CLIENT ALERT

EPA Rebuffs California Prop 65 Glyphosate Labeling

Aug.20.2019

On Wednesday, August 7, the United States Environmental Protection Agency (EPA) notified pesticide and herbicide registrants that it will no longer approve or permit labeling of glyphosate-containing products that include California's Proposition 65 (Prop 65) warnings. EPA's announcement includes both a discussion of its own thorough evaluation of the medical and scientific evidence and a powerful rebuke to the International Agency for Research on Cancer's (IARC) 2015 classification of glyphosate as "probably carcinogenic to humans." At bottom, it throws a wrench into plaintiff personal injury lawsuits against Monsanto Company[1] alleging failure to warn of glyphosate's carcinogenicity.

California listed glyphosate under Prop 65 as a substance "known to the state to cause cancer" based on IARC's 2015 monograph. IARC's determination sparked a wave of tort litigation against Monsanto, in which plaintiffs allege they developed non-Hodgkin's lymphoma or other blood cancers as a result of exposure to the company's glyphosate-containing herbicide, Roundup®.

Following IARC's assessment, EPA conducted its own independent evaluation and concluded in 2017 that glyphosate is "not likely to be carcinogenic to humans." EPA notes its evaluation is based on a more extensive dataset than IARC's and is consistent with the determinations of numerous other international regulatory authorities and expert panels.

In its August 7 notice, EPA emphasizes that, based on its comprehensive review, "EPA disagrees with IARC's assessment of glyphosate." Given its conclusion that glyphosate does not pose a cancer risk, the EPA notice advises registrants that it considers Prop 65 warning language on glyphosate product labels to be "false and misleading." Accordingly, a glyphosate-containing product bearing the Prop 65 glyphosate warning language would be "misbranded" in violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In light of this decision, EPA will not approve labeling that includes the Prop 65 warning language, and registrants whose products currently include Prop 65 glyphosate warnings must submit amended labeling within 90 days of the August 7 notice.

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) responded on August 13 with a cursory statement defending its Prop 65 listing of glyphosate. OEHHA notes its reliance on IARC and denigrates EPA's position on labeling while simply ignoring the thorough reviews conducted by EPA and numerous other agencies worldwide. Thus, while touting that Prop 65 "ensures consumers receive accurate, science-based information," OEHHA is curiously silent in failing to address the extensive science behind the EPA notice.

While EPA's disagreement with IARC has been known for several years, its decision to prohibit Prop 65 warnings regarding glyphosate's carcinogenicity is a new and aggressive step, and a potential evidentiary and legal blow for plaintiffs' attorneys. Plaintiffs in the Roundup® cases routinely assert failure to warn claims, including the three plaintiffs who have secured jury verdicts against Monsanto to date.EPA's notice and enforcement of FIFRA, however, suggests that state law claims alleging the necessity for carcinogenicity warnings may not be viable pursuant to the doctrine of federal preemption. FIFRA does not permit

states to impose "any requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b).United States Supreme Court and other rulings have significantly reduced the impact of FIFRA's preemption language in recent years. But the new EPA determination will likely prompt a round of vigorous motions in the Roundup® litigation to determine whether the express position of EPA will now suffice to preempt state law warning claims.

This new circumstance will necessarily impact future court rulings on preemption issues, both in Roundup® trials to come and in appeals of rendered verdicts. The issues of general and specific medical causation will also be impacted because the determination of the controlling federal agency could be vigorously asserted as part of Monsanto's defense. The EPA position statement also escalates the criticisms by scientists and others of IARC's increasingly aggressive positions on carcinogens, which are driving several mass tort litigations today.

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[1] Now a Bayer AG subsidiary

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