EPA IMPLEMENTS A "NEW PARADIGM" FOR ASSESSING ENDANGERED SPECIES IMPACTS WITH PUBLICATION OF THREE DRAFT BIOLOGICAL EVALUATIONS

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On April 11, 2016, the U.S. Environmental Protection Agency (EPA) published a notice announcing the availability of the much-anticipated draft biological evaluations (BE) for chlorpyrifos, diazinon, and malathion. 81 Fed. Reg. 21,341; see https://www.epa.gov/pesticides/epa-releases-draft-biological-evaluations-three-chemicals-impacts-endangered-species. The draft BEs include preliminary "effects determinations"—i.e., EPA determinations regarding the potential impacts of the registration of these three pesticides on threatened and endangered species (listed species) and their critical habitat. Significantly, this marks the first implementation of interim approaches and scientific methods developed by EPA and the U.S. Fish and Wildlife Service and the National Marine and Fisheries Service (collectively, the Services) in response to recommendations set forth in an April 2013 National Academy of Sciences (NAS) report, Assessing Risks to Endangered and Threatened Species from Pesticides. According to EPA, the interim approaches establish "a new paradigm for analyzing pesticides for effects on endangered species." Moreover, as noted by the registrants of these chemicals, EPA's actions "constitute a trial run for the integration of ESA analysis into dozens of FIFRA registration review cases in the next few years, many more in future registration review cycles, and many in the context of new product registrations." See https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0850-0858. Accordingly, the outcome of these assessments—and any associated litigation—will have far-reaching consequences for farmers and other pesticide users, pesticide manufacturers, EPA, the Services, state and local governments, and other stakeholders.

FIFRA, the ESA, and the Establishment of Interim Approaches to Assessing Endangered Species Impacts

The draft BEs represent EPA's most recent effort to interpret and implement its statutory obligations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA). A foundational aspect of FIFRA is the registration scheme whereby registrants obtain a license to sell and distribute a pesticide product after EPA assesses, among other things, the product's intended use and its impact on human health and the environment. Once registered, products are subject to "registration review," which entails a periodic assessment by EPA (at least every 15 years) to ensure that such products continue to meet the FIFRA registration standard, i.e., "that the pesticide can perform its intended function without unreasonable adverse effects." 81 Fed. Reg. 21,341. The draft BEs at issue here have been prepared in connection with these products' registration review.

Section 7 of the ESA obligates federal agencies—in consultation with the Services—to "insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any [listed species] or result in the destruction or adverse modification of [critical habitat]." 16 U.S.C. § 1536(a)(2). EPA's and the Services' handling of their obligations under these authorities has been the subject of extensive litigation, including several ongoing cases. See https://www.epa.gov/endangered-species/endangered-species-litigation-and-associated-pesticide-limitations (discussing completed and active litigation involving FIFRA and ESA issues). Furthermore, the agencies' respective approaches toward conducting scientific assessments have differed historically, with the Services generally applying a more precautionary approach that relies on overly conservative models, and EPA adhering to a more practical, "real-world" risk assessment process.

The FIFRA/ESA litigation and the competing scientific approaches led, in part, to a request by EPA, the Services, and the U.S. Department of Agriculture that the NAS National Research Council (NRC) appoint experts to evaluate scientific approaches and tools for assessing what effects proposed FIFRA actions may have on listed species. The NRC issued its report in 2011, and, shortly thereafter, EPA and the Services convened a team to assess the report's findings and establish a shared approach to evaluating listed species impacts. This effort resulted in the establishment of interim approaches and scientific methods, which included an agreement to adhere to a multistep process when assessing potential impacts to listed species (see https://www.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act):

- EPA determines whether a pesticide's registered use will have "no effect" on species/critical habitat, or whether such use "may affect" species/critical habitat. If EPA reaches a "no effect" finding, no further action is required.
- If EPA reaches a "may affect" conclusion, it refines its assessment and then determines whether use of the pesticide:
    - May affect but is not likely to adversely affect (NLAA) species/critical habitat; or
    - May affect and is likely to adversely affect (LAA) species/critical habitat.
- If EPA reaches an NLAA determination, then it engages in "informal consultation" with the Services. EPA expects this process to culminate with the Services issuing a letter through which they concur or do not concur with the NLAA determination. If the Services concur, no further action is required.
- If EPA reaches an LAA determination—or if the Services do not concur with an NLAA determination—then EPA initiates "formal consultation." This process culminates in the Services' issuance of a biological opinion, which, among other things, determines whether the proposed action is likely to jeopardize the continued existence of a listed species, and identifies alternatives for EPA to implement that would ameliorate risks to listed species.

According to EPA, "[a]fter EPA's risk assessment or formal consultation . . . , if EPA determines that a pesticide's registration, label, or use instructions should be altered to ensure use of a pesticide will not take or jeopardize the continued existence of a listed species, EPA may require changes to the use conditions specified on the label of the product." Id. Depending on the product, such use conditions—which could include buffer zones and other use restrictions—have the potential to limit significantly the ability of farmers, mosquito control districts, and others to use pesticide products.

Draft BEs for Chlorpyrifos, Diazinon, and Malathion

The draft BEs are significant in their scientific scope, and are immense in length. As noted by the products' registrants, EPA's analyses invoke over a dozen scientific disciplines, and the dockets for the draft BEs contain over 75 documents for each of the products and include several thousand pages of material. See https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2008-0351-0042&attachmentNumber=1&disposition=attachment&contentType=pdf. Indeed, the complexity and scope of the administrative record and its underlying science are without precedent.

EPA's draft effects determinations preliminarily conclude that the continued registration of these products will present risks to hundreds of listed species. Key findings in the draft BEs include:

- Continued registration of chlorpyrifos is likely to adversely affect 1725 species (approximately 97 percent of species evaluated).
- Continued registration of diazinon is likely to adversely affect 1416 species

(approximately 80 percent of species evaluated).
- Continued registration of malathion is likely to adversely affect 1725 species (approximately 97 percent of species evaluated).

EPA stated that these are draft determinations and that, based on comments, it may alter the BEs and also "request public input on risk mitigation before completing proposed registration review decisions." 81 Fed. Reg. at 21,342. EPA indicated that the final biological opinions for these three chemicals are scheduled for completion by December 2017. Id. at 21,343.

Implications of the "New Paradigm"

Pesticide industry observers will be closely following the outcome of these endangered species assessments and any related litigation. In particular, the Services' biological opinions could lead to EPA seeking significant restrictions on the use of these three chemicals, which could have a profound impact on pesticide use in many parts of the country. The precedential impact of implementing the interim approaches is also critical, and many questions remain: Will future registration and registration review decisions be similar in their scope and complexity? How long will it take for EPA and the Services to conduct their reviews? Who will fund the agencies' work? Is it possible to implement a reasonable and predictable program for the licensing and use of pesticides? The answer to these and many more questions will gradually emerge as EPA and the Services implement this "new paradigm."

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