EPA-EVALUATED AND APPROVED LABELS SHOULD SUFFICE IN CIVIL LITIGATION RELATED TO PESTICIDE LABELING

Pesticides are among the most highly-regulated products on the market. Before any pesticide can be sold, its manufacturer must obtain pre-market approval from the U.S. Environmental Protection Agency (EPA) as part of a robust registration process that confirms human health and safety and includes approval of the labeling in accordance with strict federal requirements. The pesticide also must be registered with the North Dakota Department of Agriculture prior to sale.

Despite adhering to these strict requirements and regulatory approvals, pesticide manufacturers and sellers are often subject to lawsuits challenging the adequacy of EPA-approved labels. Companies typically win the cases, but the cost of defending such claims is substantial. And there is extreme unpredictability in the courts, even as to claims that are essentially identical. Some plaintiffs have obtained "nuclear verdicts" totaling hundreds of millions of dollars in recent cases.

Case-by-case outcomes undermine the decision-making of expert regulators charged with protecting the public. Further, tort lawsuits involving EPA-approved labels can negatively impact the availability of pesticides, both as to products on the market now and with respect to the development of next-generation products. To offset high litigation costs, pesticide manufacturers may be forced to raise the price of their products, hitting farmers in the pocketbook. Consumers, in turn, have to pay more for farm products, hitting their pocketbooks too.

EPA experts have specialized knowledge, access to broad information, and the time and resources to carefully study the relevant science and literature in-depth; this allow them to reach the most informed decisions. A manufacturer or seller of a pesticide should not be subject to liability for using a label that has been approved by EPA or that is consistent with the EPA's most recent human health assessment or carcinogenicity classification for the pesticide.

Pesticide Regulation

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) establishes a comprehensive statutory scheme that governs the use, sale, and labeling of pesticides.[1] Pesticides are "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; or intended for use as a plant regulator, defoliant, or desiccant."[2] Thus, pesticide products include insecticides to kill bugs; rodenticides to kill rodents; fungicides to protect against fungus, mold or mildew; and herbicides for weeds.

FIFRA prohibits pesticides that pose unreasonable risks to humans, animals, or the environment.[3] Before a new pesticide can enter the market, EPA conducts both a human health risk assessment and an ecological risk assessment. During this process, EPA requires manufacturers to submit extensive test data and the agency evaluates scientific literature, such as epidemiological studies. EPA also evaluates carcinogenicity potential when a pesticide is proposed for registration.[4] It is illegal for a pesticide manufacturer to knowingly falsify an application for registration,[5] falsify testing information,[6] or knowingly submit false data in support of registration.[7]

FIFRA also requires EPA to determine that the pesticide's "labeling … compl[ies] with the requirements of [FIFRA]."[8] According to EPA, "The label on a pesticide package or container and

[1] 7 U.S.C. § 136 et seq.
[2] 40 C.F.R. § 152.3.
[3] EPA, *About Pesticide Registration*, https://www.epa.gov/pesticide-registration/about-pesticide-registration.
[4] EPA, *Evaluating Pesticides for Carcinogenic Potential*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential.
[5] 7 U.S.C. § 136j(a)(2)(M).
[6] 7 U.S.C. § 136j(a)(2)(Q).
[7] 7 U.S.C. § 136j(a)(2)(R).
[8] 7 U.S.C. § 136a(c)(5)(B).

the accompanying instructions are a key part of pesticide regulation. The label provides critical information about how to handle and safely use the pesticide product and avoid harm to human health and the environment."[9]

Federal regulations provide specific requirements for pesticide labels.[10] Registrants must submit both a proposed and final label to the EPA. EPA must review and approve the labeling.[11] Based on its safety assessment, EPA may require a product's labeling to feature specific health and safety statements or personal protective equipment requirements.[12]

EPA's Office of Pesticide Programs includes experts who are specifically trained to review labels based on science to ensure that pesticide labels adequately communicate directions and precautions. EPA explains:

> We [EPA] review pesticide product labels as part of the licensing/registration process and must approve all label language before a pesticide can be sold or distributed in the United States. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment.[13]

