA notes that it expects "most, if not all" conventional pesticides registered for non-residential outdoor use would need a reference to BLT on their product labels.

Moving forward, EPA plans to continue developing bulletins for the twenty-seven species used in the pilot program, while expanding the program to include other vulnerable species In an update on the VSPP that EPA issued in November 2023, the agency briefly summarized modifications it plans to make to the program as it moves ahead (US EPA 2023e). Those modifications include developing more precise species maps, clarifying the scope of the VSPP for non-agricultural uses, clarifying potential exemptions to the proposed mitigations, revising some of the already proposed mitigations, revisiting how vulnerable species are selected, and developing a "consistent approach" for the strategies used to reduce pesticide exposure to listed species. The EPA intends to provide further updates on the VSPP by fall of 2024.

Importantly, many of the milestones identified in both the April and November 2022 work plans are now subject to a settlement agreement between EPA and two environmental organizations to resolve litigation involving over 1,000 pesticide products (Ctr. for Biological Diversity v. U.S. Envtl. Protection Agency 2023). The agreement, which was issued on September 12, 2023, commits EPA to finalizing the Herbicide Strategy by no later than May 30, 2024, and to issuing a final insecticide strategy by no later than March 31, 2025 (US EPA 2023b). The settlement also requires EPA to work towards expanding the VSPP by identifying additional species that would benefit from the mitigation measures developed under the program. While these were goals EPA

had already established in its April and November 2022 work plans, by including them in a settlement agreement, the deadlines have become court enforceable.

Remaining Questions

Overall, many questions remain as to the legality and practicality of EPA's policy proposals. Perhaps one of the most important questions to consider when reviewing EPA's new policy is whether the proposal actually fulfills the requirements of Section 7 consultation. In comparing EPA's current approach to its previous attempts, what appears to be missing is direct consultation with the Services. Both the Draft Herbicide Strategy and the VSPP focus on developing "early mitigations" that EPA hopes will result in fewer jeopardy or adverse modification findings during future Section 7 consultations. However, it is not clear whether these early mitigations were themselves developed through consultation with the Services. In a comment submitted during public comment for the VSPP, the USDA expressed its disagreement with EPA's plans to require mitigation measures before completing Section 7 consultation (USDA 2023). USDA also expressed concern over the scope of the avoidance areas identified in the VSPP. Specifically, USDA pointed to avoidance areas recommended to protect the Taylor's checkerspot butterfly which could include large portions of Benton, Lane, Lincoln, Linn and Polk counties in Oregon which are responsible for 60% of the hazelnut production in the United States. USDA further noted that in certain circumstances, Section 7 consultation could reveal that less restrictive mitigations than those proposed in the VSPP would be sufficient to prevent jeopardy or adverse modification.

Although it is not clear where the early mitigation measures proposed by EPA fit into the Section 7 consultation scheme, at least some may be required pursuant EPA's authority under Section 7(d) of the ESA. Under this provision of the ESA, any agency that has initiated formal consultation with the Services is prohibited from making any "irreversible or irretrievable commitment of resources […] which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures[.]"In other words, Section 7(d) provides that once an agency has initiated formal consultation, they must not take any action that would make it impossible to implement any reasonable and prudent measures that the Services identify in the final BiOp. Importantly, Section 7(d) is only relevant after an agency has initiated formal consultation, but before the Services have issued a final BiOp. In early 2022, EPA issued a decision to extend the current registrations for the pesticides Enlist One and Enlist Duo for an additional seven years (US EPA 2022c). Prior to issuing that decision, EPA had initiated formal consultation with the Services over its decision to extend the registration (US EPA 2022b). Because the Enlist registrations were set to expire well before formal consultation would conclude, EPA moved ahead with its decision to extend the registration while taking steps to comply with Section 7(d). In order to ensure that extending the Enlist registrations would not cause an "irreversible or irretrievable commitment of resources," EPA introduced a variety of new mitigation measures to the Enlist labels, including new limitations intended to reduce runoff and spray drift. EPA justified the addition of these new restrictions by concluding that they were necessary to ensure compliance with Section 7(d). Critically, the addition of these mitigation measures to the Enlist labels could only be done during this time when Section 7 consultation had been initiated, but not completed. This may provide some insight to EPA's timeline for introducing early mitigation measures to registered pesticide labels. The agency may need to initiate formal Section 7 consultation before it can add early mitigation measures to the label through its Section 7(d) authority.

While there are some concerns that introducing early mitigations to pesticide labels could dissuade the Services from consulting with EPA in the future, the text of the ESA makes it clear that once the action agency has initiated the consultation process, the Services have a duty to consult. However, it is possible that by adding early mitigation measures to pesticide labels, EPA may choose to rely on informal consultation rather than formal consultation when taking future FIFRA actions. Informal consultation is less stringent than formal consultation. Formal consultation results in the development pf a BiOp that thoroughly examines the impacts the proposed action is likely to have on listed species, and results in a jeopardy/adverse modification finding that includes any reasonable and prudent measures the Services believe necessary. On the other hand, informal consultation has no such requirement. The informal consultation process concludes either when the Services provide written concurrence that the proposed agency action will have either no effects or will be unlikely to adversely affect listed species. Because formal consultation can result in suggested reasonable and prudent measures that are less strict that early mitigations proposed by EPA, a reduction in formal consultations could ultimately lead to labels with more restrictions than necessary.

Questions also remain as to whether EPA's policy proposal satisfies the legal requirements of FIFRA. When a pesticide registration is amended under FIFRA, EPA must ensure that the registration continues to meet FIFRA's "unreasonable adverse effects" standard. Changes to a registered pesticide's label must also meet that standard. As discussed, the "unreasonable adverse effects" standard is a balancing test that requires EPA to conduct a risk-benefit analysis to fully consider the costs and benefits of using a particular pesticide. When carrying out this risk-benefit analysis, FIFRA directs EPA to take multiple factors into consideration, including economic, social, and environmental costs. Many commenters on EPA's Draft Herbicide Strategy expressed concern that both the Strategy and the VSPP were proposing label changes that had not been evaluated pursuant to the "unreasonable adverse effects" standard (National Barley Growers Association 2023; National Cotton Council 2023). In a comment submitted by the University of Arkansas Division of Agriculture (2023), it was noted that the proposed mitigations in the Draft Herbicide Strategy were likely to result in economic costs to agricultural producers in the forms of yield loss, increased weed pressure, productivity costs as producers worked to come into compliance with the

new requirements, and reduction of acres planted. The comment also highlighted potential social costs that could occur as a result of the proposed label changes, including increased pressure on relationship between producers and landowners, applicators, lenders, regulators, and the public. In 2020, the Ninth Circuit Court of Appeals issued a ruling to vacate the registration for the pesticide dicamba *(Nat'l Family Farm Coal. v. U.S. Envtl. Protection Agency 2020)*. One of the reasons the court cited as grounds for overturning the registration was EPA's failure to consider the economic and social costs of registering the pesticide. If EPA fails to ensure that labeling changes made pursuant to its new ESA-FIFRA policy do not meet the "unreasonable adverse effects" standard, it is possible that those labels could be at risk of judicial review.

Finally, EPA's policy proposal presents confusion over what the impacts will be to state and federal laws that conflict with the proposal. While FIFRA does allow states to regulate the sale or use of any federally registered pesticide, it prohibits states from "impos[ing] or continu[ing] in effect" any labeling or packaging requirements that are "in addition to or different from" those required under FIFRA. Therefore, if EPA added language to a pesticide label requiring additional mitigation measures pursuant to its new policy, no state would have the authority to alter that language. However, it remains unclear what would happen to state laws that conflict with the EPA's policy but do not involve making changes to the pesticide's label. It is generally the case that federal law will preempt state law when the laws conflict (Mikolajczyk 2022). This is especially true if it is impossible to comply with both state and federal laws at once. However, determining whether a state law is in fact preempted by federal law can be a challenge, and may require judicial review. This could result in a long period of confusion for pesticide applicators as regulators work to determine which law prevails. Such confusion could be even more pronounced if EPA's new ESA-FIFRA policy puts federal law at odds with itself. A producer may be enrolled in a USDA program that requires them to carry out certain conservation measures on their farm. If those requirements are incompatible with mitigation measures added to pesticide labels under the new policy, it is unclear which law would prevail.

Currently, it remains uncertain whether EPA's new policy for meeting its ESA responsibilities while carrying out FIFRA actions will be a success. Questions remain as to the policy's legality and overall practicality. More in-depth information on the legal structure of the ESA and FIFRA can be found with the National Agricultural Law Center.

Improving the Science Behind the Process: Implementing Better Data and Tools to Streamline the FIFRA/ESA Process

Valery Forbes and Richard Brain

Current Practice and Its Limitations

In the United States, registering a new pesticide necessitates that the EPA generate a "biological evaluation" (BE; essentially a generic endangered species risk assessment, typically at the national level) and consult with the Services in cases where the proposed regulatory action is deemed to likely adversely affect (LAA) listed species (as opposed to no effect [NE] or not likely to adversely affect [NLAA]). Subsequently, the Services issue a biological opinion (BO; essentially a species-specific assessment, typically at the local or regional level of analysis) concluding jeopardy, or no jeopardy, and likely to adversely modify critical habitat or not. Pesticide labels under FIFRA are then modified to reflect the outcome of this process. Within this BE/BO consultation cycle there are necessary procedural steps that could result in potential noncompliance; for example, if the EPA fails to consult or if the Services fail to assess.

In 2020 EPA released the "Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides" detailing a three-step framework where Step 1 involves a deterministic process (geospatial overlay of threatened and endangered ("listed") species critical habitat and range with a crop use footprint for a given active ingredient) to differentiate may affect (MA) from NE, and Step 2 describes a risk assessment methodology to delineate may affect calls between LAA and NLAA (US EPA 2020). Step 2 is intended to refine conservative assumptions employed in Step 1 and utilize probabilistic analyses, though conservative assumptions are still prevalent throughout. Steps 1 and 2 comprise the BE, which focuses on the individual, whereas Step 3, the BO is the domain of the Services and focuses on the population to determine jeopardy and adverse modification (J/AM) of critical habitat. In the cases considered to date, Step 1 has typically resulted in wholesale inclusion of listed species considered in the BE given that the range of listed species overlaps with land identified as "cropland" by ~96% (329 million acres) in the contiguous United States (Brain et al. 2023). Step 2 is a conservative deterministic (with some probabilistic elements) risk assessment that relies on prescribed models, model inputs, and endpoints from standard test species intended to be broadly representative of taxa generically.

The number of species listed as threatened or endangered has risen steadily from 70 in 1967 to more than 1700 currently, an increase of nearly 25-fold (US FWS 2023a). Moreover, land allocation to listed species designated critical habitat (identified in the Environmental Conservation Online System database) accounts for 114,082,035 acres, with an additional 3,634,870 acres being proposed. The extensive overlap between listed species critical habitat and range with cropland is primarily an artifact of imprecise range maps, which vary considerably in resolution and size, from less than one acre (narrow ranges) to over 800 million acres (US FWS 2020). Some ranges cover nearly 50% of the total land acres in the contiguous United States, and the vast majority (~84%), have ranges ≥25,000 acres. Thus, not surprisingly, when a geospatial proximity analysis of listed species range relative to cropland is conducted, per Step 1 of the EPA's Revised Method (US EPA 2020), nearly all species are routinely flagged

in this low-resolution capture. Although the EPA has detailed refinements in the recently released Herbicide Strategy (US EPA 2023a), the approach is still highly prescribed, extremely conservative, and does not provide accommodation for higher-tier data or methodologies. This increases the likelihood of erroneous risk conclusions in the resulting BEs, which are then transmitted to the Services for concurrence. In an attempt to ensure compliance with ESA requirements, the EPA has recently proposed an a priori picklist or menu of mitigations whereby growers and applicators can select from a menu of practices intended to minimize potential pesticide exposure to listed species (e.g., US EPA 2023b). However, there are technical, practical, and financial challenges associated with this approach. The fundamental weakness is the lack of calibration regarding the menu of mitigations relative to conservatively projected risks to listed species, resulting in potentially onerous and unwarranted demands for applicators and growers. For example, how much do cover crops reduce exposure relative to a vegetative filter strip, and how wide does a filter strip, buffer or setback need to be to reduce exposure sufficiently? There has been little evaluation of proposed picklist/menu mitigations and no calibration of their effectiveness relative to offsetting potential risks. Although we agree that up-front mitigations may offer a viable strategy, they need to be grounded in solid science.

Fundamental Obstacles That Need to be Addressed

Fundamentally, there are at least three major obstacles that are critically limiting effective implementation of the FIFRA/ESA consultation process. The first is a prevalent and persistent lack of staff and resources for the EPA and Services to do the necessary work. The second is excessive litigation. The third is key differences in the objectives of FIFRA and ESA. Without giving EPA and the Services resources to actually do what they're currently obligated to do by law, and without somehow stopping the all-too-frequent lawsuits against every registration action, there is little hope for substantive progress. Over and above these changes, action by Congress to modify one or both of the statutes so that they can operate more seamlessly should not be beyond the realm of possibility.

Obstacle 1 - A lack of resources has forced a reliance on screening-level risk assessments in Steps 1 and 2. This is not the requisite level of analysis needed to adequately characterize potential exposure and effects to listed species and adequately and accurately inform and calibrate proposed a priori mitigations intended to offset species exposure/risk.

Consideration and integration of higher-tier data and methodologies are essential, and the current procedure to develop BEs does not provide necessary flexibility to consider non-standard data and methods. Every pesticide active ingredient is unique, and although all conventional pesticides must at a minimum reflect the mandatory standard data requirements under 40 CFR Part 158 (CFR 2014), non-standard higher-tier data exist for many compounds. Not making use of available higher-tier data means that the assessments are not based on the best available science.

An additional consequence of resource limitations is that the consultation process, including the associated analyses, reporting, and reviewing, has been far too slow. This can have undesirable consequences for growers in delaying the registration or re-registration of products on which they depend (to grow more crops on less land) as well as manifesting in unnecessary mitigations. Moreover, from a listed species perspective it can also have undesirable consequences in delaying actions that might be needed to ensure continued species protection.

Obstacle 2 - Litigation as the driver of the FIFRA/ESA consultation process forces action—even if not the most scientifically supported action—in the interest of demonstrating compliance. Given the complexity of the FIFRA/ESA interface, it is inevitable that multiple stakeholders with diverging perspectives and priorities have a significant interest in the outcome of regulatory decisions. But contentious legal battles are not likely to result in stakeholder consensus; they rather lead to further delays in the consultation process and registrations of new active ingredients. The result is negative impacts on growers, listed species, or both. This is broadly a consequence of the litigious nature of the U.S. pesticide regulatory framework. Pesticides are an easy target given that they have a contentious origin (Brain and Anderson 2020), plausible biological relevance (BCPC 2018; Carson 1962; Fukuto 1990), and an easily exploited legal construct in the United States, e.g., citizen suit provisions (US FWS 1973; US EPA 2002). Replacing litigation as the driver behind the consultation process with a multi-stakeholder approach that embraces consensus-oriented dialogue, explication, and mediation would likely be much more desirable for all parties.

