

Pesticides

Practitioner Insights: Do Inerts Trigger ESA?

Another front recently opened in the complex framework of pesticides and endangered species that targets inert ingredients used in pesticides. On July 9, the Center for Food Safety (CFS) filed a citizens petition for rulemaking that calls on the Environmental Protection Agency to require testing and approval of full pesticide formulations and tank mixtures, including the additives that generally are categorized as “inerts.” Failing to respond favorably, CFS argued, would violate both FIFRA and the ESA.

This petition expands on several other CFS forays into related areas. A year ago this month, CFS joined the Center for Biological Diversity’s (CBD’s) Petition for rulemaking to evaluate the synergistic effects of pesticides during registration and registrant review. In 2013, the CFS joined in a yet-unresolved lawsuit against the EPA alleging the agency’s failure to protect pollinators from neonicotinoids. And the CFS has joined with other activists in challenges to particular pesticide registrations on Endangered Species Act grounds.

But this is the first recent effort to expand these efforts to address inerts. Inert ingredient manufacturers and companies that use them should pay close attention to how the EPA responds to this petition. This petition—or litigation following any EPA response or failure to respond—may eventually result in mandates to generate more data than is currently required to support new and/or existing inert ingredient clearances.

Inert Ingredient Background Under the Federal Insecticide, Fungicide and Rodenticide Act, a registration from the EPA generally is required before sale or distribution of a pesticide. EPA is to regulate the uses of the pesticide in a manner that will “prevent unreasonable adverse effects” on the environment or human health. FIFRA authorizes the EPA to require supporting studies to meet the statutory safety standard, and the core data requirements for pesticide registration are found in the Code of Federal Regulations at 40 CFR Part 158. Part 158 also establishes data requirements for pesticide tolerances under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA).

Most pesticide products contain both active ingredients—the substances intended to have pesticidal effects—and emulsifiers, solvents, carriers, aerosol propellants, fragrances, dyes or other ingredients. These historically have been referred to as “inerts,” although

activists argue that they in fact may have ecological or safety impacts. A FIFRA tolerance or exemption is required before many inerts can be used. Such clearances are increasingly difficult to obtain and, as a condition for granting one, the EPA may require a considerable amount of additional data. Indeed, the agency routinely imposes its testing authority to impose testing requirements analogous to—but sometimes even more complex than—those applied to active ingredients. Companies seeking to clear an inert ingredient thus are well-advised both to consult the data requirements in FIFRA’s regulations for the use pattern and check for precedents before concluding how extensive their data obligations may be.

An example of when testing for an inert ingredient can be even more onerous than testing for an active ingredient is when a single diluent will be marketed for use in a number of pesticide products that have different pre- and post-harvest applications. (In contrast, the sale of the active ingredient may be limited to use in one specific pesticide or family of pesticides.)

EPA also will review an inert ingredient strictly if it is a nanoscale chemical. Each nanoscale form of an inert ingredient needs its own data and is subject to a lengthy review.

The agency recommends that a submitter request a pre-submission conference call or meeting with the Inert Ingredient Assessment Branch (IIAB) prior to submitting the petition. This initial consultation is quite important for determining whether a company has enough information to proceed with the petition process. Because of the case-by-case way that EPA makes these determinations, there is no better way for a company to establish what data it will need with any degree of certainty. Companies that file an inert ingredient application without such a meeting risk a deficiency letter and substantial delay.

Companies should be well-prepared for these meetings. They should be ready to explain the information they have regarding the chemical, including use information, limitations, and toxicity and environmental fate data. They also should be prepared to negotiate with EPA staff about what additional data, if any, would be appropriate. Then, when it comes time to submit an inert application, companies can submit the negotiated identified studies as well, perhaps, as formal waiver requests for the studies that the agency has indicated are not required.

In addition, the rationale determinations as to whether to require, waive, or rely on data from similar chemicals should be transparently documented. The chosen path may implicate data compensation issues,

which have to be considered and addressed vis-à-vis follow on manufacturers of a cleared inert.

EPA imposes use limitations and quantity restrictions on the use of approved inert ingredients. In addition, FFDCA and FIFRA require that inert ingredients in a pesticide product, like active ingredients, have all needed tolerances or exemptions for tolerances before a pesticide is registered. A tolerance or exemption from the requirement of a tolerance is required if the proposed labeling bears instructions for use of the product on food or feed crops or if the intended use of the product may result directly or indirectly in pesticide residues in or on food or feed.

As a result of all these requirements, the testing costs associated with inert applications (and EPA's related fees) are non-trivial. Under PRIA3, the fee for review of a new non-food inert ingredient application is \$11,025. In the case of a new inert for food contact applications the PRIA3 fee is \$19,895. Fees for reviewing even simple amendments, changes in tolerance levels, and polymers of low concern are lower, in the range of \$1,654 - \$5,513.

