

New Evaluations Confirm Glyphosate Not Carcinogenic to Humans

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Glyphosate is the most widely used herbicide in the world. Paired with glyphosate-tolerant crops, it is a mainstay of ecologically beneficial no-till agriculture worldwide. Regulatory assessments for years have concluded that glyphosate has a generally benign toxicological profile. Notwithstanding consistent findings by regulatory agencies from around the globe that glyphosate is relatively non-toxic, the International Agency for Research on Cancer (IARC) in 2015 issued a monograph that classified glyphosate as a probable human carcinogen. This categorization was immediately challenged by a number of competent risk assessment agencies, including the European Union European Food Safety Authority (EFSA) and the German Federal Institute for Risk Assessment (BfR). The U.S. Environmental Protection Agency (EPA) also confirmed its previous assessments finding that the existing data provide no basis to conclude that glyphosate is a human carcinogen. Both BfR and EPA have recently issued updated assessments confirming that a growing body of data do not support any findings that glyphosate is a carcinogenic risk to humans. In addition, the overwhelming global regulatory consensus contradicting the IARC classification was recently recognized by a U.S. District Court in granting a preliminary injunction against the State of California requiring that glyphosate-containing products carry a Prop 65 warning that glyphosate “is known by the State of California to cause cancer.”

On February 27, 2018, EPA opened a 60-day public comment period on its draft glyphosate human health risk assessment, which included a comprehensive evaluation of the existing data relevant to the determination of the carcinogenic potential of glyphosate. This included an assessment of existing epidemiological data, animal

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carcinogenicity studies, and genotoxicity studies related to glyphosate. In addition, EPA considered the comments of the 2016 FIFRA Scientific Advisory Panel that evaluated charge questions regarding potential human health effects of glyphosate. Based on a weight of the evidence evaluation, EPA's glyphosate human health risk assessment concluded that glyphosate should be classified as "not likely to be carcinogenic to humans." The draft glyphosate human health risk assessment is available [here](#). The draft glyphosate human health risk assessment is part of the regular pesticides Registration Review process. EPA has stated that it will publish its proposed glyphosate Registration Review decision in 2019. The comment period on the draft risk assessment provides interested parties with an opportunity to weigh in on EPA's ultimate regulatory finding regarding continued registration of glyphosate-containing products.

On December 22, 2017, BfR released Communication No. 036/2017, titled "Glyphosate: New epidemiological study finds no connection between cases of cancer and use of plant protection products containing glyphosate", which is based on BfR's assessment of a new study published in the *Journal of the National Cancer Institute*, which evaluates data generated by the U.S. Agricultural Health Study (AHS) – an epidemiological study of over 89,000 farmers and their spouses in Iowa and North Carolina that, starting in 1993, has evaluated prospectively the incidence of cancers and other health outcomes in pesticide applicators and those in close contact with them. Based on the updated analysis of AHS epidemiological data, the study published in JNCI concludes that these data do not support a finding of a statistical association between the use of glyphosate-containing products and the occurrence of any type of cancers. BfR evaluated the data and conclusions presented in the study and concluded that it further weakens previous claims as to glyphosate's possible carcinogenic effects, and that "based on the estimation of the BfR and responsible authorities of the European Union" glyphosate should not be classified as carcinogenic to humans.

In addition to the recent EPA and BfR glyphosate carcinogenicity assessments, numerous regulatory bodies worldwide have assessed the potential carcinogenicity of glyphosate and reached conclusions inconsistent with the 2015 IARC classification. These include an April 28, 2017 regulatory determination by Health Canada that glyphosate is not genotoxic and is unlikely to pose a human cancer risk; a March 15, 2017 report by the European Chemicals Agency's Committee for Risk Assessment (RAC) that concludes that "[t]he available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction"; a finding by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in May of 2016 that glyphosate is "unlikely to be genotoxic" at anticipated dietary exposures and that it is "unlikely to pose a carcinogenic risk to humans from exposure through the diet"; EFSA's November 12, 2015, finding that glyphosate is unlikely to pose a carcinogenic hazard to humans and that consideration of the full database of toxicological evidence does not support classification of glyphosate with regard to carcinogenic potential; and BfR's March 23, 2015 statement responding to the IARC report that the classification of glyphosate as probably carcinogenic to humans "comes as a surprise, since other evaluations performed by supranational bodies such as the WHO-Panel of the Joint Meeting of Pesticide residues (JMPR, 2004), and also by national regulatory agencies such as the U.S.EPA had concluded the contrary, i.e., that glyphosate was not carcinogenic."

On February 26, 2018, the United States District Court for the Eastern District of California issued an injunction enjoining the State of California from requiring Prop 65 warnings related to glyphosate. *Nat'l Ass'n of Wheat Growers et al. v. Lauren Zeise, Director of the Office of Environmental Health Hazard Assessment*, Civ. No. 2:17-2401 (E.D. Calif., Feb. 26, 2018). The California Office of Environmental Health Hazard Assessment (OEHHA) had determined that IARC's classification of glyphosate as a probable human carcinogen compelled it to require warning under Prop 65 for glyphosate-containing products. OEHHA's determination was challenged and upheld in California state courts. Monsanto and a number of national crop growers associations then challenged the OEHHA action in U.S. District Court. The District Court ruled that requiring a Prop 65 warning related to glyphosate-containing products would be compelled commercial speech and would fail the first prong of the Supreme Court's *Zauderer* test in that such compelled warning would be neither factual nor uncontroversial. The required Prop 65 warning would not be factually accurate and uncontroversial because it "conveys the message that glyphosate's carcinogenicity is an undisputed fact, when almost all other regulators have concluded that there is insufficient evidence that glyphosate causes cancer." *Id.* at 15 (citing regulatory assessments by EPA, EFSA, ECHA, BfR, WHO, and, interestingly, OEHHA). While this decision on a motion for a preliminary injunction is not dispositive of the case, the Court necessarily found that plaintiffs are likely to succeed on the merits of their First Amendment argument. It bears paying attention as to whether this decision by the District Court in the Prop 65 case, which is based on the growing scientific and regulatory consensus that existing data do not support a finding that glyphosate is a human carcinogen, will be followed in the ongoing multi-district glyphosate products liability litigation in the U.S. District Court for the Northern District of California, where hundreds of cases have been consolidated that allege a causal connection between exposure to glyphosate and development of various cancers and the critical question now before the Court is whether plaintiffs meet the threshold established by the Supreme Court in *Daubert*.