Obstacle 3 - In working through the ESA consultation process, it has become obvious that the objectives (i.e., protection goals) of FIFRA (i.e., ensuring no adverse effects to non-target species or critical habitat from registering a pesticide) and ESA (i.e., ensuring that listed species are not further impacted from any human-related cause) are very different. Registration/re-registration of a pesticide active ingredient under FIFRA takes the benefits of the product into consideration, whereas ESA does not. Also, FIFRA is designed to assess risk to all non-target species from one pesticide at a time, whereas ESA is designed to assess all potential risks to one listed species (population) at a time. Finally, FIFRA considers risk at a national level for the purpose of product registration and labeling, whereas ESA generally considers risk at a regional level for the purpose of developing recovery plans at the local level.

If under FIFRA, a pesticide is determined to have no significant adverse effects on non-target species, it should, in principle, not have any adverse effects on listed species. Because only a small subset of species are tested under FIFRA, legitimate questions can be raised about whether these tested species are sufficiently representative of listed species to ensure the latter's protection. Are there any reasons to expect listed species to be more vulnerable to the effects of pesticides than non-listed species? In particular, are they likely to be more toxicologically sensitive? Are there features of their biology that would exacerbate

the population-level impacts of pesticide impairments to survival, growth, or reproduction (i.e., the most common toxicity test endpoints), thus making their populations more vulnerable to the same levels of pesticide exposure as non-listed species?

In that ESA is focused on ensuring protection of listed species, it would seem essential to assess the potential risks of pesticides in a more holistic context that includes other potential factors that are impacting endangered species. However, the present consultation process is solely focused on assessing the risks of pesticides to listed species independent of other potential anthropogenic drivers. More effective protection of listed species would benefit from a greater separation of the FIFRA and ESA processes in which risk assessments under FIFRA focus exclusively on potential risks of pesticides to all species (including listed species), and risk assessments under ESA focus on relative risks of all potential stressors (including pesticides) to listed species. In this scenario, EPA could still provide input to ESA assessments, in the form of information produced under FIFRA, which the Services would subsequently consider relatively, within a broader anthropogenic context.

How Science Can Better Inform Assessments Under FIFRA and ESA

In what follows, we propose a way forward that leverages recent developments in the science to streamline the FIFRA/ESA process, achieve greater consensus among stakeholders, and more effectively balance the need to secure the human food supply with the need to protect the environment, and endangered/threatened species.

Considering how science can help to improve and streamline risk assessments under FIFRA and ESA, it is essential to recognize that science changes as understanding increases and technology improves. This implies that our regulatory processes should also change to reflect scientific progress. Regulators have been reluctant to make changes to historical practices, despite acknowledged improvements in the science for (perhaps justifiable) fear of litigation. Despite numerous advances in the science, procedures used by the EPA for ERAs (including endangered species assessments) have not substantively changed in decades. They rely heavily on highly prescribed and standardized screening-level risk quotients and levels of concern and often use worst-case assumptions that can be compounded, leading to overestimates of risk (Raimondo and Forbes 2022). This methodology is employed by design, for efficiency, consistency, and reproducibility; however, such an approach lacks flexibility to consider and incorporate non-standard, and often novel higher-tier data and approaches. This approach needs to be reformed. Engaging all stakeholders more productively is one way to achieve this. Regulatory actions should not be considered in a vacuum; rather the process should assess potential risks judiciously, accordingly, and relatively in order to identify the most significant factors contributing to species decline. If pesticides are among the most significant contributing factors, then we should explore a priori mitigation options or conservation offsets. However, such options should be thoroughly and rigorously vetted to consider geographic appropriateness, feasibility, likely grower adoption, economic considerations, and potential benefits to listed species.

Risk assessments are characterized by both uncertainty (e.g., lack of knowledge, measurement errors) and variability (e.g., differences in species sensitivity, differences in exposure scenarios). Science can help to distinguish between these so that we can reduce uncertainty and incorporate variability for more robust assessments. Science can also provide data, theory, and tools to more quantitatively and robustly link what we measure (e.g., individual survival, growth, or reproduction) with protection goals (e.g., the persistence of listed species populations).

One question that is often posed in the context of ESA is what constitutes "best available data"? Not all research and studies are created equal, so how do we decide which studies and which data constitute "best available"? Klimisch and colleagues (1997) developed a system that considered the reliability, relevance, and adequacy of studies, where adequacy is defined as the "usefulness of data for risk assessment." This system categorizes studies using four reliability codes: (1) reliable without restrictions (preferably Good Laboratory Practice (GLP) studies), (2) reliable with restrictions (open literature articles, mostly non-GLP studies), (3) not reliable, and (4) not assignable. Studies rated as "reliable without restrictions" and "reliable with restrictions" may be used in a risk assessment. Relative scoring criteria and rubrics have also been developed and employed to evaluate the strength of methods, which facilitates identifying the most reliable endpoints for use in risk assessment (e.g., Hanson et al. 2019) and similar approaches exist for assessing the consistency of results (e.g., Hanson and Brain 2021). Moreover, quantitative weight of evidence approaches also exist to compare and contrast data based on a priori scoring criteria (e.g., Van Der Kraak et al. 2014). Data quality and relevance should be a fundamental tenant in any step of any ERA. If meaningful and accurate estimates of risks are to be developed, then the approach must have broad agreement across stakeholders on the specific criteria (related to quality and relevance) determining best available data. Granted it must be acknowledged that any evaluation of data quality necessitates some degree of expert judgment, regardless of how objective and quantitative the criteria is. This potential subjectivity can introduce elements of bias; however, this can be addressed through transparent, consistent, and systematic application of data quality and relevance standards that are agreed-upon and validated. A useful template to evaluate, at least the basic elements of study quality, is provided by the Health Effects Division (HED) of the Office of Pesticide Programs within the EPA (US EPA 2012).

In principle, ERAs use a tiered approach that starts with worst-case assumptions about exposure and effects at initial (screening-level) tiers. If the screening-level ERA finds potential risks to be unacceptable, exposure and/or effects estimates are refined to more realistic (i.e., less worst-case) values, providing more accurate estimates of risk. This is laid out in elaborate detail by the EPA's overview document for

threatened and endangered species evaluations (US EPA 2004). Because obtaining more realistic estimates of exposure and effects generally requires more information and resources, using a tiered approach makes sense. However, there are two ways that the tiered approach can go awry: if the initial screening-level ERA is not sufficiently worst-case, resulting in inherently 'risky' chemicals entering the marketplace; or if the higher tier ERA is not effective in screening out low-risk chemicals, resulting in the need for resource-intensive higher-tier assessments for too many chemicals, potentially requiring unnecessary restrictions on their use or keeping them out of the marketplace all together. The latter was the situation for the first three national level FIFRA/ESA BEs performed by EPA for chlorpyrifos, diazinon, and malathion. Step 1 used a deterministic geospatial overlay of listed species critical habitat and range with a crop use footprint for widely used active ingredients, and nearly all species had to proceed to Step 2. Step 2 assessed pesticide exposure at the national level and pesticide effects using the lowest available individual-level toxicity data. In these cases, neither the Step 1 nor Step 2 ERAs were capable of eliminating the vast majority of listed species from detailed consideration by the Services in Step 3 (i.e., only 3% of 1,835 listed species were eliminated in Steps 1 and 2 for chlorpyrifos and malathion with 21% eliminated for diazinon).

National screenings are not likely to be helpful at eliminating listed species from further consideration (especially for widely used products, as was the case in these assessments). Assuming that effects on survival, growth, or reproduction of a single individual of a listed species population are likely to adversely affect the population is very conservative, and therefore not surprising that very few species were screened out from further consideration. In short, the tiered approach in these cases was ineffective and resulted in nearly all species having to proceed to more intensive Step 3 assessments, which, at least in theory, are intended to assess population-level impacts.

Ecological risk assessments are generally intended to protect populations and ecosystems and not individuals (Suter 2020). Even for threatened and endangered species, for which it might be argued that the loss of any individuals is to be avoided, risk assessments are intended to determine conditions under which species populations are likely to decline (i.e., to be in jeopardy). This implies that any measure of chemical effects used in ERAs needs to either be a direct measure of population-level impact or linked quantitatively to such impacts (Raimondo and Forbes 2022). There have been numerous advances over the last couple of decades in the science of population modeling. These include guidance on model development, documentation, and evaluation (Raimondo et al. 2021), case studies (Hommen et al. 2015), and advances in the technology facilitating more sophisticated modeling approaches. Although population modeling has yet to make it into EPA's standard toolbox to any meaningful extent, increasing acceptance of population modeling for pesticide risk assessments in Europe is a sign of progress (EFSA 2014).

Admittedly, developing population models for non-target species requires a certain amount of data, and lack of data for many species is a real challenge. This is especially true for listed species because of restrictions in collecting or working with them, and they certainly cannot be used in toxicity tests. Ongoing research into traits-based approaches is exploring how particular life-history, physiological, behavioral, or ecological traits may influence the vulnerability of species to pesticides and other stressors. This work should help to identify species that can represent larger groups of species sharing similar traits. Population models could be developed for vulnerable representatives of larger groups with the expectation that estimates of risk based on the model outputs would be protective of species sharing similar traits.

For example, freshwater mussels are among the most critically imperiled taxa globally, with 91 of nearly 300 species listed as threatened or endangered under the ESA (US FWS 2018). Using literature data on five life-history traits (maximum life span, age at maturity, mean fecundity, maximum adult size and glochidia size) for 55 species, including 15 listed species, Moore and colleagues (2021a) grouped the species into three life-history categories (equilibrium, opportunistic, periodic). Listed species occurred in both the equilibrium and periodic categories, but not the opportunistic category. Population models are being developed for one or more data-rich representatives from each category to use in assessing risks of pesticides and other stressors to species for which data are lacking. Exploring how perturbations of individual-level responses (as would typically be measured in toxicity tests) extrapolate to population-level impacts for the different categories will improve understanding of how data measurements are linked to protection which could potentially result in ERAs that are better informed by the science.

Traits-based analyses can also be used to explore whether listed species share particular traits that make them especially vulnerable to pesticides and other stressors and how they differ from non-listed species. Using a combination of phylogenetic and life-history analyses, Rueda-Cedial and colleagues (2022) found that listed terrestrial plant species were distributed widely across plant phylogeny and life-history clusters. This indicates that listed plant species do not share a common evolution or life-history traits that would make them uniquely vulnerable. It also suggests that non-listed species (that have fewer restrictions and are often more data-rich) may be suitable representatives for listed species in the context of ERA.

Additional tools, approaches, and resources include field studies, probabilistic geospatial frameworks, several higher-tier aquatic exposure models, as well as monitoring data. Field drift bioassays, when available, should be evaluated and used to refine buffer predictions (Brain et al. 2017; Brain et al. 2019; Moore et al. 2021b; Perkins et al. 2022). Such studies better reflect how non-target plants (or organisms in general) experience off-field exposure and empirically define a conservative buffer distance directly without the need for extrapolation. Probabilistic geospatial frameworks, such as the Automated Probabilistic Co-Occurrence Assessment Tool (APCOAT) (Dunne et al. 2023) (which is a freely available: https://www.stone-env.com/our-expertise/

environmental-systems-modeling/apcoat) can also be useful. APCOAT generates batches of probabilistic maps and statistical summaries of species distributions, pesticide use, and co-occurrence. With respect to aquatic exposures, the Pesticide in Water Calculator (PWC) represents a simplistic, generic, farm pond that does not consider inflow or outflow to derive an extreme exposure scenario. Examples of available watershed models that could be used in refined pesticide risk assessments for listed species include the Soil Water Assessment Tool (SWAT) (Neitsch et al. 2005), the Agricultural Policy Extension (APEX) model (Steglich and Williams 2008), and the Pesticide Root Zone Model-Riverine Water Quality (PRZM-RIVWQ) model. The Vegetative filter strip modeling system (VFSMOD) (Muñoz-Carpena and Parsons 2004) specifically predicts the effects of vegetative filter strips and can be linked between PRZM and VVWM. Monitoring data should also be leveraged where possible in conjunction with the seasonal wave with streamflow adjustment and extended capability (SEAWAVE-QEX) tool developed by the USGS (Vecchia 2018).

The EPA's "Revised Method for National Level Listed Species Biological Evaluation of Conventional Pesticides" (USEPA 2020) outlines changes that have been made to the 2013 Interim Method (https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report; accessed July 19, 2023) that was applied to the first three national-level BEs (for chlorpyrifos, diazinon, and malathion). In this document, the EPA commits to applying current methods and best available data as the biological opinions evolve and to continue methodological discussions with the Services and USDA (USEPA 2020, p. 8). The recently released Herbicide Strategy also indicates that "In fulfilling the requirements of ESA section 7(a)(2), EPA must use the best scientific and commercial data available" (USEPA 2023). Although certain improvements have been made, for example regarding probabilistic methods and weight of evidence, overall improvements in the scientific basis of the approach appear minimal, and consideration of higher-tier data and newer methodologies is notably lacking.

Streamlining the Process with More Science and More Stakeholder Involvement

There are a number of ways that better use of science can streamline the FIFRA/ESA process. The first is ensuring that the criteria used to screen out low-risk cases are indeed effective screens. As the first three biological evaluations for organophosphates clearly demonstrated, national-level exposure assessments are unlikely to screen out species from further consideration for widely used pesticides. A solution to this would be to develop agreed-upon regional scenarios that are tailored to ESA needs. Since preventing decline of listed species populations is the goal of ESA, choosing methods that more directly reflect population-level impacts could save time and effort. A multi-stakeholder initiative to develop a suite of standardized population models, using all of the guidance now available, for a handful of representative species, would be another way to streamline the process. While both of these efforts would take considerable time and energy, they could have the benefit of engaging all of the relevant stakeholders in a constructive dialogue that, over time, could lead to greater consensus building and less litigation.

Over a shorter timescale, it may be feasible to distribute the ERA workload to speed up the process. This could mean engaging the Services at an earlier stage than current practice, skipping the current Step 1 and possibly 2 to free up EPA resources to focus on higher tier, population-level assessments, and/or having registrants produce the ERAs for EPA/Services to review, consistent with EU/EFSA approach. This should be possible given that ESA applicants for other types of actions (developments, bridges, roads, pipelines etc.) generate and submit such assessments, rather than these being conducted by the action agency (EPA) or the Services.

With respect to prioritization, under ESA all listed species are created equal by design. In reality, the degree of imperilment and the relative drivers of listed species decline vary considerably. For the FIFRA/ESA process, it may be helpful to rank-order species relative to the unique and individual threats posed by agriculture (i.e., pesticides). To some extent recovery plans and 5-year reviews issued by the Services do reflect an element of prioritization, which reflects a species expert judgment call, however, this is not reflected in the EPA's BEs at this time. Prioritizing more time and effort to assessing potential risks of pesticides to listed species in the middle of the corn belt and less to remotely located and geographically isolated species, would be in keeping with the tiered philosophy of ESA.

