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ALERT

EPA Considering Petition to Require Submittal of Efficacy Data for Neonicotinoids and Other Systemic Insecticides

December 11, 2023

On November 24, 2023, the U.S. Environmental Protection Agency (EPA) announced that it is accepting comments on a petition for rulemaking submitted by the Public Employees for Environmental Responsibility (PEER), the American Bird Conservancy (ABC), and several other groups. The petition asks EPA to amend regulations implementing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to require submission of efficacy data for neonicotinoid insecticides and other systemic insecticides (both for existing and any pending or future registrations) and to review currently registered products in view of that data. Comments are due by **January 23, 2024**. The full petition for rulemaking can be found in the docket at EPA-HQ-OPP-2023-0428.

The requested change would be a paradigm shift in how EPA evaluates a large percentage of the pesticide products it registers and would create significant administrative burdens on EPA. Against the backdrop of EPA's longstanding procedure for evaluating registration applications, the petition in effect challenges the rationality of EPA's prior registration decisions for a large number of widely used pesticide products. Neonicotinoid insecticides include clothianidin, thiamethoxam, and imidacloprid. Systemic pesticides are chemicals absorbed by an organism that make the organism toxic to pests; they include fipronil, flupyradifurone, and sulfoxaflor. Petitioners do not define the extent of what active ingredients would be considered "systemic insecticides" for purposes of their proposal, though they do reference a list maintained by a third party. *See* Xerces Society's "Systemic Insecticides List."

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EPA currently only requires submittal of efficacy data (i.e., data concerning how a pesticide product performs against target pests) for a subset of pesticides, notably antimicrobial pesticides and pesticides that claim to control public health pests. Most agricultural pesticides do not fall into these groups and, as such, while registrants are expected to possess data showing that their products are efficacious when used in accordance with label directions, they need not submit that data to obtain, or maintain, a registration unless EPA requires it on a case-by-case basis.

The petition suggests that the Petitioners believe that efficacy data will, at best, show that neonicotinoids and other systemic insecticides are overused and, at worst, that they are not effective at all. However, as EPA explained when first establishing the waiver for most efficacy data almost 40 years ago, EPA would request submittal of efficacy data on a case-by-case basis if a risk analysis (based on the ecotoxicological, human health, and environmental fate data that EPA does require) showed "substantial" risk to humans or the environment. In cases where EPA determined the risks were "substantial" (so great that EPA might determine the product "ought not be registered at all"), EPA reserved the right to require efficacy data to confirm whether the FIFRA registration standard was met. *See* 49 Fed. Reg. 42,856, 42,880 (Oct. 24, 1984). The petition currently before EPA, therefore, may also be understood as seeking a determination from EPA that neonicotinoids and other systemic insecticides carry risks "of such a magnitude that it is presumed they ought not be registered at all" absent evidence of substantial benefits from their use which can only be confirmed – in the Petitioners' view – through review of efficacy data.

The precise types of efficacy data the Petitioners are seeking to require within "180 days of promulgation of this Rule" is unclear. Thus, if EPA is inclined to grant the petition in some form, EPA would need to confirm the specific studies that it would require for particular product classes and confirm the associated testing guidelines, which would take substantial time.

Separately, the petition proposes regulatory language setting forth that EPA will, after considering the efficacy data, "not register [or cancel] any neonicotinoid or other systemic insecticide that lacks a demonstration that its benefits exceed its environmental and overall costs." This proposed text appears to deviate materially from the statutorily-established FIFRA registration standard (7 U.S.C. 136a(c)(5)) which speaks in terms of guarding against unreasonable adverse effects – itself a statutorily defined term. Regulations, of course, cannot amend statutes, but the Petitioners' proposed gloss on the FIFRA registration standard would likely lead to needless confusion.

In sum, the petition asks EPA to do something EPA is already statutorily obligated to do: obtain and review data as necessary to confirm that pesticides meet the statutory standard for registration in FIFRA. EPA has stated that it will, when necessary, ask for and review efficacy data. The petition effectively seeks a special review process for a targeted group of products which is based on the Petitioners' presumption that EPA improperly registered them in the first place because it could not have done so rationally without access to efficacy data.

As noted above, comments are due by **January 23, 2024**. Registrants should consider commenting to encourage EPA to reject the petition as unnecessary in view of EPA's established practices and existing regulations or, if EPA is inclined to grant the petition in some form, to correctly recognize the scale and timeline of the guideline development and validation process.