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NEWSLETTER

Will the NAS FIFRA-ESA Report Lead to Anything Useful?

November 2013

The U.S. Environmental Protection Agency (EPA or the Agency) and the two Endangered Species Act (ESA)-enforcing services (the National Oceanic and Atmospheric Administration's National Marine Fisheries Service and the Department of Interior's Fish & Wildlife Service (the Services)) are expected to hold a public meeting on November 15 to explain their response to the April 30, 2013, National Academy of Sciences (NAS) report, "Assessing Risks to Endangered and Threatened Species from Pesticides." A lot is at stake.

From the earliest days of the current round of litigation over the relationship between EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide registration authority and the Agency's ESA obligations—now over a decade ago—EPA staff pushed for appointment of a "blue-ribbon panel" to resolve the differences between it and the Services in approaches to risk assessment. That role was finally undertaken by NAS' National Research Council in 2011 after a joint request from EPA, the Services, and the U.S. Department of Agriculture (USDA), and its outcome is embodied in the April report.

Since the release of the report, EPA and Services staff have been meeting to try to see if its recommendations help overcome the increasing frustration of registration activities that has arisen from ESA. For example, EPA is now well into the first round of 15-year registrations reviews of existing products mandated by the 1996 Food Quality Protection Act (FQPA), and has only scratched the surface in beginning ESA consultations as part of those reviews. EPA, USDA, and the Services published in March 2013 an outline of a new "Stakeholder Process" to be employed in those reviews. And increasing numbers of registration actions relating to new products or

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uses are being held up as EPA flounders on ESA policy.

A year or so ago, stakeholders believed that the recommendations of the NAS report would be implemented through a process comparable to the one used when FQPA was implemented in the late 1990s. That process involved considerable stakeholder outreach, establishment of a formal multi-stakeholder advisory committee, and circulation of a series of science policy papers to the committee for public review and comment. It was widely viewed as a successful Agency response to significant new regulatory challenges FQPA had created.

But the November 15 presentation is occurring at the end of a process from which the governmental actors have excluded outside stakeholders. There is considerable frustration in both the regulated and non-governmental organization communities, and at the state level, with this and concern that what may be announced in mid-November will reflect decisions made without adequate extra-governmental review.

That would be extraordinarily unfortunate, since the registration and reregistration delays arising from ESA disputes are threatening to reach crisis levels. EPA has a statutory obligation to complete the registration review program by 2022, but has yet to develop substantive guidelines as to how to incorporate the ESA consultation process into registration review. (The much-heralded March 2013 "Stakeholder Process" was a step in the right direction, but entirely procedural.) And several registration actions pertaining to products critical to addressing the growing list of glyphosate-resistant weeds apparently are being held up by ESA concerns.

Furthermore, the NAS report suggests several ways to overcome these difficulties. One, for example, arises from the report's characterization of the risk assessment process as having three stages, as summarized in Table 2-1, appearing below.

TABLE 2-1 Steps in the ESA Process as Related to Elements in the Ecological Risk Assessment (ERA) Process for Pesticides.[a]

Element of the ERA Process Step in ESA Process [Responsible Agency]Exposure Analysis (Chapter 3)Effect (Exposure-Response) Analysis (Chapter 4)Risk Characterization (Chapter 5)

1 [EPA]

Determine whether use of a pesticide "may affect" any listed speciesDistribution of listed species in space and timeDistribution of the pesticide in space and time if used as labeled (toxicity is assumed)Possibility that species and pesticide distributions would overlap in space and time

2 [EPA]

Determine whether use of a pesticide is "likely to adversely affect" any listed speciesModeled exposure concentrationsExposure-response function for an individual receptor's survival and reproductionProbability of adverse effects on survival and reproduction of individual receptors

3 [SERVICES]

Determine whether use of a pesticide is likely to cause "jeopardy"Modeled or measured exposure concentrationsExposure-response functions for survival and reproduction ratesProbability of adverse effects on population viability over space and time

[a] See section "Coordination among Agencies" for a discussion of problem formulation, the first element of the ERA process.

Step 1 in the report is essentially making a "no effect" determination; Step 2 is essentially making a "not likely to adversely affect" (NLAA) decision, and Step 3 is a full-scale, detailed risk assessment. These stages parallel the elements addressed in the Services' 2004 "FIFRA Counterpart Regulations." But those regulations assigned to EPA authority to make the NLAA decision, and in 2006 a court ruled that portion of the regulations unlawful. That decision was based largely on the court's concern that EPA's scientific evaluations were not the equal of the Services'.

With the publication of the NAS report, and assuming concurrence by EPA and the Services on implementing its recommendations, it seems likely that this judicial concern can be overcome. Particularly important in this regard is NAS report conclusion that, as a matter of science, it is logical and appropriate for EPA to make the NLAA decision.

This may not be the only, or even the best, approach to follow now that NAS has provided its guidance. But the only realistic way for EPA and the Services to proceed to fix the FIFRA-ESA mess, if indeed they can without legislative directive, will be for the Administration to involve all stakeholders in an ongoing, interactive process. And whether that is going to occur will be signaled on November 15.