Relative Threat of Pesticides and Other Stressors to Listed Species

Acknowledging that comparison of the relative drivers of listed species decline is not within the remit of the Section 7 ESA consultation process and would require Congressional debate, context warrants consideration. The FIFRA/ESA process is solely focused on assessing the risks of pesticides to listed species, ignoring both the other facets of agriculture (e.g., land use change, fertilizers) and, more importantly, other potential human stressors (e.g., invasive species, climate change, urbanization [homes, malls, recreation, highways], point-source industrial pollution etc.) that may be contributing to species decline. The available literature indicates that many of these other anthropogenic stressors represent primary threats to listed species and far surpass any potential impacts of pesticides. For example, based on data generated by Pimentel (2000) and compiled by the US FWS (2017) cats (domestic and feral) account for 72% of all bird mortalities in the United States annually (Brain and Anderson 2019; Figure 2), with a further (combined) 25% attributable to collisions with buildings, structures, and vehicles etc., and only 2% attributable to "poisons" (not broken out by household, industrial, or agricultural). Similar trends are evident when mammals and fish are considered (Brain and Anderson 2020; Brain and Prosser 2022). Consequently, a prudent question to ask would be whether we are judiciously focusing our efforts

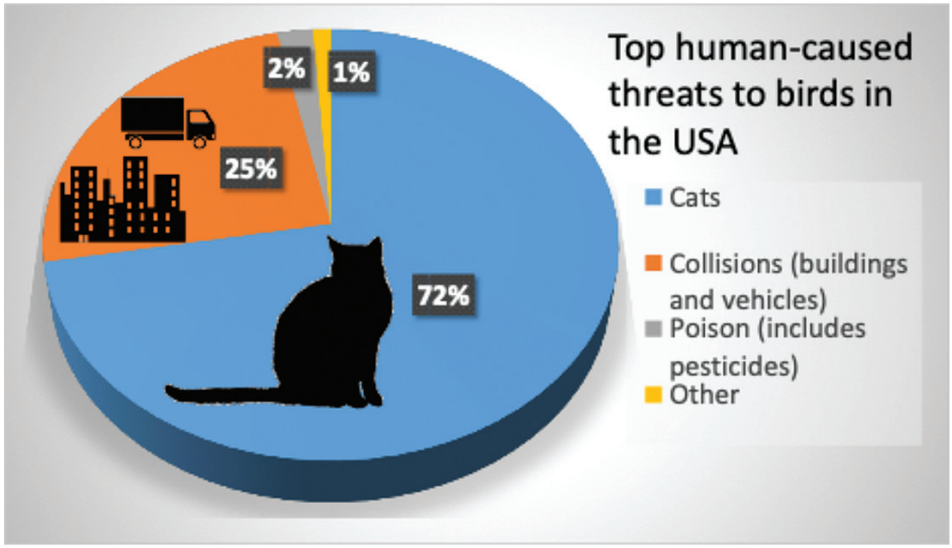


Figure 2. Anthropogenic contributions to avian declines in the United States (redrawn from Brain and Anderson 2019).

relative to the potential risks presented accordingly. The data suggest, for example, that spay, and neuter programs would be far more effective in reducing listed bird declines in the US than upfront pesticide mitigations, but that is not the reality reflected in existing practice. Clearly spay and neuter programs and awareness are beyond the purview of FIFRA but are within the scope of ESA, given the remit is to recover and preserve listed species, whatever the source contributing to their imperilment. Thus, it appears that the current FIFRA/ESA consultation process focuses maximal effort on a minimal contributor to potential jeopardy of listed species. Taking a more holistic approach to assessing potential risks would, not only better reflect our existing scientific knowledge, but would lead to more effective and pragmatic strategies to protect listed species.

In the United States the number of acres characterized as "land in farms" have decreased by ~23% over the past 70 years, and "cropland" has shrunk by ~17%, yet the U.S. population has more than doubled during this timeframe, and agricultural productivity has increased three-fold (Brain et al. 2023). Habitat loss is the single most significant factor contributing to listed species decline, and agricultural expansion was the primary driver up to 1950. However, both habitat and farmland are now being consumed by urbanization, which is increasing at a rate of change of 858,504 acres per year (Brain and Anderson 2019). Growing more food from less land has been made possible by synthetic pesticides and fertilizers and regulatory decisions that do not reflect the best available science will compromise these tools, stress land use and food security, and will not likely improve listed species status.

Recommendations for Better Informing Assessments Under FIFRA and ESA

There are legitimate concerns that the FIFRA/ESA consultation process – constrained as it is by law – is missing the forest for the trees by focusing solely on pesticide risks to listed species when the science points to other major drivers that need to be addressed for effective species protection and recovery. Attempting to find shortcuts through mitigations that are not sufficiently informed by science may give the sense that actions are being taken, but the overall effectiveness of such actions is questionable and may sacrifice dependable science-based outcome solely for the sake of an operational process. As science continues to advance, better data and tools are becoming available to inform FIFRA/ESA risk assessments than those currently being used. The EPA appears to be committed to "continue to evolve as EPA gains experience and as scientific methods and data improve" (USEPA 2020, p. 8). Improving upon existing approaches will likely involve a more proactive, transparent, and consensus-driven engagement of multiple stakeholders and a shift away from litigation as the primary consultation driver. Achieving a more efficient FIFRA/ESA consultation process, more accurate ERAs that continuously improve as the science advances, and workable mitigations where necessary should be in the best interests of all stakeholders.

Several immediate steps that could be taken include:

1. Contextualizing risks posed by pesticide active ingredients relative to other more prominent drivers could better inform strategies for supporting listed species recovery and viability.
2. Changing the existing screening-level approach for BEs (Steps 1 and 2) to reflect a truly tiered system would save resources for where they are really needed. Although there is obvious utility in screening-level assessments, these are intentionally very conservative and may point to a priori mitigation strategies that are not feasible in practice. Flexibility and expert judgment are necessary to incorporate higher-tier data and methodologies, which can be accomplished through a tiered framework that has been publicly vetted.
3. Setting the tiers appropriately to reduce the number of species that need to proceed to Step 3 would improve efficiency. Reliance on a screening-level risk assessment that results in inordinate numbers of listed species (i.e., LAA designation) being referred to the Services for J/AM analysis is highly challenging and slows the overall process. Greater integration of state-of-the-art tools and methodologies through transparent and multi-stakeholder collaborative engagement would reduce uncertainty, facilitate realistic a priori mitigation options, better inform which species should proceed to J/AM analysis, and ameliorate litigation pressure.
4. Although resource allocation to support the EPA and the Services is the domain of Congress, there are

collaborative opportunities to reduce the burden of Section 7 consultations. Registrants can provide support in the form of data, methods, tools, and assessments. Potential concerns of bias can be addressed through transparent data evaluation criteria and by pursuing a multi-stakeholder approach that also includes non-government organizations (NGOs).

Developing and Adopting Economically Effective Pesticide Mitigation Strategies: Critical to the Survival of Agriculture and Endangered Species

Leah Duzy and Taylor Randell-Singleton

Developing a mitigation approach that fulfills the statutory obligation of protecting listed species under ESA, but also strikes a balance between economic feasibility, environmental soundness, and continued use of pesticides in a practical manner for agricultural entities is proving to be a significant challenge. Production agriculture, especially family farms, can provide the space and resources for habitat and protection for many listed species and other wildlife. If ESA mitigations are not implemented carefully, regulatory actions taken with the intent to protect listed species will threaten the sustainability of these farms, and thereby may inadvertently destroy the wildlife and habitat they aim to protect. Without the ability to effectively control pests in a practical manner, many farmers will not be able to grow an economically productive crop and may be forced to sell the land for development or other industrialized purposes to continue providing for their families, resulting in changes in land configuration that could effectively eliminate habitat for listed species.

Thus, the approach of incorporating mitigation measures must be transparent, scientifically sound, flexible, and developed in cooperation with stakeholders. As it is required to implement mitigation measures when making pesticide applications moving forward, it is critical to understand: (1) how pesticide use, mitigation measures, and ESA-listed species interact with each other, (2) the current extent and practicality of including best management practices (BMPs) already used across the agricultural landscape into the pesticide mitigation measures dialogue, (3) the role of existing, externally funded conservation programs in mitigating potential pesticide movement and protecting ESA-listed species, and (4) the importance of measuring outcomes of proposed mitigation measures.

The Intersection between Pesticide Use, Mitigation Measures, and ESA-listed Species

There is a long list of stakeholders across the United States including university agricultural extension, private crop consultants, local land and water protection agencies, commercial retailers, state departments of agriculture, professional organizations, agricultural industry, and numerous USDA entities, serving to educate, recommend, and enforce the implementation of smart pesticide use practices at the local level. Across entities, current efforts in support of the role pesticide stewardship plays in protecting humans, the environment, and wildlife are at an all-time high. For example, Georgia's flagship pesticide stewardship program, Using Pesticides Wisely, was created as a collaborative effort between the University of Georgia and state department of agriculture, as a way to share innovative research results on improving on-target pesticide applications with farmers and other pesticide applicators. Since its inception in 2014, more than 17,130 pesticide applicators have been trained on applying pesticides safely, while minimizing impacts to sensitive sites from pesticide movement (Culpepper et al. 2020). A similar example from the pesticide industry is the BeSure! Stewardship Program through the Growing Matters coalition, which is a coalition of numerous pesticide companies committed to science-based stewardship of neonicotinoid insecticides (Growing Matters 2020).

There has been, and continues to be, tremendous research and educational efforts across the United States to ensure pesticide applicators have access to science-based information on improved application practices, precision technology, and parameters directly influencing the ability of all products to remain in the field. While EPA's recent draft Vulnerable Species and Herbicide Strategy documents identify mitigation measures that are common conservation practices and actions for some growers, there is a lack of flexibility for complex production systems and the site-specific nature of conservation planning (EPA 2023a; EPA 2023f). In the Herbicide Strategy, the EPA outlined mitigations focused on reducing the potential for off-field pesticide movement into terrestrial and aquatic habitat through spray drift, aqueous runoff, and/or erosion to protect non-target species, specifically listed plants, obligates of plants, and generalist animals. However, in the Herbicide Strategy, the EPA did not identify specific types of terrestrial and aquatic habitat for listed species like they did in "Vulnerable Listed (Endangered and Threatened) Species Pilot Project: Proposed Mitigations, Implementation Plan, and Possible Expansion" (EPA 2023f) or in the recently released Endangered Species Protection Bulletins for malathion (EPA 2023f). By providing a general description of terrestrial and aquatic habitat, the proposed Herbicide Strategy does not consider the specific characteristics that constitute suitable habitat for individual species, therefore requiring growers to install and/or adopt mitigation measures around more generalized habitat than may be scientifically necessary or effective.

As the EPA focused on intentions to improve on-target pesticide applications with these documents, they strongly emphasized the use of spray drift buffers to reduce airborne pesticide particles blowing away from the intended target (spray drift) to terrestrial and aquatic habitat. Factors being considered to influence the size of the required buffers include the maximum single application use rate, application method, nozzle selection, and droplet size distribution, release height, use of a windbreak, and wind speeds. Although each of these factors influence on-target pesticide applications, current options to reduce required buffer dis-

tances neither do not encompass all the effective approaches pesticide applicators already implement nor are they given fair scientific credit as to how they can be used to reduce drift. While the Herbicide Strategy specifically expands upon previous definitions and defines the areas and structures that may be included as part of the buffered area (areas where the pesticide cannot be applied to offset airborne particle movement towards a sensitive site; typically, downwind of the application). However, the diverse landscape, field shapes, and cultural production practices across the country often lends to the inability to maintain this buffer outside of the crop field. It is likely that growers will have to include in-field areas in order to reach the required buffer width. The overly conservative approach of requiring growers to implement areas around and within the field where pesticides cannot be applied is an example of one mitigation measure that would severely limit the ability of growers to effectively manage pests while continuing to maintain production yields and profitability. Therefore, the EPA's proposed approach will likely lead to overly conservative and potentially large in-field buffers. In-field buffers (areas within the field where the pesticide cannot be applied to offset airborne particle movement towards a sensitive site; typically, downwind of the application), are an example of one mitigation measure that would severely limit the ability of growers to effectively manage pests while continuing to maintain production yields and profitability.

While some growers may be able to achieve the required buffer width without sacrificing productive areas of the field, it is important to understand the potential loss of production area and economic impact for those required to include cropland in the buffer. To gain a sense of the farm-level impacts from including in-field areas as part of the buffer, spatial data representing best- and worst-case scenarios were collected in Georgia. A best-case (least impactful) scenario was defined by selecting fields that were larger and covered a more continuous area while a worst-case (most impactful) scenario was defined as smaller fields surrounded by trees. When considering a downwind in-field spray buffer of 110 ft, the loss of land in the field to be treated with a pesticide ranged from 10 to 15% while a 240 ft downwind buffer eliminated from 20% to 33% of the land to be treated within the field. For an expanded buffer of 310 ft downwind plus 57 ft omnidirectional, the loss in land ranged from 31 to 50%. Losing the ability to control pests within production agricultural fields can effectively eliminate the ability to harvest a crop within that area because of the impacts of competition from weeds, insects, or pathogens. Furthermore, increasing pressure from unmanaged weeds and other pests may begin to creep into the terrestrial habitat, placing ecological strain on the listed species the mitigation practice was intended to protect.

As the process of spray drift mitigation advances, providing science-based data to pesticide applicators is critical. In fact, education is a crucial and effective mitigation method for pesticide stewardship and has successfully been utilized to protect nontarget species and sensitive sites from pesticide exposure around the county. As many landowners and farmers are not aware of the listed species that are potentially in and around their operation, education can provide an opportunity to increase awareness and foster protection for species and their critical habitat. The FWS has identified lack of knowledge of the species occurrence across the landscape as one limitation for population improvements and includes public education as an action towards recovery/delisting of the species, while also listing education as part of individual species recovery plans. For example, in the 5-year review for the Georgia pigtoe, an endangered freshwater mussel in Alabama, Georgia, and Tennessee, the FWS stated: "Commercial applicators must also be tested and permitted on the proper application of pesticides, but applicators may not necessarily be aware of the presence of the Georgia pigtoe in the watersheds where pesticides are being applied. If applicators are aware of the presence of a rare species, they may be more likely to use proper application techniques" (US FWS 2021). In the recovery plan for the Georgia pigtoe, the FWS identified voluntary stewardship and the development and implementation of programs and material to educate the public as actions that are needed to aid in recovery (US FWS 2014). While farmers may not be aware of the listed species in their area, they are already making decisions to maintain productive farmland, protect natural resources such as water quality, and protect sensitive species and nontarget areas from the impacts of pesticide exposure, which are all components maintaining a healthy ecosystem and a thriving environment. By providing credit for education, growers could continue to seek up-to-date information on pesticide application techniques and practices, while learning more about the species in their areas and how to get involved in the development of stewardship plans and activities that benefit the species around them. As stewards of the land, farmers strive each day to protect the land that provides for their families, ensure the resources are available for generations to come, and, either directly or indirectly, benefit listed species.