EPA oversight does not end when a label is approved and a pesticide is registered for sale. After a pesticide is registered, EPA regulations require pesticide registrants to report any new adverse effects within 30 days,[14] including harmful effects and scientific studies such as an epidemiological study showing "that a correlation may exist between exposure to a pesticide and observed adverse effects in humans."[15] EPA can immediately suspend or can cancel registration of a pesticide when serious risks are identified.[16]

Finally, FIFRA requires EPA to complete a full reassessment of each registered pesticide at least every 15 years to determine whether the pesticide continues to meet FIFRA's registration requirements.[17]

In addition to federal regulation, North Dakota requires every pesticide sold in the state to be registered with the Commissioner of Agriculture.[18] Before approval, a registrant must submit the "current label of each product to be registered."[19]

The Legislation

The bill provides that the warning label on a pesticide that is registered with the Commissioner of Agriculture or EPA is sufficient to satisfy any state-law duty to warn if the label is (1) approved by EPA; (2) consistent with the most recent human health assessment performed by EPA under FIFRA, or (3) consistent with the EPA's carcinogenicity classification for the pesticide under FIFRA.

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[9] EPA, *Pesticide Registration, Labeling Requirements*, https://www.epa.gov/pesticide-registration/labeling-requirements.
[10] 40 C.F.R. Part 156.
[11] 7 U.S.C. §136a(c)(5)(B).
[12] 40 C.F.R. §§156.60-156.70; 156.10(i)(1), (2).
[13] EPA, *About Pesticide Registration*, https://www.epa.gov/pesticide-registration/about-pesticide-registration#label.
[14] 40 C.F.R. § 152.125; 40 C.F.R. § 159.155; EPA, *Incident Reporting by Pesticide Manufacturers/ Registrants*, https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants.
[15] 40 C.F.R. § 159.170.
[16] 7 U.S.C. §§ 136d(c)(3), 136d(b).
[17] 7 U.S.C. § 136a(g)(1)(A).
[18] N.D. Cent. Code § 4.1-34-03.
[19] *Id*. at § 4.1-34-03(1)(c).

Legal Analysis

The bill provides narrow liability protection that will apply only to lawsuits challenging the adequacy of the warning label on government-approved pesticides, such as product liability actions claiming that the product's label should have warned of a particular health risk.

The bill would not apply to any claim that is unrelated to the pesticide's label. For example, the bill would not preclude a lawsuit alleging that a different formulation may have been as effective but less risky (i.e., a design defect claim). A manufacturer could be sued if a contaminant in a bad batch of its product causes crop losses (i.e., a manufacturing defect claim). Claims that a pesticide did not work as advertised are not precluded either. The bill would also not impact a negligence claim alleging that a pesticide was misapplied by an applicator and caused harm to a neighboring farmer's crops.

The Public Policy Need

The legislation will prevent unfounded lawsuits involving pesticides that bear a label that has been evaluated and approved by EPA or that is consistent with the EPA's most recent human health assessment or carcinogenicity classification for the pesticide under FIFRA. The bill respects the decision-making of experts based on sound science.[20]

Given the extensive use of and critical role of pesticides in modern agriculture, these products must remain available and affordable to farmers and others who utilize them, such as in agricultural operations. Pesticides increase agricultural efficiencies in a market faced with rising demand for food products.

Failure-to-warn claims negatively impact the agricultural community as they can make needed products unavailable or result in redirection of funds that could be used for researching and developing next-generation products to cover unwarranted litigation costs.

Finally, the legislation would help reduce costs for farmers and consumers.

[20] One federal appellate court has held that once EPA approves a pesticide's label, federal law bars any civil action alleging that the product should have had a different label. *Schaffner v. Monsanto Corp*., 113 F.4th 364 (3d Cir. 2024); *but see Carson v. Monsanto Corp*., 92 F.4th 980 (11th Cir. 2024); *Hardeman v. Monsanto Corp*., 997 F.3d 941 (9th Cir, 2021), *cert. denied*, 142 S. Ct. 2834 (2022).