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CAST Commentary

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

Introduction

Fifty years ago, the Endangered Species Act of 1973 (ESA) was first passed by Congress with the intent to provide a means whereby endangered and threatened 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 in regards to 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. 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.

Crop systems and respective pests are dynamic and often

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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 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 implemented 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 issue papers, authors seek to explore how FIFRA and the ESA can work together to overcome the challenges of historical dysfunction, logistical overload, and unmanageable burden. This first of the series reviews the history and repeated cycle of regulation to bring appreciation to the challenge before us in a FIFRA/ESA consultation.

ReadyChallenges 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 "not effect" 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.

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 measure have been applied (FWS 2023).

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 process, it is important to highlight the influence 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, have 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 their 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 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 reevaluation) 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 of 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 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 changes 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 resolve the issues blocking successful ESA assessments, demonstrated as early as 1958 when the first uses of DDT were banned. However, an effective path out of the FIFRA/ESA do-loop is yet to be discovered, leaving us without a consistently functioning consultation process.

Although the process has failed historically, will there be a different 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 2022b), the 2023 Vulnerable Listed Species Pilot Project (draft, EPA 2023), and the 2023 Herbicide Strategy (draft, EPA 2023a) are all significant and, in unique ways, have components of better science, improved mapping techniques for listed species and agricultural fields, 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 Figure 1's do-loop 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 the "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." 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 to meet the requirements of both Acts, while understanding the importance of protecting wildlife and developing or maintaining the tools needed to safely, economically and effectively manage pests 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 to 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, the FIFRA was amended due to wildlife and other environmental concerns and the ESA was adopted in 1973. Only eight years after the EPA was established and five years after the enactment of the ESA, in July of 1978, the 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 the 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 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 as a whole 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 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" (EPA 2013).

A partially parallel "reworking" of policy was through Counterpart Regulations proposed in 2003, accompanied by an EPA risk assessment restatement ("Overview Document, 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 of 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—(EPA 2013), and a revamp of county bulletins as Bulletins Live 2 during 2014 (EPA 2014). The first Bulletins Live had previously been applied but faded into history similar to the original bulletin system established in 1988 (EPA 1988). But these iterations were not comprehensive enough to result in a working consultation process.

The cycle started again with a Revised Interim Method (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 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 noted with the 2023 Vulnerable Listed Species Pilot Project (draft, EPA 2023) and the 2023 Herbicide Strategy (draft, 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 platform and current action-by-action consultation policy, will an abbreviated process work, and will the decisions be scientifically sound, defensible, and implementable? Or are we simply at the end of the cycle on the verge of trying to find another way to "regroup?"

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