In addition to spray drift, the proposed Herbicide Strategy focused heavily on mitigation practices to reduce movement of pesticides through surface runoff and/or erosion. The number of mitigation measures suggested by the agency for implementation by pesticide applicators depends on the location of the field, herbicide used, land characteristics, and production practices. First introduced in the 2022 Workplan Update and expanded upon in the Herbicide Strategy, the options available are referred to as the mitigation menu, with each option receiving a point value related to its effectiveness. As currently proposed, pesticide users will need to reach a specified number of points through implementing options from the menu to apply the herbicide. Options currently are summarized within five categories: (1) field characteristics, (2) application parameters, (3) in-field mitigation measures, (4) adjacent to field mitigation measures, and (5) other mitigation measures.

Points associated with field characteristics (one point for each) draw on the specific location and features of the application site, including geographic location, soil texture, and slope. As the characteristics of a field are not easily changed, mitigation measures in the remaining categories introduce options

for growers to implement or adopt through changes in management or installation of physical measures. Application parameters include varying points for application rates, depending on the percent applied compared to the maximum labeled application rate, and two points for incorporating the product into the soil after application. In-field mitigation measures, such as contour farming, cover cropping, grassed waterways, in-field vegetative filter strips, irrigation water management, mulch amendments with natural materials, residue tillage management, and terrace farming, range in point values from one to three. These practices are centered around mitigating surface runoff within the field; however, these measures are not easily implemented in many cropping systems, installation can result in the loss of productive land, and a significant financial burden can be placed on the grower who is implementing the practice (Duzy et al. 2023). Adjacent to the field or other mitigation measures (one to three points) include maintaining riparian areas, vegetated ditches, vegetative filter strips (adjacent to the field), and water retention systems.

While the concept of preventing pesticide movement through the suggested mitigation measures is scientifically sound, it is important to recognize the tremendous challenges that come with requiring the diverse and dynamic agriculture production systems of the United States to adopt similar conservation practices irrespective of actual need of such practices and relevance to the species being protected. For example, while the use of cover crops is an excellent option for reducing erosion in one part of the country, this practice may not be feasible in other regions where there is limited moisture for establishment and maintenance. An additional challenge to national adoption is how each category is given a ranking (point value) by the EPA regarding the anticipated effectiveness of the respective mitigation measure around the country. For cover crops, the EPA determined the practice to have a minimal impact on pesticide residue runoff (EPA 2023a). However, as an example, field research conducted over four years by Potter and colleagues (2016) in Georgia observed that when a high biomass rye cover crop was used, a 98% reduction in fomesafen runoff was recorded. The fact that this practice was given a low effectiveness score and subsequent low point value on the draft Herbicide Strategy mitigation menu suggests a need for more scientific refinement through evaluating the practice in various production regions and cropping scenarios around the country. One suggestion is, working with the USDA, the EPA could develop criteria allowing growers the ability to produce cover crops through different management practices, which would enable them to achieve low, medium, or high pesticide runoff reduction, thereby providing the pesticide applicator the opportunity to achieve flexibility in point options from the mitigation menu. Working with conservation practitioners, EPA could develop a system to tier efficiency points for any of the mitigation measures on the menu based on site-specific conditions, lifespan of the mitigation measure, and management of the measure, creating a system of tiered efficiency points to better represent site-specific conditions and farm-level management considerations, while providing improved flexibility to growers.

It is critical for the EPA to continue working closely with agricultural stakeholders to identify mitigation measures that work for various production systems across the country, especially specialty crop and permanent cropping systems, which face the greatest challenge in adopting proposed mitigation measures. Additionally, it will be critical for stakeholders, industry partners, regulators, and academics to generate scientifically sound data that defines exactly how effective proposed mitigation measures are in reducing pesticide movement from the field, but the conversation surrounding ESA compliance with pesticide use cannot end here. As a scientific community, we must understand direct pesticide interactions with listed species and their habitats, and how the proposed mitigation measures interact with these species. Are growers being asked to implement and adopt mitigation measures that are not necessary, protective of, or provide a benefit to listed species? If the ESA is driving the move to incorporate additional spray drift, sediment, and erosion mitigations into pesticide registration and use, what is the specific link to listed species and is more or less mitigation scientifically necessary?

Best Management Practices Being Used on the Agricultural Landscape

Identifying practices that support water quality protection, the conservation of soil resources, and prevention of pollutants from entering sensitive habitats has been a priority of numerous federal and state governmental agencies along with extension programs at land grant institutions for many years. Early concerns on the quality of watersheds because of nonpoint source pollution during the 1930s and 1940s led to the introduction of "better land-management practices," and the subsequent idea that our land management decisions had direct influence on environmental quality (Ice 2004). These practices served as the precursor to BMPs which are practiced in many industries around the country today.

Expanding industrialization and urbanization, along with growing agricultural and forest management entities have confirmed that human intersection and interaction with the environment is greater than ever (Costanza et al. 2007). As defined, BMPs are a combination of physical soundness and social actions developed to decrease the movement of pollutants into sensitive areas, such as watersheds or bodies of water, while considering overall environmental protection and stewardship (US EPA 2003; USDA ARS 2006). These practices generally take into consideration the regional geography and production practices that are already being implemented, to determine the best, most effective pollutant mitigation practices for a particular site. In Kansas for example, the city of Wichita has worked with farmers to provide incentives for implementing atrazine BMPs to reduce atrazine entering the Little Arkansas River. From inception in 2006 through 2022, more than 1,300 farmers implemented atrazine BMPs (92% participation rate) on nearly 300,000 acres, reducing runoff by approximately 50% (Graber 2023).

Because of the wide range of indus-

tries that use the land and its resources, tremendous work identifying and understanding BMPs has taken place through various entities around the United States. For decades, federal agencies such as the EPA, USDA (specifically the Agricultural Research Service (ARS), National Resource Conservation Service (NRCS), and U.S. Forest Service (USFS)), U.S. Department of the Interior (DOI), along with land grant universities, have generated methods to implement BMPs on farmland, forests, and natural landscapes to mitigate negative impacts of pollutants on the environment. The national, regional, state, and local approach offered by this diverse group of stakeholders representing various agricultural and environmental entities ensures that a broad variety of pollutant mitigation options are available to account for the diversity of production systems and land uses present across the United States.

Driven by those with a desire to pursue farm sustainability and protect the land and its resources for generations to come, conservation practices on agricultural lands have been adopted by farmers throughout the country (Prokopy et al. 2019). In most cases, the region, climate, topography, and specific characteristics of the land determine what conservation practices can be implemented on a site, and how effective these practices are in achieving the overall goal. For example, in various parts of the country, cover crops, conservation tillage, terrace and contour farming, vegetative filter strips, and grassed waterways are successfully used to promote water filtration, improve soil structure, provide wildlife habitat, and enhance other conservation efforts (Chow and Daigle 1999; Abu-Zreig et al. 2004; Nouri et al. 2018; Bergtold and Sailus 2020). Unlike the EPA's proposed options to address the ESA on a national level, these conservation actions have been developed locally for specific site needs, and vary greatly from farm to farm, based on the dynamic changes that occur even within a single cropping or ecological system.

Adoption data have demonstrated that producers are willing to implement creative solutions on-farm in order to conserve the land and mitigate the movement of pollutants. By combining the concepts behind BMPs with conservation practices that growers are currently using on the farm, this provides an opportunity to improve awareness and continue working towards the protection of listed species habitat and other sensitive sites without the need to incorporate these practices into the regulatory process. Throughout the country, production agriculture has coexisted with populations of listed plants and animals for decades, indicating that by ensuring access to the tools needed to effectively manage pests and maintain conservation practices (i.e., herbicides to burndown cover crops or control invasive weeds in a native plant filter strip), farmers can continue to voluntarily take personal responsibility in stewarding the land and protect sensitive species from urban encroachment and other habitat threats. Without demonstrating the need, using regulatory mechanisms to force farmers to adopt mitigation measures to address resource concerns that either do not exist on their operation or they have already addressed is unlikely to provide additional needed benefit to listed species. However, working within the current environment of voluntary conservation programs, locally and regionally led projects, and targeted conservation efforts provides opportunities to engage farmers in new and innovative practices—which has always been the nature of agriculture.

The Role of Conservation Programs in Mitigating Pesticide Movement

The agriculture industry faces numerous daily threats to its ability to provide a continuous supply of safe and affordable food, feed, and fiber for our country and the world. With increasing input costs, fluctuating markets, and uncertainty surrounding the ability to effectively manage pests that threaten yield, an economic profit on the farm is more difficult than ever to achieve. Programs that promote and support endeavors to implement BMPs and conservation practices on farms are a critical component of overall farm sustainability but also these programs are essential in providing the infrastructure needed to mitigate the movement of pollutants. Existing programs through the USDA, specifically the NRCS and USDA Farm Service Agency (FSA), provide opportunities for farmers to receive financial assistance to establish costly BMPs and establish habitat on their farms, without which installation and maintenance may not be economically feasible (Hernandez et al. 2020). Programs such as these offer a unique opportunity to work with area experts at a local or regional level, who understand the unique characteristics of the local landscape, to design and implement conservation practices that have a greater chance at successful implementation, mitigating off-field pesticide movement, and overall listed species protection compared to making conservation practices part of the regulatory framework for pesticide use.

There are also commodity specific programs, as well as state and local programs, which highlight and reward farmers for maintaining or increasing conservation practices on the landscape. The Michigan Agriculture Environmental Assurance Program (MAEAP) is an example of a state verification program that assists farmers in voluntarily reducing or eliminating risk to the environment from agricultural pollution. They have verified more than 6,000 farms in Michigan (MAEAP 2023). Programs such as these can help growers overcome financial hurdles associated with starting BMPs and other mitigation measures, which can lead to a greater chance of successful implementation. Including participation in a commodity specific, state, or local conservation program as an endangered species mitigation option offers a local bridge to regulatory compliance.

According to the EPA, there are more than 182 different ecoregions in the United States, and with this level of diversity, a one-size-fits-all approach to mitigating pesticide spray drift and surface runoff and erosion across the landscape is extremely challenging (Omernik and Griffith 2014). Leveraging financial assistance programming opportunities, such as NRCS conservation assistance programs, coupled with effective science-based mitigation measures would provide a realistic opportunity of successful voluntary mitigation adoption on the farm. In fact, within the Herbicide Strategy, the EPA

has included participation in a conservation program on land where the pesticide application would be made as an exemption and alternative to implementing practices from the mitigation menu. This is an excellent option for growers who participate in these programs, however for this effort to be successful, it is worth considering the barriers to continued participation or lack of participation in traditional conservation programs. With many farmers throughout the US implementing BMPs on their farms independently of conservation program participation, there must be opportunities for these farmers to continue to grow their conservation efforts and have the ability to participate in financial assistance programs, whether at the federal, regional, state, or local level.

Measurable Outcomes

Measurable outcomes are needed to scientifically document the need for and impacts from adopting endangered species mitigation efforts. With an overall goal of avoidance and minimization of impacts from pesticides to listed species, we must collectively as a scientific community continue to conduct research across the landscape that: (1) determines if additional mitigations are necessary, (2) identifies existing conservation practices that have been adopted by growers, and (3) understands the level of reduction in off-site movement of pesticides that already occurs from existing conservation programs. It is imperative to fully understand the baseline in order to clearly identify any need for additional mitigation measures to protect listed species and, if there is a need, understand which measures are most appropriate and effective.

As noted earlier, the proposed Herbicide Strategy addresses species at a general habitat level and is not specific to an individual species or habitat type. The lack of specificity outlined by the agency likely eliminates the scientific ability of identifying a measurable outcome since mitigation measures are applied to general habitat types instead of species-specific habitats.

FIFRA, ESA and Pesticide Consultation: Understanding and Addressing the Complexities

Michael Aerts, David Epstein, and Michael Willett

For decades growers have been engaged in developing workable approaches to reducing impacts of pesticides on non-target species. These efforts not only yield positive benefits for the environment but often provide growers with substantial economic and ecological benefits that accrue from the conservation of beneficial species. Over the last several decades, the focus on pesticide use has shifted from optimizing on-farm pest management to the responsibilities and obligations created by label changes driven by the ESA to pesticide actions under the FIFRA.

Recently fulfilling understanding and meeting those obligations of the ESA has become more difficult as advocacy organizations began filing procedurally based lawsuits against the EPA for perceived violations of the ESA, resulting in court rulings intervening in the FIFRA process. Judicial rulings are especially challenging for the EPA in assessing the impacts of pesticide use on listed (threatened and endangered) species while meeting court-ordered deadlines in shortened timeframes and with declining staffing levels.

Why has consultation among federal agencies addressing the ESA proven to be such a difficult task in assessing the risk of pesticide use and delivering regulatory actions that protect species in a practicable manner that allows farmers to provide food security for the nation?

Identifying the Complexities

As the EPA rapidly implements pesticide label restrictions to protect listed species per court requirements, these restrictions are limiting the practical use of pesticides for the agricultural community. Label restrictions that, while well-intentioned, can be the product of an insufficient amount of on-the-ground data combined with what also can be overly protective assumptions where data are lacking, can severely limit a farmer's ability to manage pests effectively and efficiently. The EPA, the National Research Council (NRC) Committee and the agricultural community have all voiced concerns that must be understood if effective solutions are to be developed.

The EPA has identified at least six key challenges that they believe must be overcome (US EPA 2022d).

- First is the large and growing number of FIFRA actions that trigger ESA review, at a time when the Pesticide Program's staffing is roughly at the FY 2013 level. "Apart from the growing workload and backlog challenges, the Pesticide Program's staffing levels have declined from a high of 808 (2005) to 603 (2021)." Data from FWS or NMFS regarding the number of staff positions with responsibility for working with the USEPA on interagency ESA consultations are more difficult to determine.
- Second is that the current ESA-FIFRA process generally does not result in protections for Listed (threatened and endangered) species that are both practical for pesticide users to implement and timely to protect species.
- Third is that FIFRA registrations are often geographically broad, cover many pesticide uses, and affect many types of listed species. All of this creates unique scientific and practical challenges for the EPA's ability to meet its ESA obligations.
- Fourth is the need to better harmonize the FIFRA process with the ESA process. For example, the current FIFRA process assesses each pesticide on a chemical-by-chemical basis, but this approach is unsustainable across hundreds of pesticides. This is one reason that the entire ESA-FIFRA process currently spans at least four years for one pesticide.
- Fifth is a series of challenges related to data and scientific methods. For example, having better and more refined data on where species occur and how best to protect them from pesticide exposure would result in more effective and cost-efficient protection. However, gathering and analyzing these data would likely extend the ESA-FIFRA process even longer and require ad-

ditional agency capacity. Thus, EPA needs to balance the benefits of more or better data, to expedite the ESA-FIFRA process.

- Finally, an effective ESA-FIFRA process requires strong working relationships among EPA, FWS, NMFS, and USDA. "All four agencies are working toward this goal but still have room for improvement."

