

EPN Comments on Notice: Petition Seeking Rulemaking to Modify Labeling Requirements for Pesticides and Devices

Docket No.: EPA-HQ-OPP-2024-0562 February 20, 2025

The Environmental Protection Network (EPN) harnesses the expertise of more than 650 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

On January 21, 2025, EPA published a Notice in the Federal Register announcing the opportunity for the public to comment on a petition filed by the State Attorneys General from eleven states¹. As explained in the Notice, the petition asks EPA to "modify its requirements such that any state labeling requirements inconsistent with EPA's findings and conclusions from its human health risk assessment on human health effects, such as a pesticide's likelihood to cause cancer, birth defects, or reproductive harm, constitute misbranding." EPN believes that EPA should not undertake the requested rulemaking for several reasons, which are summarized in the following comments:

- 1. The requested rulemaking would be legally vulnerable to the extent that it purports to interpret the definition of "misbranded" in The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) sec. 2(q) but does not relate the rule's provisions to the specific elements of the definition. For example, the rule should not be written so broadly as to preclude the inclusion of factual statements about the hazards or risks of ingredients in pesticides, unless EPA can show how those factual statements are misleading.
- 2. The requested rulemaking may not be necessary. Because FIFRA already clearly prohibits states from imposing labeling requirements on pesticide registrants, the only real change advocated by petitioners has to do with state failure-to-warn product liability lawsuits. For more than 50 years, both EPA and States have had the authority to interpret what constitutes misbranding of a pesticide product, and this shared jurisdictional authority has worked well. It seems unnecessary to change fundamentally this successful allocation of authority between EPA and States. Moreover, the petitioners offer as a rationale for their requested rule the controversy over the carcinogenicity of glyphosate and whether pesticides containing glyphosate should have labels warning of that hazard. Although not expressly stated, the petitioners seemingly are interested in blocking state tort actions premised on a "failure to warn" against glyphosate's potential to cause cancer. Absent any other example, it seems particularly unwise to base a broad rulemaking to address a perceived problem that concerns only a single pesticide.
- 3. If the rulemaking were successful in blocking tort lawsuits premised on a "failure to warn" about the hazards or risks of a pesticide, it would effectively deprive many users farmers and others who

¹⁹⁰ FR 7037

are injured by harmful pesticides of any way to be made whole, since FIFRA does not create a private right of action against pesticide registrants.

- 4. There is a need for States to be able to address shortcomings in EPA's risk assessments and regulatory decisions. Although EPN believes EPA generally makes sound scientific judgments about the hazards and risks of pesticides, EPA risk assessments may be out-of-date or may be based on incomplete information. Although rare, as former EPA employees, we are aware that these situations have caused EPA's risk assessments not to reflect the best scientific understanding of a pesticide's ability to pose risks. Moreover, given the huge workload of conducting the registration review program and processing thousands of applications, it often takes EPA a long time to act. Many States have the ability to act more quickly than the federal government and they should not be constrained in how they protect their citizens. The clear sense of FIFRA sec. 24(a) is to preserve such State authority.
- 5. The requested rulemaking seems unlikely, however, to completely block tort lawsuits premised on a failure to warn about dangerous pesticides. Although it might protect registrants from having to add unwanted warnings to their product's labeling, it would not preclude failure to warn lawsuits since there are other ways pesticide defendants could provide warnings, e.g., through advertising or point-of-sale notifications.
- 6. There could be large unintended, negative consequences from adopting this rule. Currently, EPA's pesticide risk assessments during registration review do not constitute final agency action because, under FIFRA, the agency must first make a regulatory determination that may require some modification of the pesticide's registration. Therefore, registration review risk assessments are not subject to judicial review. External stakeholders who disagree with EPA's risk assessments cannot go to court without first filing a petition or waiting for the agency to reach a decision in the registration review process. Adopting the requested rule would, however, change the status of a risk assessment. Because a risk assessment would place limitations on what is considered acceptable labeling, it would have immediate regulatory effect. Consequently, it is likely that a court might be willing to consider a challenge to the adequacy of the agency's risk assessment. This possibility could mean that EPA will find itself in court more often and that its risk assessments will receive much closer scrutiny.

In addition, EPA may find itself with more work to address frequent petitions to revise its risk assessments. Whatever the merits of the proposed rule might be when applied to a recent EPA risk assessment that has considered all relevant information, those merits begin to look very different when new information becomes available, or where information may have been wrongfully withheld by registrants under section 6(a)(2). If EPA adopts the requested rule and thereby limits potential plaintiffs from bringing tort cases notwithstanding the fact that EPA's risk assessment may no longer be current or may have been flawed from the outset, such parties will have strong incentives to seek changes to the risk assessment. EPA may be presented with numerous petitions to revise their existing risk assessments (with the accompanying threat of unreasonable delay lawsuits if EPA fails to act in a timely manner). The scientific community around the world is constantly conducting and publishing the results of research on pesticides. We have seen such reports frequently, sometimes as often as weekly. Stakeholders could easily argue that EPA should evaluate each new study to determine how it affects the agency's existing risk assessment. And while 6(a)(2)-related petitions may be rare (because the existence of such information may be difficult to uncover), it is possible

that the discovery associated with tort litigation may uncover information that should have been provided to EPA under section 6(a)(2) and should have been included in the agency's risk assessments. In sum, although it is incumbent on EPA to consider all relevant, sound scientific information, and to keep its risk assessments up to date, responding substantively to these petitions – even ones involving studies that do not change the conclusions of the risk assessment – could impose a significant additional burden on the already overworked staff of the agency.

7. The petition states EPA's regulations that implement "FIFRA already requires that a label include EPA's toxicity findings and EPA's required 'signal' word for toxicity categories. The same should hold true for EPA's other health-related findings." If this means that pesticide labeling should contain the agency's risk conclusions, EPA will need to consider many new policy positions: which kinds of hazards should be the subject of label warnings, how the existence of a hazard relates to risk, whether there should be warnings that concern the risks from misuse, and more. Overall, EPA will need to consider whether adding such text will promote safe and effective use of pesticides.