EPA Seeks Comment on its Risk Assessment Methodology for Evaluating Potential Synergistic Effects of Pesticides on Non-Target Organisms

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On September 9, 2019, the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) published a notice in the Federal Register announcing the availability of, and an opportunity for comment on, a document describing an “interim process” that OPP’s Environmental Fate and Ecological Effects Division is currently using to evaluate potential synergistic effects of mixtures of pesticide active ingredients on non-target organisms. As part of a lawsuit challenging the 2012 decision by EPA to register Enlist Duo Herbicide (a combination of 2,4-D and
glyphosate), OPP scientists learned that patent applications for some registered pesticide products included claims that particular combinations of active ingredients provide “synergistic” control of target species. Although EPA was not at that time considering potential synergies in assessing the risk for ecological effects on non-target organisms, based on the patent application claims regarding synergy for Enlist Duo, EPA decided to request that the reviewing court vacate its registration decision and remand the application for Enlist Duo for further study of these effects and any measures that might be needed to mitigate the risk to non-target organisms. This decision sparked much controversy, and many in industry were concerned that patent application claims were not being correctly interpreted by EPA for the category of pesticide products at issue.

The new document released by EPA for review and comments is entitled: “Process for Receiving and Evaluating Data Supporting Assertions of Greater Than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants.” EPA states that it “has generally been applying this interim process since 2016.” The process described in the document has five steps: (1) registration applicants must search for any granted patents that include synergy (GTA) claims for combinations of pesticides; (2) applicants must review the patent claims and supporting data for relevance to ecological risk assessment; (3) applicants must report to EPA all effects testing data from the relevant patents; (4) applicants must do a statistical analysis (using a method prescribed by EPA) to determine whether any observations of GTA effects are statistically significant; and (5) EPA will review all submitted information to decide whether it should be utilized in ecological risk assessment.

In the Federal Register notice, OPP lists five specific areas pertaining to the interim risk assessment process described in the document on which it is requesting comment:

- Are there technical aspects of the interim process that warrant change? If so, what changes are recommended?
- What aspects of the process could be applied to the evaluation of open literature sources of GTA effects pesticide interactions?
- Should EPA consider standardizing a more detailed search and reporting approach, and how should EPA do that?
- Should EPA continue the evaluation process as described in this document? If so, what performance metrics (e.g., number of evaluations) should EPA consider before deciding the utility of this approach?
- What applicant burden is associated with the activities described in this memorandum, including compiling, analyzing, and submitting the information? Specifically, does an estimate of 80-240 hours of burden per applicant cover the respondent burden associated with the interim process?

When the National Research Council (NRC) evaluated the importance of toxicological interactions between pesticide active ingredients in 2013, the NRC concluded that such interactions are rare, but that EPA should nonetheless consider
such interactions when the best available scientific evidence supports such an evaluation. In the current Federal Register notice, EPA makes it clear that it is uncertain concerning the utility for risk assessment of the information used by manufacturers to support synergistic effects claims in pesticide patents. According to EPA, 24 applicants for new registrations have submitted patent data to date, but only three of these submissions contained information that indicated a need for further testing and no submission ultimately led to any adjustment of the ecological risk assessment. At this juncture, EPA will continue collecting patent data that may be pertinent to GTA effects, but when it has sufficient experience upon to base a general policy it may either continue or improve this process or discontinue it after explaining why.

Commentary

When EPA requested that the reviewing court vacate and remand the registration EPA had granted for Enlist Duo, the parties seeking judicial review located data in the patent applications that EPA had not previously seen or reviewed and that EPA believed could possibly be pertinent to potential adverse effects on non-target plants. EPA concluded that it should revisit the decision based on the additional data. Although EPA decided to request vacatur and remand, the applicant Dow AgroSciences had arguably followed all of the procedures then in place, because FIFRA Section 3(c)(5) allows EPA to waive data requirements pertaining to efficacy, and EPA typically registers pesticide product that are not intended to protect public health without any independent evaluation of efficacy data. Nevertheless, in general EPA may choose to evaluate pesticidal efficacy data; such circumstances in the past often involved cases where EPA was required to consider whether pesticide benefits are sufficient to outweigh identified risks. In the Enlist case, EPA determined that it should do so where potential synergy in pesticidal efficacy is pertinent to evaluating ecological effects on non-target species.

What EPA must decide now is how often efficacy data that has been deemed adequate by the Patent and Trademark Office to support a patent for a new pesticide mixture will have any material significance in the context of ecological risk assessment. Before EPA makes a determination whether or not patent data has sufficient pertinence to continue requiring routine collection and evaluation of such data, EPA has decided it is prudent to afford all stakeholders an opportunity to comment on whether EPA has been asking the right questions.

All comments on the draft document must be submitted no later than October 24, 2019.

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