Additionally, in its report "Assessing Risks to Endangered and Threatened Species from Pesticides" (a report requested by EPA, NMFS, and the FWS), the National Academies of Sciences, Engineering, and Medicine, National Research Council (NRC) Committee on Ecological Risk Assessment under FIFRA and ESA noted three major areas that would benefit from improvement (National Research Council 2013).

The first is a lack of a common approach, which the NRC noted: "has created scientific obstacles to reaching agreement between the EPA and the Services during consultation." Second, is an improvement in "recognizing and analyzing uncertainty" by adopting a probabilistic risk assessment approach "that allows uncertainty in exposure and effect to be explicitly recognized and then combined in forming a risk estimate." Finally, the report suggested that a unified definition of "best data available" should include stakeholder data.

The agricultural community has also identified areas of concern, some of which overlap with those discussed by the EPA and the NRC (Cranney 2023).

- The need for improved regulatory cooperation across agencies.
- The need for developing accurate maps for listed species ranges, habitats, and farm fields being treated with pesticides.
- The need to have regulatory decisions based on practical/historical pesticide use rates as typically applied.
- The need to have regulatory decisions based on more realistic predicted pesticide sensitivity levels of listed species.
- The need for scientifically sound and flexible mitigation measures that apply to variable crop production systems.
- The need for refining pesticide modeling to reflect likely pesticide exposures more accurately.
- Improved communication between federal agencies and agricultural stakeholders.

Addressing These Complexities from a Grower Perspective

Improved Cooperation Among Regulatory Partners: The EPA, NMFS, and the FWS must continue to work toward developing an agreed-upon, reliable, and efficient process for meeting ESA responsibilities. However, a decade after receiving the advice from the NRC that they solicited, the federal agencies continue to differ on key theoretical and analytical approaches to risk assessment, and significant logistical and legal issues remain. It is hard to envision how EPA will be able to meet its legally mandated timetables without changes in the process and without being forced by partnering federal agencies or the courts to implement mitigation practices that are overly restrictive to agricultural production. Several tactics to improve collaboration between agencies have been proposed by the agency (US EPA 2022a), but it is not clear that all the regulatory parties agree. Nor is it clear that users have had a chance to review the impacts of interagency consultations, such as for herbicides. The potentially impacted parties must have a seat at the table since agencies are making a significant change in how ESA decisions will be made, thereby having significant impacts on pesticide user stakeholders.

Accurate maps for listed species range, habitats, and farm fields: Identifying specific locations where listed species and their habitats are located, and where these locations overlap with agricultural production is essential to protecting both species and minimizing undue disruption. By documenting species ranges, habitats, and agriculture fields, a scientific determination of sensitive sites can be achieved by fostering protections as needed. If pesticide restrictions are to be put in place, the overlap mapping process of listed species and pesticide use sites must be reasonably accurate. Currently, the process of using outdated species range maps, or maps based on habitat that may have historically occurred, lacks scientific merit as does aggregating mapped data on unrelated species, grouping crops without consideration of differences in use patterns, and other map consolidation shortcuts that remove precision in tradeoff for faster review processes.

Pesticide Usage Data

The incorporation of pesticide usage data is particularly important for a credible consultations process under the ESA, but, since the release of the NRC report in 2013, there has been little agreement among Federal Agencies involved in ESA risk assessments regarding what constitutes credible pesticide usage data. The datasets that are most highly valued by the EPA appear to be from the California Department of Pesticide Regulation Pesticide Information Portal or proprietary data from a commercial provider, Kynetec. User data collected by USDA's National Agricultural Statistics Service (NASS) seems to be considered by EPA to be of lesser value, primarily due to its overall frequency of collection and how often certain use sites are surveyed (e.g., small acreage crops and non-agricultural use sites). NASS usage data for biopesticide and antimicrobial active ingredients are generally unavailable (US EPA 2022d). The Kynetec usage data is the most highly used private data source but is limited to those who purchase access, a cost that limits access for many. Data reconciliation becomes difficult when user data differs from that provided by Kynetec because users do not have access to the raw Kynetec data.

Determining the Sensitivity of Listed Species to Pesticides

Since protected species cannot be treated with pesticides to test for effects, it is understood that the EPA ESA pesticide risk assessment process must use an alternate methodology for the prediction of species sensitivity to a given pesticide. Since these values are determined by estimating the sensitivity of respective pesticides on surrogate species, the agency's typical approach of using the most biologically sensitive relationship currently documented can result in overly conservative estimates. This assessment process is extremely

complex, but it is solvable through cooperative research that identifies and tests closely related surrogates (to the listed species) to observe their response to pesticides. The results of this effort could have monumental implications, offering a more realistic and data-driven approach to understanding the sensitivity of listed species to pesticide exposure.

Mitigation

There is great concern among many agricultural producers about ecological mitigation measures proposed recently by the EPA (US EPA 2022d). Agriculture is not monolithic. Great differences are seen in production practices in perennial (tree crops) versus annual cropping (most field crops) systems and production regions. Whereas annual cropping systems may deploy practices such as contour plowing, no-till, or alternate cropping in the same field, perennial crop producers are unable to employ the full range of these practices and question how existing sustainability practices will be valued.

Most cropland is used for producing livestock feed, feed exports, or is left idle to allow the land to recover. According to Bloomberg (Merrill et al. 2018), the total cropland in the United States was approximately 391.5 million acres. Of that total, 127.5 million acres were in livestock feed, 21.5 million acres were being cultivated for wheat exports, 62.8 million acres were devoted to other grains and feed exports, 13.6 million acres were used for cotton and non-food production, 38.1 million acres for ethanol, biodiesel production, and 52 million acres were idle. Approximately 77 million acres (less than 20% of the total U.S. cropland acreage) were used for human food production. Specialty crop production (fruits and vegetables, tree nuts, dried fruits, horticulture, and nursery crops, including floriculture) falls into this category. For most specialty crops, the average acreage farm size is far less than 100 acres.

Consequently, many specialty crop producers do not have as much flexibility or economic wherewithal as major commodity producers in terms of reducing planting acreage or installing new systems for producing their crops. Some of the EPA proposed ESA mitigation measures would require wholesale changes to established cropping systems with substantial adverse economic impacts on the affected growers. Regulatory agencies must consider the differences in farm size, production region, and production practices when proposing mitigation requirements on pesticide labels. These must be practicable for farmers to implement for their cropping system.

Specialty crop producers believe that most of the mitigation measures recently proposed by the EPA are not suitable for specialty crop production and that many of the mitigation measures identified may be more suitable for those farmers producing major crops such as corn, wheat, soybeans, and cotton. However, it is also apparent that major crop producers have significant concerns with the current proposed EPA mitigation measures (Culpepper and Randell-Singleton 2023).

Additionally, both specialty and agronomic crop growers are likely to lease land. These growers must secure the approval of the land-owner lessor to make changes to the leased land. Securing multi-year commitments from the lessor is particularly problematic. Consequently, mitigation measures that may involve substantial changes to the farm, especially those involving multi-year commitments are essentially not feasible for these growers.

Specialty crops must be approached individually when considering mitigation measures for pesticide runoff and erosion mitigation. These cropping systems are highly dynamic and complex and consist of many components such as diverse tillage practices, planting of grass strips, irrigation methods, seed/planting practices, fertilization, pest management practices, and harvesting procedures. Specific production practices are often conducted due to the sensitive and delicate nature of the crop, and many are not compatible with the mitigation measures being suggested by EPA (Culpepper and Randell-Singleton 2023).

Spray drift buffers to protect against the theoretical risk of off-site movement of the applied pesticide are notable features of endangered species protection. The EPA and its federal partners should join with the user community in the development of drift reduction technologies, especially for air blast sprayers, to offer greater options for mitigation. Currently, there is growing interest in adopting spray equipment technologies which may help to reduce drift. Increased federal and state research funding would enable the development of technology that would allow growers to reduce buffer zone sizes by documenting drift reduction. A commitment by the agency to support the development of drift reduction technology, consider the impact of those technologies in pesticide product risk assessments, and reflect that technology on pesticide labels would speed the adoption of proven new technologies, particularly in perennial crops.

Modeling

The EPA's heavy dependence on models that have not been validated across all the use scenarios where the output is applied concerns growers. Grower stakeholders expect that regulatory modeling, which could result in the withdrawal of products or cropland, would provide a level of accuracy at least equivalent to other models that growers rely upon for pest control and crop production. Additionally, there are significant stakeholder concerns that modeling used to make regulatory decisions is in many cases not as robustly validated as the weather-based decision support tools routinely and voluntarily used by growers to support integrated pest management and other decision-making. Additionally, the federal agencies' decision to incorporate estimates of environmental contamination based on modeling data into ESA analyses when actual field monitoring data exists showing lower levels of contamination is of particular concern to the grower community. The below discussion highlights just some instances comparing field-validated models to those less robust.

To provide an example of validation that provides a level of certainty at the field level, currently growers use several Integrated Pest Management (IPM) predictive models to aid in improving pest management decision-making. Perhaps one of the most widely used models is the codling moth growth model which predicts population development in apple, pear, and walnut orchards (Jones et al. 2013). Developed by entomologists at Washington State University, the model demonstrates that it accurately predicts

1st egg hatch, a critical event in codling moth management. The reliability of the model provides growers confidence that pesticides can be accurately timed targeting specific codling moth life stages thereby enhancing control and reducing insecticide costs. Figure 3 shows the level of validation growers expect when predicting events that may have economic impacts on their operations. In the graph, the zero-day designation refers to the date on which the first egg hatch is observed in a heavily infested apple orchard. The blue bars note the often-significant difference between this observed egg hatch and the date on which the standard calendar timing (seven to ten days after petal fall) compared with the increased accuracy of the model in predicting egg hatch (black bars). Note that in six years of the ten for which data is presented egg hatch predicted by the model and observed egg hatch occurred on the same day. This level of granularity in validation is not a feature of most or all the ecological models used to project environmental contamination, yet the economic impacts may be further reaching.

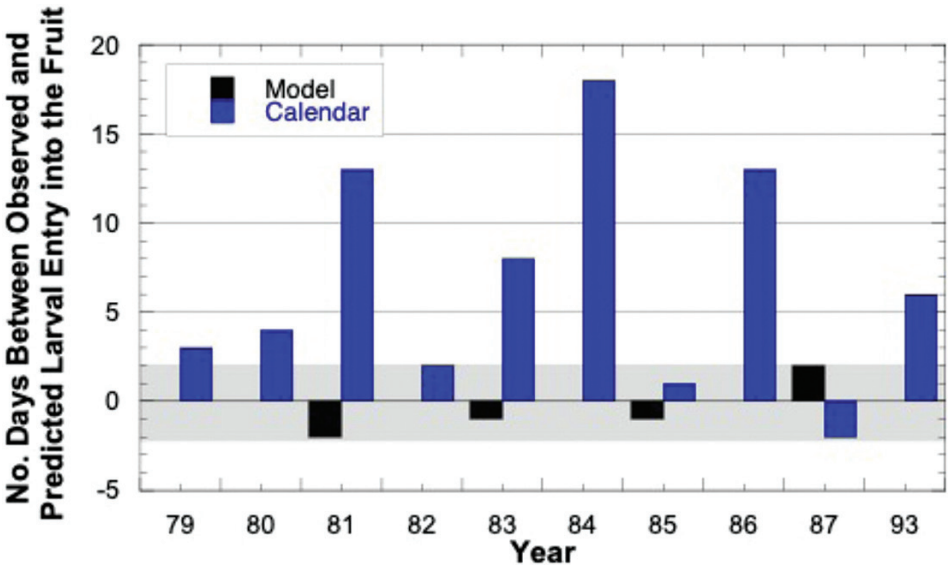


Figure 3. Calendar-based and degree-day model-based spray timing for codling moth compared with actual observations of first egg hatch in Wenatchee, Washington.

As an example, Florida has many years of actual field-level monitoring data specific to atrazine. From 1996 to 2011, monitoring recorded a maximum of 23 ppb of atrazine (Perkins et al. 2021). However, the Watershed Regressions for Analysis Pesticides (WARP) model (Larson and Gilliom 2001) used by the EPA for estimating runoff into water complexes, predicted maximum likely detections (95% PI) in the 1,200 ppb range within these very same farmlands (https://www.regulations.gov/document/EPA-HQ-OPP-2013-0266-1665). Florida growers were put at risk of losing access to a valuable herbicide due to the WARP modeling overly conservative outputs. While this may be an egregious example, Florida growers do not have a clear understanding of the factors in the model that drove this difference.

Similar concerns exist in other cropping systems. For example, most of Oregon's pear production occurs in the Hood River Valley (Figure 4). Historically, chlorpyrifos had been one of the tools applied to the crop (USDA NASS 2022) for insect control. In a study conducted by Temple and Johnson (2011), the maximum measured chlorpyrifos detection in Neal Creek was 0.482 ppb (Figure 5). The low levels of chlorpyrifos detected in Neal Creek were likely the result of pest control applications using an air blast sprayer, with many acres across the landscape being treated at about the same time. The models used to generate potential concentrations in water for the various types of water bodies adjacent to orchard and vineyard crops provided estimates of 1-day chlorpyrifos concentrations [effective environmental concentration (EEC)] in surface water which ranged from just over 0.72 ppb to just under 59 ppb. The maximum EECs were associated with applications modeled on tart cherries (Rossmeisel and Bohatty 2020).

In its 2013 report, the NRC (National Research Council 2013) notes that Bird and colleagues (2002) compared field data with AgDRIFT model evaluations for "161 separate trials of typical agriculture aerial applications under a wide range of application and meteorological conditions." The comparisons all relied on case-specific meteorological data (wind, temperature, and humidity) and application data, such as observed aircraft heights and nozzle equipment. With such inputs, the investigators concluded that the "model tended to overpredict deposition rates relative to the field data for far-field distances, particularly under evaporative conditions" by about a factor of three. However, the AgDRIFT estimates were in good agreement (to within less than a factor of two) with "field results for estimating near-field buffer zones needed to manage human, crop, livestock, and ecological exposure." Bird and colleagues (2002) concluded that "the model appears satisfactory for regulatory evaluations…. However, greater uncertainty in the output of the model will arise when it is applied as a general screening tool and case-specific input parameters, such as wind speeds and mode of application, are not known." (emphasis added). This would be the case when, as in the chlorpyrifos example above, a general screening tool such as AgDRIFT, is used to estimate drift from air blast sprayers.

For ground applications using air blast sprayers, AgDRIFT only allows for the use of simple deposition curves, and for Tier I screening-level assessments, the stochastic model of a young, dormant apple orchard is used as a surrogate for all crops, as it represents the worst-case scenario. Unfortunately, while available for aerial applications, a higher level (Tier III) approach is not available in AgDRIFT for air blast sprayer application,

Figure 4. Blooming pear orchards in Hood River Valley of Oregon looking south up the Hood River toward Neal Creek drainage.

