Natural Resources Defense Council v. U.S. EPA—Ninth Circuit vacates 2020 Interim Registration Review decision for glyphosate in part and grants EPA's motion for remand without vacatur in part

In the mid-1990s, Monsanto Company began marketing Roundup Ready crop system that combines use of the chemical glyphosate and genetically modified crop seeds that tolerate the chemical's effects to eradicate all vegetation in the application area. This system greatly increased the utility of Roundup to agricultural producers and has enlarged its nationwide use to approximately 300 million acres. Glyphosate, however, also has engendered substantial controversy over its possible carcinogenetic relationship with non-Hodgkin's lymphoma.

The Environmental Protection Agency registered glyphosate in 1974 and began a registration review in accordance with 2007 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act in 2009. It eventually issued an Interim Registration Review Decision in 2020 that had three main parts. In the first, it concluded that a human-risk assessment "'determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans.'" This part further confirmed a prior ecological risk assessment "that 'potential risks of concern were identified for mammals and birds' as well as for 'terrestrial and aquatic plants.'" In the second part, the EPA set out a cost-benefit analysis in which it "reiterated that glyphosate poses potential risks to mammals, birds, and plants" but found that "'the benefits outweigh the potential ecological risks when glyphosate is used according to label directions.'" The third part set forth through labeling changes mitigation methods aimed at reducing potential ecological risks. The Interim Decision has been preceded by internal criticism during its development from the EPA's Office of Research and Development and subsequently, with regard to a draft paper entitled Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Cancer Paper), from "'many members'" of an agency-commissioned Scientific Advisory Panel. The EPA responded to SAP's criticisms by issuing a revised Cancer Paper relied upon in the Interim Decision. Under FIFRA, the agency must complete the registration review by October 1, 2022.

Various groups, including the Rural Coalition and the NRDC, petitioned for judicial review of the Interim Decision in the Ninth Circuit. The Rural Coalition "challenge[d] EPA's conclusions on human health and insists that EPA should have followed the [Endangered Species Act's] procedural requirements before issuing the Interim Decision. NRDC's petition primarily challenge[d] EPA's ecological risk assessment, cost-benefit analysis, and risk-mitigation requirements, though NRDC also asserts that EPA failed to address NRDC's comments on human-health risks made during the public-comment period." The panel agreed with the Rural Coalition that the EPA's human-risk analysis was unsupported by the administrative record, remanded, and vacated that portion of the Interim Decision. It also agreed that the agency had violated the ESA consultation requirements, remanded for consultation, but did not vacate that portion of the Decision. Lastly, the panel granted the EPA's motion to remand the "ecological portion" of the Decision without vacatur as to the NRDC's challenges. *Natural Res. Def. Council v. U.S. Env't Protection Agency*, Nos. 20-70787 & 20-70801, 2022 WL 2184936 (9th Cir. June 17, 2022).

As to the Rural Coalition's human-risk assessment attack, the panel accepted the Coalition's contention that the EPA's "not likely" descriptor did not comport with the Cancer Paper or the

2005 Guidelines for Carcinogen Risk Assessment. First, its choice of that descriptor "conflict[ed] with a determination EPA made earlier in the Cancer Paper" where the agency "explained that 'a conclusion regarding the association between glyphosate exposure and risk of NHL cannot be determined based on the available evidence.'" The Cancel Paper itself, moreover, selectively relied upon historical-control data in a manner inconsistent with the Guidelines, which counsel such use "both when the data bolster and when the data undermine studies' results" by "us[ing] [them] only to discount studies indicating that glyphosate may cause tumors." The Paper also ignored the Guidelines by relying on a pairwise comparison—which "asks whether tumor incidence in a treatment group was higher than in the control group"—but ignoring the results of a trend test—which "asks whether tumor incidences in all treatment groups increased as the glyphosate dose increased." Although Guidelines provide that statistical significance in either test "'is sufficient to reject the hypothesis that chance accounts for the result[,]'" the EPA "discount[ed] tumor incidences because those incidences were not statistically significant in pairwise comparison tests—when those same tumor incidences were apparently statistically significant using trend tests." Last, the Preliminary Decision invoked "the Cancer Guidelines' criterion that a chemical can be considered 'not likely to be carcinogenic' when there is 'convincing evidence that carcinogenic effects are not likely below a defined dose range.'" But this reliance failed to honor the Guidelines' instruction that use of this "not likely" descriptor is warranted only "'when the mode of action is sufficiently understood to conclude that a key event in tumor development would not occur below a certain dose range.'" Here, however, "the Cancer Paper provide[d] no explanation of any 'mode of action' indicating that tumors are not likely to occur below a certain glyphosate dosage range, nor [did] it offer two different hazard descriptors for dosages above and below that range."

