

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 7, 2019

Dear Registrant,

We are writing to you concerning label and labeling requirements for products that contain glyphosate.

On July 7, 2017, California listed glyphosate as a substance under Proposition 65¹, based on the International Agency for Research on Cancer's (IARC's) classification of the pesticide as "probably carcinogenic to humans." EPA disagrees with IARC's assessment of glyphosate. EPA scientists have performed an independent evaluation of available data since the IARC classification to reexamine the carcinogenic potential of glyphosate and concluded that glyphosate is "not likely to be carcinogenic to humans." EPA considered a more extensive dataset than IARC, including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review. For more detailed information on this evaluation, please see the 2017 Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential². Further, EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

On February 26, 2018, the United States District Court for the Eastern District of California issued a preliminary injunction enjoining California from enforcing the state warning requirements involving the pesticide glyphosate's carcinogenicity, in part on the basis that the required warning statement is false or misleading³.

Given EPA's determination that glyphosate is "not likely to be carcinogenic to humans," EPA considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading statement. As such, pesticide products bearing the Proposition 65 warning statement due to the presence of glyphosate are misbranded pursuant to section 2(q)(1)(A) of FIFRA and as such do not meet the requirements of FIFRA. In registering pesticides, EPA must determine that the labeling complies with the requirements of FIFRA including that the product

¹ California's Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65) requires businesses to inform Californians about significant exposures to chemicals that, under the terms of Proposition 65, are believed to cause cancer, birth defects or other reproductive harm. See California Office of Environmental Health Hazard Assessment, "Proposition 65," at https://oehha.ca.gov/proposition-65.

² https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073

³ National Association of Wheat Growers, et al. v. Zeise, 309 F.Supp.3d 842 (E.D.Cal.)

not be misbranded. See FIFRA 3(c)(5)(B). Therefore, EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products. The 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.

For any pesticide product that currently contains Proposition 65 warning language exclusively on the basis that it contains glyphosate, EPA requests the submission of draft amended labeling that removes such language within ninety (90) days of the date of this letter.

Sincerely,

Michael L. Goodis,

Director, Registration Division
Office of Pesticide Programs