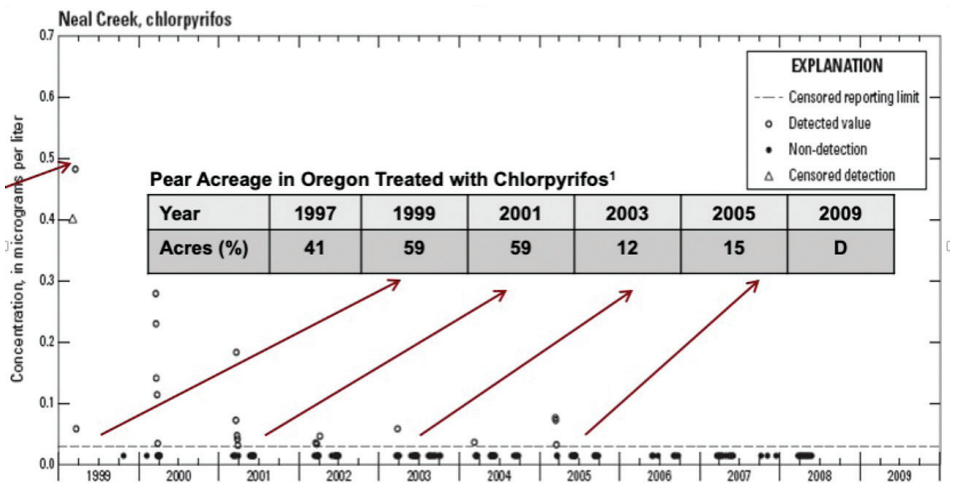


Figure 5. Detections of Chlorpyrifos in Neal Creek and acreage of pears treated with chlorpyrifos over 13 years.

the most common way to apply pesticides in perennial fruit and nut crops.

When high-frequency water monitoring data from aerial applications of malathion to sweet cherry orchards near The Dalles, Oregon was compared to malathion concentration predictions made by using AgDRIFT, the predictions improved from a 43.6- to 45.7-factor overprediction with the Tier I screening-level parameterization to a 1.0- to 1.8-factor overprediction at the most refined Tier III parameterization (Winchell et al. 2018).

Over the past several years, grower groups representing producers of tree and vine fruits and nut crops on the U.S. West Coast have spent almost $500,000 to collect validation data in apples, almonds, citrus, and grapes to begin the development of a mechanistic model (Tier III) to assess drift more accurately in perennial fruit and nut crops (Willett and Thistle 2023, personal communication) but more resources are needed to complete the model. Even if the difference between the screening level model and a more refined estimate does not result in a 40x to 50x overprediction when using air blast sprayers, clearly more refined estimates are justified. Financial support to complete the development of a Tier III model for air blast sprayers would benefit the federal and state agencies in conducting more accurate assessments and would also benefit stakeholders who must live with the results of these drift assessments. In addition, more highly refined drift models for air blast sprayer applications in fruit and nut crops would help evaluate and support the adoption of proven drift reduction technology.

Communication - Bulletins Live! Two (BLT)

The EPA developed Bulletins Live! Two as a part of their Endangered Species Protection Program. These Bulletins set forth geographically specific (i.e., county, or sub-county) pesticide use limitations for the protection of threatened and endangered (listed) species and their designated critical habitat associated with that area. The approach using a resource such as BLT is meant to bring more specificity to mitigation needs, although there are numerous concerns from pesticide applicators' standpoints.

Few agricultural producers are familiar with BLT name that lacks connection or meaning to its use and purpose for a pesticide applicator. It is incumbent on the EPA to connect more effectively with pesticide users, helping them understand the importance and relevance of the site. Additionally, access to BLT is only currently through a web browser on a desktop/laptop computer and not through a smartphone or tablet. To be accessible to all pesticide users, the program must be developed into some type of app that is accessible on mobile devices as well as computers. Access to a stable internet connection is paramount for BLT to be successful, as loading maps and other imagery can be cumbersome on less reliable internet connections.

If the decision is made to develop a mobile-accessible app, developers and the EPA would benefit from having practical input from both the Cooperative Extension System and growers. This web-based, technologically progressive

approach for communicating targeted restrictions on pesticides will only be successful if applicators find the app easily understandable and available on customarily used hardware platforms.

Currently, the BLT process for accessing instructions for restricted products in some states is simple. However, when considering the nearly 1,200 registered active ingredients that could be added, the potential for confusion is a tremendous concern. This process of accessing mitigation information on BLT will likely get extremely complicated very quickly as new restrictions are added; thus, the EPA must first evaluate procedures with dozens, or even hundreds of active ingredients in each regional area. Also, concerning mapping, the ESA geographical areas which will be used to determine the mitigations listed within the BLT system should be further refined. In many instances, the available maps are developed on a county-level resolution or larger basis. This potentially overstates the affected area. Efforts should be undertaken to refine these maps to a sub-county, species-specific level. This would help ensure that needed restrictions are appropriately targeted, and an undue regulatory burden is not placed on growers to adopt application restrictions that are not necessary because the listed species are not impacted by that farm's operations.

The ideal user experience on BLT would include the ability to add multiple pesticide products into a single pesticide application event, allowing the user to provide either EPA registration numbers, pesticide chemical names, or product names. Also, a 9 to 12month time interval between implementing new restrictions on BLT and requiring pesticide users to follow them would provide stakeholders ample time to plan for planting and pest management needs.

Requiring pesticide applicators to access a webpage for specific instructions before applying a pesticide will be a significant change in standard practices for grower applicators. Reliance by the agency on web-based labeling is likely to expand over time, particularly since the introduction of many new pesticide products will include BLT references. Both EPA and registrants should ensure that the required label language regarding BLT is prominently displayed and highlighted to ensure that the important legal use information is not accidentally overlooked.

State Regulatory Agencies as Conduit for Informing Local Conditions in Federal Pesticide Processes

Gary Bahr and Ashlea Frank

Pesticide regulatory agencies in each U.S. state and Territory, known as State Lead Agencies (SLAs), play a key role in this process and function as co-regulators with the EPA to ensure successful implementation and enforcement of pesticide labels and applications. The EPA funds cooperative agreements that help SLAs implement the EPA's pesticide program and oversee registration, rules and regulations governing pesticide use, notification or posting requirements prior to application, registering complaints concerning a misapplication, certification and training programs for applicators, and exposure or misuse reporting, investigation, and enforcement of labels at the state level. The responsible SLA varies by state and examples from around the nation are the Alaska Department of Environmental Conservation, California Department of Pesticide Regulation, Florida Department of Agriculture & Consumer Services, Office of Indiana State Chemist, Maine Department of Agriculture, Conservation, & Forestry, New Jersey Department of Environmental Protection, and Washington State Department of Agriculture.

Because SLAs help the EPA implement their pesticide program, SLAs also play a role in implementing pesticide program activities related to the ESA. The registration, sale, and distribution of pesticides under FIFRA by the EPA is considered a federal action and is therefore subject to the ESA (US EPA 2023a). The EPA initiated the first pesticide consultation with the FWS concerning the active ingredient, toxaphene, on October 17, 1977 and resulted in a Biological Opinion (BO) from FWS on July 11, 1978. In 1988, the EPA established the Endangered Species Protection Program (ESPP) to meet its obligations under the ESA. The original ESPP was not an enforceable program but relied on cooperation between the EPA, FWS, states, tribes, and pesticide users. In December 2002, the EPA published for public comment its proposed approach to field implementation of the ESPP and then published its final approach on November 2, 2005, making field implementation of the ESPP an enforceable program under FIFRA (US EPA 2005). The goal of the EPA's ESPP is to carry out the EPA's responsibilities under FIFRA in compliance with the ESA, without placing unnecessary burden on agriculture and other pesticide users. When the EPA determines that an adverse impact to listed species or their designated CH is anticipated, the EPA may change the terms of the pesticide registration which can include geographically specific pesticide use limitations, reflected in Endangered Species Protection Bulletins in the EPA's Bulletins Live! Two (BLT) system. US EPA Endangered Species Protection Bulletins identify areas of concern and pesticide active ingredients that may affect listed species or designated CH. Bulletins also provide a description of the protection measures necessary for protection and maps showing the geographic area(s) associated with the protection measures.

The evaluation of a pesticide's potential to adversely impact listed species or destroy or adversely modify designated CH can be a resource intensive process considering there are over 1,700 species with over 700 CHs designated under the ESA in the US (FWS 2023). To advance the EPA's compliance with the ESA and improve efficiency when evaluating impacts to listed species and CH, the EPA released an ESA Workplan in April 2022 outlining strategies for incorporating protections for listed species earlier in its FIFRA process (US EPA 2022d). The ESA Workplan was followed by an update that included a menu of mitigation measures, "Interim Ecological Mitigations," to reduce off-site movement of pesticides through spray drift, surface water runoff, and erosion, thereby reducing pesticide exposure to nontarget species,

including listed species and CH (US EPA 2022d). Interim Ecological Mitigations are designed to broadly address ecological risks and are to appear on pesticide labels nationally. Where additional protections for listed species are needed, the ESA Workplan Update also includes information on the EPA's BLT system. To expedite the EPA's implementation of the ESA Workplan, the ESA Workplan Update also outlined various strategies to protect listed species, including a Vulnerable Species Pilot Project, mitigations across types of pesticides (herbicides insecticides, rodenticides, fungicides), and regionally specific strategies.

Successful implementation of FIFRA in compliance with the ESA can be better achieved by involving SLAs early in the pesticide program process. Early involvement of SLAs will improve information exchange for federal decisions and better prepare applicators. This paper will explore the areas of SLA responsibilities related to pesticide label implementation and enforcement and provide suggestions towards successful and more efficient implementation of pesticide programs activities related to ESA from the state perspective.

EPA FIFRA Cooperative Agreement Guidance for States, Territories, and Tribes

The SLAs regulating pesticides work cooperatively with the EPA as delegated agencies with equal primacy to implement FIFRA. The EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pesticide Programs (OPP), and Office of Enforcement and Compliance Assurance (OECA) issue national guidances (Guidance) for states, territories, and Tribes to implement FIFRA. The Guidance is used by EPA headquarters and the EPA regional offices in negotiating and overseeing cooperative agreements with states, territories, and Indian Tribes (grantees), as authorized under Sections 23(a)(1) and 23(a)(2) of FIFRA.

- The current OCSPP National Program Guidance is for fiscal years (FY) 2023-2024, and the purpose is to set FIFRA program priorities for the nation, EPA regions, and states (US EPA 2022e). The OCSPP Office of Program Support (OPS) also works with EPA Regions, SLAs, and Tribes on the revising and implementing the Guidance. OPS has the responsibility for this Guidance and other pesticide and toxics work related to the regions, states, Tribes, and territories. OCSPP provides funds to support "program activities" for pesticide program development and implementation, including education, outreach, training, technical assistance, and evaluation activities.
- The current OPP FIFRA Cooperative Agreement Guidance is the joint OPP/OECA 2022-2025 FIFRA Cooperative Agreement Guidance for FY 2022-2025 (US EPA 2021). EPA OPP has historically co-authored the guidance with OECA, and the agencies work with the grantees to negotiate and revise the Guidance on a regular and timely basis. This joint Guidance is intended to help coordinate the pesticide program and compliance, and enforcement activities in support of the goals of the National Pesticide Program. Thus, the two sets of activities are interconnected, but may be handled either independently or under a single cooperative agreement.
- The current OECA National Program Guidance is for FY 2023-2024 (US EPA 2022f). OECA's Office of Compliance (OC) and Office of Civil Enforcement (OCE) coordinate closely on enforcement issues and work regularly with OCSPP OPS and OPP to ensure all four offices are providing consistent, coordinated leadership to regions, states, Tribes, and territories. The purpose of this Guidance is to identify pesticide program, and compliance and enforcement program areas that must be addressed in state, Tribe, and territory cooperative agreements and to provide information on work plan generation, reporting and other requirements. OECA provides funds to support "compliance and enforcement activities," which include compliance assistance, compliance monitoring, case development, and enforcement.

Pesticide Program Requirements

SLAs work to maintain overall pesticide programs. This includes implementation, compliance assistance, and enforcement to ensure a viable pesticide regulatory and enforcement program, achieve environmental results, and maximize success with the SLA and EPA performance measures. SLAs perform required work related to the goals of OCSPP and OECA by maintaining complete administration and management of the pesticide programs and perform fiscal and reporting requirements associated with the cooperative agreement (US EPA 2021). SLAs are required to build or maintain qualified and trained staff and management expertise on pesticide program issues and enforcement, and respond to pesticide inquiries, concerns, tips, and complaints from the public.

The basic pesticide program includes required program areas such as enforcement, certification and training, applicator and worker safety, worker protection, water quality, container containment, and soil fumigation (US EPA, 2021). SLAs also provide outreach, communication, and training as appropriate because of new and emerging issues, rules, regulations, and pesticide registration and registration review decisions. SLAs implement all basic programs following EPA procedures while using EPA guidance documents.

Enforcement and Inspection

Generally, the EPA has deferred the authority to enforce FIFRA requirements to the states. However, the EPA is authorized by Section 27 to rescind a state's primary enforcement responsibility if it is not being adequately carried out (Yen and Esworthy 2012). Different sections of FIFRA authorize officials from the EPA and state agencies to inspect pesticide storage and distribution facilities, issue orders to stop sales, supplies of products, assess civil and criminal penalties for violations of FIFRA, and order indemnity payments to end users, distributors, and dealers of pesticides when registrations are suspended and canceled. Additionally, under FIFRA, states have broad authority to regulate pesticides; however, it is

unlawful for states to impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under FIFRA (US EPA 2021). Historically, the EPA has not assessed civil penalties against Federal agencies for violations of FIFRA. As a matter of practice, given the current state of the law, EPA does not intend to pursue such penalties.

SLAs work to provide outreach and compliance assistance and maintain all the standard types of inspections while utilizing a priority setting plan for inspections and investigations, addressing grantee and EPA-identified priorities, and responding to emerging and emergency investigations and enforcement. SLAs are expected to maintain adequate pesticide laws, rules, and associated implementation procedures such as maintaining and following a Quality Management Plan (QMP) for the overall pesticide enforcement programs and any environmental monitoring and data collection and laboratory work (US EPA 2021). SLAs must also maintain and follow Quality Assurance Project Plan(s) (QAPPs) for pesticide sample collection and analysis, including access to adequate laboratory support capacity through internal or external laboratory services.

SLAs must maintain and follow an enforcement response policy to develop and issue enforcement actions. Inspection and enforcement activities include reporting information on all known or suspected pesticide incidents involving pollinators to OPP and reporting other serious and unique incidents such as spills, drinking water standard exceedances, human health emergencies, and significant water quality and endangered species incidents to the Regional Office project officer (US EPA 2021). Program inspection numbers are tracked, and reports are produced on inspection and enforcement accomplishments. SLAs are obligated to develop and maintain a searchable inspection and investigation database where all enforcement and inspection history and cases can be tracked and are available for enforcement, reporting to EPA, and available to public and legal requests (US EPA 2021). SLAs work to ensure inspector training and must maintain the ability for one or more state staff to obtain and maintain an EPA inspector credentials. Specific inspections and cases can be conducted under EPA credentials and those cases are referred to the Regional Office for enforcement consideration according to a mutually identified referral priority scheme as defined and agreed to in writing (US EPA 2021). SLAs work to assist EPA, upon request, in enforcing regulatory actions and monitoring Section 18 Emergency Exemptions, Section 24(c) Special Local Needs, and Section 5 Experimental Use Permits (US EPA 2021).