Given that the "EPA's choice of a hazard descriptor is not supported by substantial evidence[,]" the question became whether remand without vacatur of the Interim Decision's human-health portion was appropriate. The panel began by stating that "[v]acatur is the traditional remedy for erroneous administrative decisions." It then examined those considerations that may counsel non-vacatur and concluded that the traditional remedy was proper. On that score, it reasoned that "no disruptive consequences will result from [vacatur] ... because that portion simply maintained the status quo—the Interim Decision imposed no new mitigation measures associated with human health." The panel additionally deemed vacatur "unlikely to risk environmental harm[,]" and, while recognizing that the EPA might reach the same conclusions on remand, observed that "the agency's explanation would need to be so different that we cannot make a confident prediction on this [non-vacatur] factor."

The panel next addressed the Rural Coalition's ESA failure-to-consult challenge. It first rejected Monsanto's contentions that the organization lacked Article III standing, that the agency's "recent consultation efforts moot this case[,]" and that the organization's objections had not been preserved during the public-comment period. On the mootness claim, the panel responded in part that "the allegedly unlawful behavior targeted by the petition is a failure to complete procedures required by the ESA before formally concluding whether and how glyphosate may be used consistent with FIFRA's safety standard, and that behavior still has not been rectified." The merits of the Coalition's claim were dependent upon "whether the Interim Decision is an 'action' that triggers the consultation procedures found in the ESA." Applying the Ninth Circuit test for ESA "agency action"—i.e., "whenever an agency makes a decision that is (1) affirmative and (2)

discretionary about whether, or under what conditions, to allow private activity to proceed"—the panel answered that question in the affirmative. It found the Interim Decision an "agency action" under this standard because through the Interim Decision the "EPA actively exercised its regulatory power, completing an assessment of glyphosate's risks under FIFRA and delineating what constituted acceptable glyphosate use under the statute's safety standard." Nonetheless, citing "the odd confluence of circumstances here," the panel determined not to order any relief for the ESA violation. It stated that "[a]lthough relief such as a consultation deadline could hasten EPA's compliance with the ESA (and thus we have held that the ESA claim is not moot), we believe that the FIFRA deadline to complete glyphosate's registration review by October 2022 is a sufficient backstop." It further declined to order the Interim Decision's vacatur because of ESA non-compliance, reasoning that "it is not clear that vacatur would be beneficial here. The Interim Decision includes certain mitigation efforts that EPA designed to limit the ecological impacts of glyphosate use."

As to the remaining issues—the NRDC's "challenges to the Interim Decision's ecological risk assessment, determination of glyphosate's costs, cost-benefit analysis, and mitigation requirements"—the panel exercised its discretion to grant the EPA's motion for a remand without vacatur to consider this "ecological portion" of the Decision. However, it also required the agency "to issue a new ecological portion by the October 2022 FIFRA deadline." It pointed out that, since neither the EPA nor Monsanto had responded to the NRDC's "ecological portion" challenges, "[i]f we were to evaluate the merits of NRDC's challenges, we first would want to request responsive briefs and to have oral argument on the ecological issues, raising the possibility that the FIFRA October 2022 deadline would arrive before we could complete our review." While hesitant "to reward what some might consider sloth or indolence, we also recognize that fully litigating the issues could result in an outcome nobody wants: more, and probably unnecessary, delay."

Decision link: https://cdn.ca9.uscourts.gov/datastore/opinions/2022/06/17/20-70787.pdf