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NEWSLETTER

A Framework Emerges for EPA FIFRA/ESA Compliance

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In a June 6, 2014 presentation to the U.S. Environmental Protection Agency's (EPA) Pesticide Program Dialogue Committee (PPCD), and in a subsequent presentation to an American Bar Association Subcommittee, Office of Pesticides Program staff confirmed the conceptual framework for approaching Endangered Species Act (ESA) compliance by the Agency's pesticide registration program that has been emerging over the last several months.

The Emerging Process

Essentially, EPA has sorted the registrations of pesticide products required under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) into three categories, each of which it is treating somewhat differently. The first, and most numerous, are the set of existing products subject to the statutorily-mandated every-fifteen-year "registration review" process. The alleged failures of EPA and the consulting Services to have adequately evaluated the potential impacts of use of those products on threatened and endangered species has been the subject of a number of lawsuits over the last decade. Those suits have resulted in a series of court imposed schedules for evaluations, which EPA and the Services slowly have been implementing.

EPA has been trying for several years to make its registration review program the vehicle for these catch-up reviews. But progress has been frustrated by disputes between EPA and the Services as to the right way to approach the complex scientific issues presented by evaluating the impact of about a thousand pesticide active ingredients, which are formulated in to many thousands more commercial products, on the long list of threatened and endangered

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species. A break-through of sorts was reached last Spring, when a National Academy of Sciences published a report purporting to resolve many of those issues. Subsequently, last November EPA and the Services announced an "interim process" for implementing ESA consultations in registration review, and that process is beginning to be implemented.

The second category of actions that may merit ESA consultation are changes in existing registrations arising from development of new genetically-modified seed technologies. As to these, EPA has indicated it will proceed cautiously, and at least initially only grant registrations where it can conclude the changed uses will have "no effect" on threatened or endangered species.

Third, as to previously unregistered products, EPA has said it will undertake an initial analysis to determine whether they appear likely to replace more older products, and to present fewer risks to threatened and endangered species. If so, EPA will defer further ESA reviews while proceeding with registration actions.

Stakeholder Reactions

Initial indications are that most environmental activists and NGOs are prepared to live with the Agency's approach to registration review, while registrants, grower groups, and a handful of activists express concern with the Agency's intentions. Those concerns focus not so much on incorporating ESA evaluations into registration review—which almost all interests seem to agree is sensible—but on EPA's intention to develop policy on a case-by-case basis. Industry and some environmentalist interests have expressed a strong preference for moving to develop policies on a more generalized basis, pointing to the successful model of implementation of new standards for human health protection evaluations mandated by the 1994 Food Quality Protection Act (FQPA). These interests also have expressed serious concern that the lack of adequate personnel resources and expertise at the Services will unacceptably slow the pace of progress.

Nonetheless, most seem prepared to give EPA time to incorporate ESA considerations more fully into registration review. For example, parties to settlements in several pending lawsuits in which schedules for ESA evaluations of existing products have been established appear willing to accept revisions to those schedules consistent with EPA's plans. For example, on June 6, EPA published for comment a revised stipulated injunction in *NCAP v. EPA*, a case challenging EPA for not completing consultation on the impact of three organophosphate insecticides on salmonids (after the Fourth Circuit declared NMFS's initial biological opinion invalid) or implementing recommendations from NMFS contained in a parallel biological opinion addressing several carbamate products. The revisions defer ESA compliance for the products until 2019, and require only that one consultation be completed by the end of 2017 and another by the end of 2018. At the June 6 presentation, EPA staff confirmed that the first of these will address the OPs and the second the carbamates.

In the meantime, EPA will defer ESA consultations on any products undergoing registration review as to which it is unable to make a "no effect" determination. This means that the current registration review process almost certainly will not be completed by its 2022 deadline. The Agency reportedly plans to adopt a strategy similar to that employed in the prior reregistation program after enactment of the FQPA: issuance of "interim" decisions that address all concerns except ESA, then finalize the determinations after ESA implementation

policies have been developed. (After FQPA was enacted, "interim reregistration eligibility decisions" were issued until policies required to implement the new statute were developed. These addressed all registration requirements not affected by the new statute's provisions. Only later were final reregistration eligibility decisions published.)

Stakeholder reactions to the Agency's approach to the second category of registration actions—amendments to existing registration to accommodate GMO seed approvals—remains to be seen. An early test will come later this month, when on June 30 the comment period closes on the Agency's proposed approval of registration changes to several Dow AgroSciences 2,4-D herbicide labels. Those proposed amendments would allow productive use of Dow's new "Enlist" seed, which is resistant to both glyphosate and 2,4-D, and may soon be approved for use by the U.S. Department of Agriculture.

In this case, however, EPA has proposed to approve the label revisions only as to product use in six states. As to each state, EPA has concluded, the increased use of 2,4-D would have no effect on threatened or endangered species and provided its rationale for public review and comment.

It will not be surprising if some of those comments address the emerging EPA ESA implementation strategy. Whether these subsequently lead to litigation remains to be seen.

The third category of registration actions was exemplified by EPA's approvals in January 2014 of registrations sought by DuPont and Syngenta for the new insecticide cyantraniliprole without any ESA consultation with a Service. The cyantraniliprole approvals already have been challenged in court, in parallel cases filed in the U.S. Court of Appeals for the D.C. Circuit and in D.C. District Court. The time for seeking review of the other approval has not yet run.

The determination that use of these new products present less risk to threatened and endangered species that existing products, combined with the limited resources available at the Services to undertake consultations and FIFRA's demand that EPA approval actions meet specified schedules, supports EPA's approach to them. But some obviously disagree, and judicial guidance no doubt will be forthcoming. But it likely will be months, if not years, before the decisions on the merits of challenges to EPA approvals are rendered.