Water Quality and Pesticide Programs

SLAs are required to implement water quality and pesticides program work to ensure that pesticides do not adversely affect the nation's water resources (US EPA 2021). The work entails conducting water quality testing and/or evaluating existing and other data from other state, local and federal partners. SLAs are required to share existing data and provide EPA with access to water quality monitoring data either collected, referenced, or discovered by the grantee, that is not available via a readily and publicly accessible website. SLAs work to identify and develop a list of Pesticides of Interest (POI) and Pesticides of Concern (POC) for each program. The processes include coordination within state and cooperating agencies and within each Regional Office. SLAs work to assess and manage pesticides which have a potential to threaten local resources, as well as pesticides that may have water quality concerns in multiple regions. SLAs work to determine whether human health or environmental reference points are likely to be approached or exceeded (US EPA 2021). Pesticides that are approaching or exceeding reference points may be considered POCs and education and management actions are required. SLAs work to actively manage POCs beyond the label to reduce or prevent further contamination of local water resources. SLAs work to train and educate applicators for water quality protection and monitor compliance. SLAs also respond to pesticide water contamination events especially where water quality standards or other reference points are threatened (US EPA 2021).

Pesticide Certification and Training

While pesticide applicators are ultimately responsible for following and complying with pesticide labels, SLAs are responsible for providing pesticide program activities related to outreach, communication, training, and technical assistance to help ensure that pesticide labels are understood and followed by pesticide applicators. SLAs are responsible for establishing Certification and Training (C&T) programs to provide initial licensing and continued recertification for a variety of pesticide applicator types including restricted use (RUP), commercial, dealers, aerial, consultants, structural pest inspectors, and numerous other categories and types. The SLA establishes C&T requirements through laws and rules to comply with EPA and FIFRA requirements. On January 4, 2017, the EPA published its final rule concerning C&T revisions to the 1974 regulations concerning the certification of applicators of RUPs (US EPA 2017). The final rule was intended to ensure federal certification program standards adequately protect applicators, the public, and the environment from risks associated with the use of RUPs. The goal of the final rule was to improve the competency of certified applicators of RUPs, increase protection for noncertified applicators using RUPs under the direct supervision of a certified applicator through enhanced pesticide safety training and standards, and establish a minimum age requirement for certified and noncertified applicators using RUPs under the direct supervision of a certified applicator. All SLAs completed revisions to C&T plans to comply with the EPA's final rule and all SLA and Tribal C&T plans were approved by each EPA Regional Administrator and EPA OPP at headquarters by the November 4, 2023 deadline. C&T requirements and programs are highly coordinated and regulated because the different license types are foundations for performing legal applications and to sell, distribute, or consult on the use of pesticides in each state.

SLAs work with various partners including the Pesticide Safety Education Program (PSEP) that are located

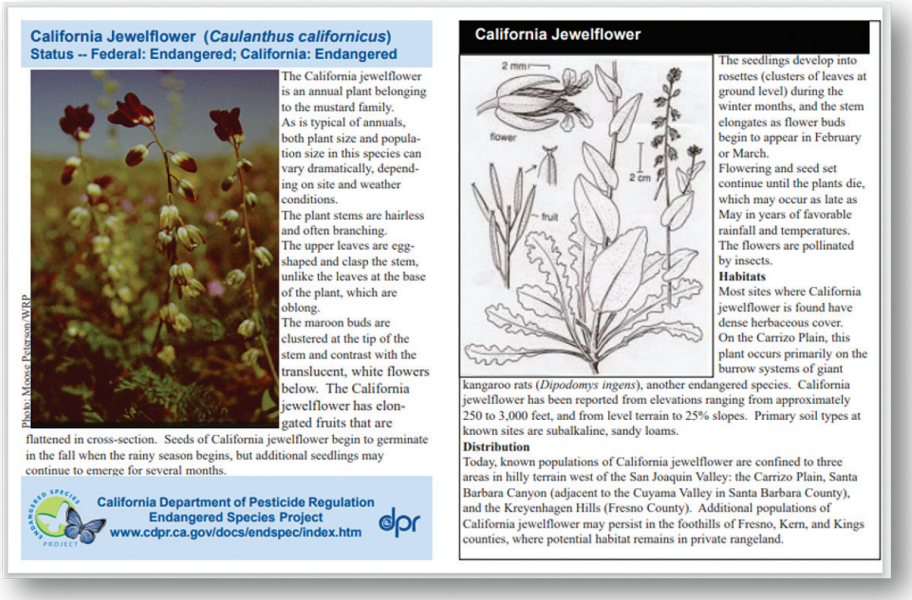


Figure 6. Example Endangered Species Field Identification Card from California's Pesticide Program.

at the cooperative university extension, industry groups, and EPA to implement C&T plans. The SLA pesticide licensing programs include many license types, category exams, study manuals and materials, and a variety of educational products. The SLA works with the PSEP staff to develop comprehensive training, certification, and recertification products and processes.

Pesticide Program Activities Related to ESA

Although ESA is not new to FIFRA, ESA and protection measures for listed species are not currently a standard or required topic in pesticide certification training. The C&T rules and revisions did not include the details for developing specific requirements and training for ESA Pesticide Programs, BLT, or mitigations related to protecting listed species. Regardless, SLAs are integral to the success of FIFRA implementation in compliance with the ESA for many reasons, including educating and training pesticide users about the ESA, pesticide mitigations required to protect listed species, the use of BLT, evaluating the effectiveness of measures required to protect listed species through inspection and enforcement activities, and other FIFRA/ESA activities.

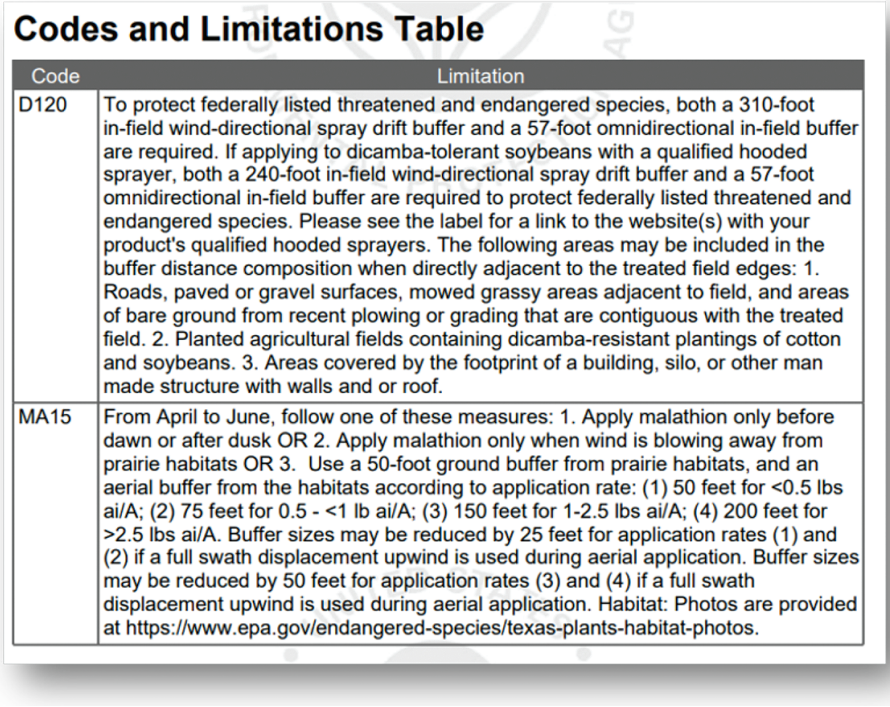
While there are standard topics that must be covered in pesticide C&T programs, topics covered can also include new and emerging issues, rules, regulations, and pesticide registration decisions. Some pesticide programs include information and training materials on listed species. For example, California Department of Pesticide Regulation's Endangered Species Project includes a search engine providing customized, location-specific measures to protect listed species from pesticides (PRESCRIBE), applicator training materials for listed species identification including field identification cards describing biology and habitat characteristics as illustrated in Figure 6, and videos. However, many state pesticide programs do not include listed species materials in any pesticide program activities.

Compliance and Enforcement Activities Related to ESA Under FIFRA

As discussed above, SLAs have responsibility for handling investigations and the enforcement of pesticide laws and rules at the state level. However, SLAs throughout the nation have not determined how the state regulatory processes will be further developed under EPA's recent ESA Workplan, listed species evaluations, and strategies. There are many compliance and enforcement processes that need to be developed so that SLAs can work towards successful implementation of FIFRA in compliance with the ESA. For example, below is language taken from a current pesticide label (label accepted by EPA on March 29, 2022):

- Endangered Species Advisory/Protection Requirements: This product may have effects on federally listed threatened or endangered species or their critical habitat in some locations. When using this product, you must follow the measures controlling the product use relevant to your location for the protection of Endangered Species. You must obtain a Bulletin no earlier than six month before using this product. To obtain Bulletins, consult http://www.epa.gov/espp/, call 1-844-447-3813 or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product.

Because this statement is on an enforceable pesticide label, the requirement to obtain and follow measures in a Bulletin is a label provision that would be subject to enforcement under the misuse provisions of FIFRA, where EPA and SLAs with authority are responsible for FIFRA enforcement actions. Pesticide applicators are responsible for keeping records for RUPs and it is recommended that similar record requirements be followed for general use pesticides, but these records are not currently required to be inspected by SLAs. The label language above related to "obtain" a Bulletin and "use the Bulletin valid for the month in which you will apply the product" implies that the Bulletin and record of application timing will need to be maintained. Additionally, application details that demonstrate compliance with "following the measures controlling the product use relevant to your location," such as the example measures/pesticide limitations in Figure 7, may also need to be maintained by users. The complexity of some of the pesticide limitations in BLT may present challenges related to documenting compliance.



Codes and Limitations Table

Code	Limitation
D120	To protect federally listed threatened and endangered species, both a 310-foot in-field wind-directional spray drift buffer and a 57-foot omnidirectional in-field buffer are required. If applying to dicamba-tolerant soybeans with a qualified hooded sprayer, both a 240-foot in-field wind-directional spray drift buffer and a 57-foot omnidirectional in-field buffer are required to protect federally listed threatened and endangered species. Please see the label for a link to the website(s) with your product's qualified hooded sprayers. The following areas may be included in the buffer distance composition when directly adjacent to the treated field edges: 1. Roads, paved or gravel surfaces, mowed grassy areas adjacent to field, and areas of bare ground from recent plowing or grading that are contiguous with the treated field. 2. Planted agricultural fields containing dicamba-resistant plantings of cotton and soybeans. 3. Areas covered by the footprint of a building, silo, or other man made structure with walls and or roof.
MA15	From April to June, follow one of these measures: 1. Apply malathion only before dawn or after dusk OR 2. Apply malathion only when wind is blowing away from prairie habitats OR 3. Use a 50-foot ground buffer from prairie habitats, and an aerial buffer from the habitats according to application rate: (1) 50 feet for <0.5 lbs ai/A; (2) 75 feet for 0.5 - <1 lb ai/A; (3) 150 feet for 1-2.5 lbs ai/A; (4) 200 feet for >2.5 lbs ai/A. Buffer sizes may be reduced by 25 feet for application rates (1) and (2) if a full swath displacement upwind is used during aerial application. Buffer sizes may be reduced by 50 feet for application rates (3) and (4) if a full swath displacement upwind is used during aerial application. Habitat: Photos are provided at https://www.epa.gov/endangered-species/texas-plants-habitat-photos.

Figure 7. Example Pesticide Limitations in EPA's Bulletins Live! Two.

Pesticide users who fail to follow label provisions for their pesticide application, whether that failure results in harm to a listed species or not, will be subject to enforcement under the misuse provisions of FIFRA. However, if unauthorized take of listed species occurs, the user will be subject to penalties under the ESA, that are enforced by the Services. This will likely require additional training and possibly staff to coordinate with the Services. SLAs have yet to determine how to conduct compliance assistance and enforcement related to EPA's proposed mitigation practices to protect listed species, BLT requirements, record keeping, C&T, monitoring and efficacy evaluations, and overall compliance for ESA protections.

Discussion: Towards Successful Implementation of ESA

SLAs have been engaged with EPA and the Services for years to become informed and provide input to the federal processes. The State FIFRA Issues Research and Evaluation Group (SFIREG) and the SFIREG Joint Working Committee (JWC) also provide science and policy information and comment to EPA. SLAs and SFIREG are engaged in reviewing and providing comments to EPA actions when there is a public opportunity to provide input such as through registration and registration decisions including EPA's biological evaluations (BEs), and the consent decree processes and strategies that EPA has produced in recent years related to evaluating the impact of pesticides on listed species (including the ESA Workplan Appendix, ESA Workplan Appendix revision, Vulnerable Species Project White Paper, the Draft Herbicide Strategy, and the Draft Rodenticide Strategy). However, SLAs and SFIREG have been left out of the development processes for EPA's new ESA Workplan and strategies and have not been engaged by EPA early in the processes to design and develop measures that can be workable and enforceable.

Early Engagement

SLAs need to be involved in EPA's pesticide and listed species assessment process as early as possible. Specifically, engaging SLAs when EPA is determining the types of mitigations or measures required for a specific pesticide to reduce impacts on listed species will help to ensure that the measures are reasonable and can be implemented by end-users. For example, if a pesticide is used mainly on specialty crops in specific states, engaging the SLAs in those states to discuss the prevalence of certain mitigation measures such as cover crops, vegetative filter strips, and double-cropping will help to inform if it is relevant to include these mitigation measures to reduce impact to listed species. Additionally, review of use limitations and maps by SLAs before implementation in BLT will help to ensure the delineated locations are reflective of on-the-ground conditions and that limitation measures include listed species habitat and other language familiar to pesticide applicators.

Early engagement will also help to ensure that SLAs are prepared for the enforcement needs related to the measures. PSEPs around the nation are struggling to complete new training and study manual revisions to meet new C&T requirements. The EPA proposed changes to BLT and label requirements due to protection of listed species will add a new burden to pesticide C&T and PSEPs because it will require rapid development and deployment of new and likely more complex safety educational, regulatory, and record keeping practices. All of this is proposed to be accomplished without any additional funding from EPA. The EPA will need to involve SLAs and PSEPs to address the many questions so that SLAs and partners can properly develop systems that will ensure that EPA's efforts are successful. For example, if SLAs are aware that there is a requirement for pesticide applicators to "obtain a Bulletin at any time within six months of the day of application" as is proposed in the EPA ESA Workplan Update, then SLAs can be prepared to educate applicators and be prepared to enforce this requirement. Additionally, as the EPA works towards implementing their ESA Workplan and more pesticide decisions and labels include mitigations to protect listed species, it will be increasingly important to educate pesticide applicators about ESA, mitigations required to protect listed species and designated CH, and listed species habitats that may be in or near the vicinity of where pesticide applications will be made. The extra C&T program development for ESA Pesticide Programs will need further development by SLAs

and Tribes but having standardized material on ESA as it relates to pesticides that all SLAs can use when educating applicators, with templates to incorporate more specific materials, is one way to encourage successful implementation of the EPA's pesticide program. Developing a standardized message about ESA as it relates to pesticides and the types of pesticide restrictions, mitigations, and other measures such as Bulletins from BLT, that may be needed to minimize adverse impact on listed species will help to improve applicator's knowledge and awareness. Incorporating state, regional, and locally specific materials when audiences are geographically limited, will provide more relatable circumstances. Examples include descriptions and images of specific listed species that occur in the area, habitat maps and images, and other site-specific information.