These fees pale next to study costs, however. The studies in Part 158 are comprehensive and provide the scientific basis for characterizing the potential risks associated with pesticide exposure. (As we have noted, EPA has some flexibility to require additional data and studies can be waived, but this must be documented and scientifically supported.) For example, the CFS petition calls for routinely conducted chronic (2 year) animal studies which cost several million dollars and take up to 4 years to complete. A smaller, sub-chronic study may cost several hundred thousand dollars for just a single chemical, and can take approximately two years to schedule and complete.

The Rulemaking Petition The EPA is charged by statute with finding that use of the product "will not generally cause unreasonable adverse effects" on the environment or human health and is given broad authority to require testing necessary of both the active and inert ingredients in a pesticide to reach this finding. The presence of both types of ingredients has led to considerable recent attention to the possibility that product constituents may have "synergistic" effects—that is, the constituents may interact in meaningful ways.

In its new petition, the CFS alleges that the effects of a mixture of chemicals may extend beyond the expected responses to the individual components of a mixture, creating a greater response on exposed biota. The petition describes this synergy as the interaction of two or more ingredients in a mixture in such a way as to enhance the pesticide's toxicity, ecotoxicity, or bio-availability. CFS specifically alleges that:

- The use of certain surfactants enhances the herbicidal efficacy of glyphosate so that it is more toxic to plants and amphibians.

- Organosilicones that are widely used as nonionic surfactants in tank mixtures for sprayed pesticides en-

hance the penetration and spread of active ingredient(s) in a way that increases their toxicity.

- Neonicotinoids and fungicides when mixed in commercial and farmer tank mixtures lead to simultaneous and increased pollinator exposure of these two classes of active ingredient.

CFS also asserts that inerts and adjuvants in tank mixtures are being intentionally added to increase the efficacy of pesticides, but that EPA is not adequately taking synergistic effects into consideration. As a result, the petition argues, EPA is failing to meet its obligations under FIFRA and is violating the ESA by registering pesticides that may harm endangered species.

The petition asks EPA to initiate proceedings to revise the existing pesticide registration regulations in several ways, so that these rules:

- take into account the effect of all pesticide ingredients on the environment,

- require whole pesticide formulation and tank mixture testing,

- require testing for inert ingredients and whole pesticide formulations for chronic toxicological effects and degradation,

- require ESA consultation on the effects of whole pesticide formulations and tank mixtures on threatened and endangered species, and

- comply with the above in conducting statutorily mandated registration reviews of pesticides.

Historically, EPA might have been tempted to address many of these issues informally, without rulemaking. That seems less likely in the current administration. But even if the EPA fails to respond to it, the petition may eventually form a basis for litigation against EPA.

Implications With EPA data requirements for inert ingredients increasing, the current pre-submission consultation process has been effective for tailoring the amount of data needed to adequately assess risk. If the EPA were to take the more formal approach sought by CFS and issue new rules, those requirements might be more predictable but could also be more rigid or be expanded to permit testing for the entire mixture.

This petition also may open another front in the long-running controversy about the relationship between FIFRA's pesticide regulatory provisions and the ESA. The petition's attempt to elevate the importance of this potential causation pathway as the basis for an unreasonable risk finding adds yet another layer to the current debate about whether pesticide consultation process is the best use of federal agency resources.

The ESA directs that federal orders should not be "likely to jeopardize the continued existence" of any threatened or endangered species ("TES") or result in the "destruction or adverse modification of critical habitat." But this "jeopardy standard" is not the threshold set forth in the regulations of the U.S. Fish and Wildlife Service and its counterparts (Services) to determine whether EPA must "consult" with them. Under those regulations, if EPA determines that a FIFRA ap-

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proval “may affect” TES, then consultation is triggered. This overly conservative approach is wasteful and prevents successful integration of EPA’s FIFRA and ESA obligations as “consistent” and “complementary,” diverting time and attention from the conservation and recovery of TES.

Resources for “consultation” were not sustainable before a proposed geometric increase in ecological risk factors for EPA to study. The services probably would need to add 5,000 personnel full time equivalents (FTEs) and spend more than \$1 billion above 2017 appropriations just to complete 740 FIFRA Registration Review dockets required by current law to be completed by 2023. This translates to a 40-fold increase in the budget of National Marine Fisheries Services; a 30-fold increase for Fish and Wildlife Service; and \$270 million more for the EPA. And that estimate does not include any work associated with decision-making outside of the registration review context, such as evaluation of new pesticides intended for use with GMO crops or expanded uses of existing products.

Increasing data requirements for inerts would only exacerbate the shortfall in agency resources. But that

fact has not historically been a matter on which CFS and its colleagues have focused.

The EPA is under no deadline to respond to the CFS petition and has a range of options. The EPA could publish the petition for public comment, convene a science advisory committee, hold public hearings to receive science and policy recommendations, propose amendments to existing regulations, commit to issuing guidance or to reviewing the potential for synergistic effects during the registration review process, or do nothing. But potentially affected companies would be wrong to await a formal invitation before raising their concerns about the petition with the Agency and other policy makers.

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