On August 7, 2019, EPA took long awaited action concerning the inclusion of Prop 65 warning statements for glyphosate on EPA registered pesticide labels, which will likely impact the broader ongoing debate over EPA approval of Prop 65 warnings on pesticide labels. EPA's August 7, 2019, letter to glyphosate registrants states that EPA “will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products.” EPA stated further that “[t]he
warning statement must also be removed from all product labels where the only basis for the warning is glyphosate and from any materials considered labeling under FIFRA for those products.” Moreover, EPA unequivocally states that “pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded” under FIFRA Section 2(q)(1)(A). Registrants with glyphosate products currently bearing Prop 65 warning language, where the exclusive basis for such warning is based on the presence of glyphosate, must submit draft amended labeling that removes this language by **November 5, 2019**.

By way of background, California’s Office of Environmental Health Hazard Assessment (OEHHA) listed glyphosate as a chemical known to the state of California to cause cancer on July 7, 2017. OEHHA’s listing of glyphosate as a substance under Prop 65 is based on the International Agency on the Research for Cancer (IARC) classifying it as “probably carcinogenic to humans.” EPA scientists subsequently completed an independent review of the available scientific data on the potential carcinogenicity of glyphosate and do not agree with the IARC classification.

Also of note is a February 26, 2018, preliminary injunction issued by the U.S. District Court for the Eastern District Court of California, in response to a motion filed by a coalition including Monsanto, CropLife America, and several growers associations alleging that the IARC classification decision for glyphosate is contrary to the international scientific consensus, that the required Prop 65 warning would be misleading to the ordinary consumer, that compelling the manufacturers of glyphosate to provide such a warning would violate the First Amendment because the warning is not factual and uncontroversial, and that the applicable criteria for injunctive relief were met. The February 26, injunction precluded OEHHA from enforcing its Prop 65 warning requirements against glyphosate registrants that otherwise would have taken effect on July 7, 2018. The Court did not rule that glyphosate should be removed from the Prop 65 list as a chemical known to the State of California to cause cancer, but did state that products containing glyphosate would not be required to comply with the warning requirements. In issuing the preliminary injunction, the Court stated that the required warnings are “false and misleading” and that plaintiffs “have shown that they are likely to succeed on the merits of their First Amendment claim, are likely to suffer irreparable harm absent an injunction, and that the balance of equities and public interest favor an injunction, the court will grant plaintiffs’ request to enjoin [Prop 65]’s warning requirement for glyphosate.” More information on that case is available [here](#). That injunction has not been appealed and remains in place.

Although the glyphosate warning that EPA has refused to allow is based on OEHHA’s recent listing under Prop 65, Prop 65 warnings on pesticide labels generally have been a significant issue since 2016 when OEHHA issued revised regulations regarding the content and transmission of Prop 65 warnings. As a result of these revisions, many registrants sought to add Prop 65 warning requirements to pesticide labels to meet Prop 65 requirements, but many registrants have not been able to obtain EPA approval for such warnings, resulting in much controversy and discussion.

In its [press release](#) announcing its guidance to glyphosate registrants, EPA
Administrator Andrew Wheeler states: “It is irresponsible to require labels on products that are inaccurate when EPA knows the product does not pose a cancer risk. We will not allow California’s flawed program to dictate federal policy.” EPA states that its “independent evaluation of available scientific data included a more extensive and relevant dataset than IARC considered during its evaluation of glyphosate, from which the agency concluded that glyphosate is ‘not likely to be carcinogenic to humans.’” Wheeler is further quoted as stating: “It is critical that federal regulatory agencies like EPA relay to consumers accurate, scientific based information about risks that pesticides may pose to them. EPA’s notification to glyphosate registrants is an important step to ensuring the information shared with the public on a federal pesticide label is correct and not misleading.”

OEHHA immediately released its own press release on August 13, 2019, in which it “objects to US EPA’s characterization of any warning concerning glyphosate’s carcinogenicity as a false claim.” After reiterating OEHHA’s listing glyphosate based on the IARC determination, OEHHA states that EPA’s position “conflicts with the determination made by IARC” and that “it is disrespectful of the scientific process for US EPA to categorically dismiss any warnings based on IARC’s determinations as false.”

**Commentary**

The Court’s February 26, 2018, preliminary injunction was considered a significant development both for glyphosate specifically and perhaps for Prop 65 warning requirements generally, especially considering the recent influx to EPA of label amendments seeking EPA approval of revised Prop 65 warning language to address OEHHA’s revised regulatory changes. EPA’s guidance is equally significant, as EPA has now rejected the inclusion of a Prop 65 warning that EPA believes is misleading on a federal pesticide product label.

FIFRA Section 24(b) expressly prohibits any State from requiring any label language for a registered pesticide product beyond the labeling approved by EPA, and EPA has now declined to approve pesticide labeling that includes the Prop 65 warning for glyphosate. In some instances, EPA has been willing as a courtesy to approve labeling changes requested by a State, but the glyphosate determination demonstrates that EPA will not accept any label revisions that conflict materially with its own determinations. Although glyphosate is a fairly complex and controversial case, it will be important for registrants to monitor the evolution of EPA’s standard for when it will or will not approve a Prop 65 warning on a federal label, since this issue has been the subject of considerable controversy over the past several years.

©2020 Bergeson & Campbell, P.C.