State Plans and Programs for Pesticides and ESA

SLAs and SFIREG has provided comment to EPA on various conservation and stewardship programs, how they can be adapted or designed for specific cropping and agricultural systems to be implemented as mitigation for listed species protection, and opportunities to develop mitigation systems and state led conservation programs to fulfill the SLA responsibilities for ESA and FIFRA. SLAs, SFIREG, and partners have also provided comments to EPA that SLAs and states in general should be properly consulted on how these programs and systems work at the state and local level. As an example, EPA's Draft Herbicide Strategy mentions recognized programs which could include those established by federal and state agencies; local, county, or municipal government; university extension programs; or independent certification programs. Growers must maintain documentation of their participation in the program, including recommendations, planning, design, implementation, and maintenance of any conservation practices. To meet Clean Water Act Nonpoint Source Plans, every state and their partners at the local level, such as Conservation Districts, have approved stewardship programs in the form of state and local conversation programs. Additionally, all states also have state conservation and district level authorities and programs to implement technical assistance, cost share, nonpoint source pollution abatement strategies, Best Management Practices (BMPs), and USDA NRCS Field Office Technical Guide Practice Standards.

A proposed solution is for SLAs and SFIREG to work further with EPA to determine and define a recognized conservation or stewardship program exception and how those could be established in each state by SLAs and partners. Guidance would be needed to detail requirements such as the process for plan approval and implementation and plans would need to allow for adaptation of listed species management needs. An example of such an effort is the pilot project with PSEPs and EPA Region 10 staff, exploring how a pesticide system that is protective of listed species could serve the region and the nation.

Formation of an SFIREG ESA and Pesticide Workgroup

Through SLAs and SFIREG comments to the EPA's Draft Herbicide Strategy and SFIREG discussions with the EPA, a request to form and fund a national SFIREG Endangered Species and Pesticide workgroup, involving SFIREG members and representatives nationwide, has been proposed. Formation and financial support for a SFIREG workgroup by the cooperative agreement grant between SFIREG and the EPA is important for properly engaging SLAs and partners throughout the country. The SFIREG Endangered Species and Pesticide workgroup should be composed of SLA representatives throughout all ten EPA regions; along with full SFIREG, JWC, and invited supportive collaborators from other University, Pesticide Safety Educators, and state and conservation group professionals. The EPA funding to SFIREG would support the SLA SFIREG Endangered Species and Pesticide workgroup to implement a science and policy-based process and to also hire contractors to assist in formation, facilitation, and management of the process. SFIREG also suggests the EPA should also properly involve and fund EPA Regional Office Pesticide Program staff to be involved in assisting SLAs and SFIREG in each region and nationwide. Formation of this group is requested before EPA finalizes the various strategies and documents being developed under EPA's ESA Workplan.

With improved interaction opportunities such as early engagement and the formation of an SLA SFIREG Endangered Species and Pesticide workgroup, state regulators can provide much needed input to inform EPA's ESA pesticide program, listed species assessments, and pesticide mitigation measures in ways that can improve compliance by ensuring that end-user needs are accounted for. Because SLAs interact with pesticide applicators in a regulatory capacity and are involved in education and certification and enforcement, pesticide state agencies are in a unique position to be a conduit for pesticide end-user information into the federal pesticide process. SLAs have a tremendous amount of knowledge about the challenges and issues that pesticide applicators face when it comes to successful implementation of labels. This is vitally important because the agricultural landscape, cropping systems, and pesticide use is highly variable throughout the country. SLAs have knowledge about what works and what does not at the applicator level, and this is key to developing programs that are protective of listed species and that are feasible to implement by local applicators.

Conclusions and Recommendations

Collective summary from series authors

Ensuring that the production of food, feed, and fiber remains economically and environmentally viable for the future is an enormous challenge. The use of pesticides to protect yields and maximize production forms the foundation of food production for sustaining the world's population, and parameters directing use of these products must be achievable by growers. As farmers work to overcome daily challenges, regulatory agencies must understand the implications of adding additional mitigation requirements for protection of listed species

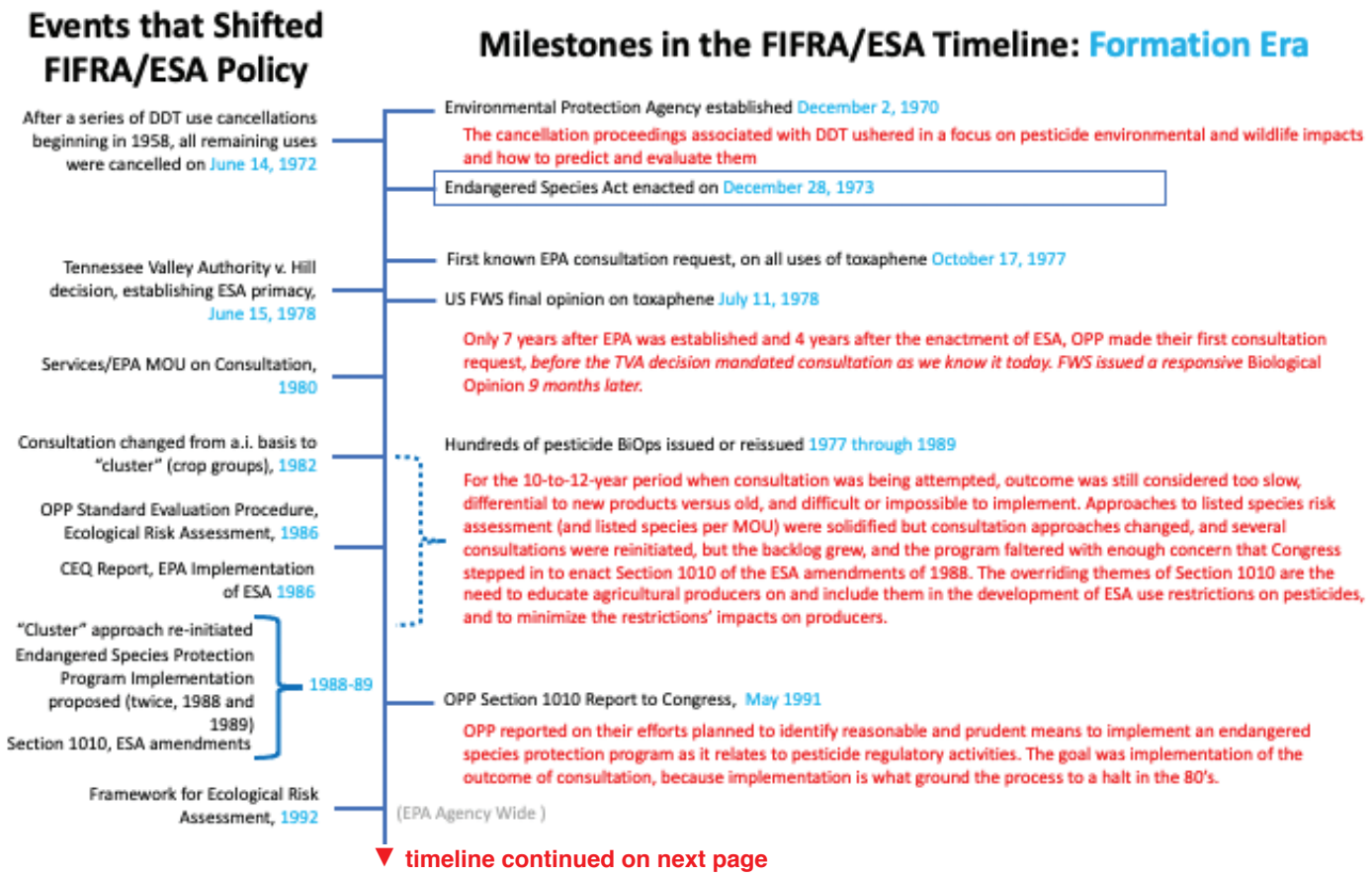
on pesticide labels that introduce a new level of complexity to pest management. It is unreasonable to expect farmers to produce enough food, feed, and fiber for a growing world population without the ability to use pesticides in a practical manner while also designing their on-farm stewardship practices to optimize environmental protection and production.

While protecting the nation's most sensitive plants and animals from pesticide stressors is critically important, incorporating conservation-focused mitigation measures as part of the regulatory framework changes the historical and current voluntary and site-specific nature of conservation planning on agricultural landscapes. Agricultural, environmental, and federal entities must all work together to understand, educate, and generate the information needed to reach the common goal of protecting the ability of our family farms to continue feeding the world while protecting listed species. With cooperation amongst all impacted parties, building mitigation practices on a foundation of sound science, and appropriate linkage of mitigation practices to species protection and health, it is possible to create regulatory actions to protect listed species that improve the long-term outlook for family farms and long-term sustainability of species and their habitats as a result of reducing the potential for land-use changes.

The challenges facing federal agencies tasked with assessing the risk of pesticide use and delivering regulatory actions to protect threatened and endangered species in a manner that minimizes the disruption to the agricultural production system are monumental. Progress has been made, but many challenges remain for the EPA to enact regulations that are "procedurally correct" for ESA while still allowing farmers to provide food security for the nation in a practicable manner. A risk assessment must be based on realistic pesticide use scenarios, even if evaluation efficiencies truncate the agencies' ability to deal with details. Similarly, modeling predicting scientifically valid toxicity endpoints using appropriate pesticide exposure estimates when forming a risk is essential. Where the use of drift reduction technology is not captured on current pesticide labels (such as for air blast sprayers), the agency should seek to support and promote these methods. Ultimately, regulatory decisions delivered by the EPA to limit risk to listed species must also minimize the potential impacts to agricultural operations regarding the scope of their action and provide continued availability and application of important crop protection chemicals. And the burden of funding refinements and developing new tools to improve ecological exposure estimates should not completely fall on the regulated community. Only with these considerations can EPA ensure the development of an effective regulatory program.

As stated previously, agriculture is not monolithic, and a "one size fits all" approach in developing a regulatory response is not appropriate. The potentially impacted parties must have a seat at the table to better inform the EPA about making a significant change in how FIFRA and ESA decisions will be made.

Appendix



▲ timeline continued from previous page

Milestones in the FIFRA/ESA Timeline: Enter the Litigation Era

Linda Fisher "New Paradigm" Memo October 29, 1992

Implementation of "New Paradigm" Memo August 25, 1993

National Academy of Sciences, Science and the Endangered Species Act, 1995

1994 Wyoming Toad Protection Program ~July 1994

First evidence of implementation of field program as a result of FIFRA/ESA consultation finding jeopardy for 43 active ingredients.

FWS/NMFS Distinct Population Segment Policy, February 7, 1996

EPA OPP "ECOFRAM" Established 1996

ECOFRAM was formed to bring consensus to aquatic and ecological risk assessment approaches and use of refined risk methodologies in the concept and implementation of the "New Paradigm."

Guidelines for Ecological Risk Assessment April 1998

(EPA Agency Wide, based on 1992 Framework)

ECOFRAM Aquatic and Terrestrial Draft Reports May 1999

Meant to be the guide for pesticide ecological risk assessment, and despite hours of expert input and discussion, no final reports were issued. EPA retains them on their webpages for reference but not guidance.

Endangered Species Protection Program Implementation, and EPA Process for Assessing Potential Risks to Listed Species, December 2, 2002

PRN 2000-2 The FIFRA Endangered Species Task Force April 17, 2000

Advance Notice of Public Rulemaking: Endangered Species and Pesticide Regulation, January 24, 2003

Extensive and repeated "Failure to Consult" litigations against EPA (Salmon, forestry uses, California Red-legged frog, atrazine-Chesapeake Bay, Barton Spring Salamander 2000 to 2004

Proposed Joint Counterpart Endangered Species Act Section 7 Consultation Regulations, January 30, 2004

Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, January 23, 2004 (and Williams-Hogarth letter reviewing it, January 26, 2004) and Draft Alternative Consultation Agreement, January 2004 (and Williams-Hogarth letter reviewing it, January 26, 2004)

Final Joint Counterpart Endangered Species Act Section 7 Consultation Regulations, August 5, 2004

Final Alternative Consultation Agreement, August 25, 2004

Step-Wise Approach to Assessing Potential Effects of Pesticides on Listed Species and Critical Habitat, March 3, 2005

Endangered Species Protection Program Field Implementation, November 5, 2005

Fourth attempt to implement FIFRA/ESA program

Milestones in the FIFRA/ESA Timeline: Litigation Era

Counterpart regulations vacated August 24, 2006

The Overview Document and Alternative Consultation Agreement were on the verge of implementation but then basically abandoned when a court case overturned the Counterpart Regulations based on procedure, not content.

First responsive NMFS BiOp on OP's August 16, 2008

Bulletins Live Implemented February 2, 2009

Multiple lawsuits on Registration Review and then on new A.I. 2006 to 2012

Carbamate NMFS BiOps April 18, 2009

Multiple NMFS BiOps June 18, 2010

NAS Panel Requested March 11, 2011

Litigation proliferated from 2006 to 2012 and beyond. It was hoped that the "pure science and fact" analysis from NAS would address the controversies and provide a scientific platform for moving forward in species assessment and regulation

Final NAS Panel Report Published, March 15, 2013

"Enhancing Stakeholder Input" workshops initiated March 19, 2013

EPA Interim Approaches initiated November 15, 2013

EPA held public workshops to attempt to bring understanding to the revised process of FIFRA/ESA methods, but these were distributional of information, not collective of information. Workshops ended with 5th in the series, and a revised method was then proposed.

Enhanced Stakeholder Input, May 15, 2013

"Enhancing Stakeholder Input" workshops initiated June 29, 2016

Revised Interim Method May 15, 2019

Repeatedly, stakeholder comments pointed out a need for better science, more transparency and early stakeholder input.

Revised Interim Method May 15, 2019

Revised Interim Method, May 15, 2019

First IWG Report to Congress, December 20, 2019

Revisions sought earlier response, mitigation and implementation

Balancing Wildlife Protection and Pesticides, April 2022

Updated Interim Method, November 16, 2022

Vulnerable Species Pilot, June 21, 2023

A series of actions which introduce adjusted FIFRA/ESA methods; a plan for blanket "early mitigations" and product-specific early mitigations, and species based general mitigations for species in the EPA vulnerability pilot

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