NRDC v. EPA: Ninth Circuit Decision to Remand-Without-Vacatur in Part May Allow EPA to Re-register Glyphosate Despite Current Public Debate Regarding the Carcinogenic and Ecological Effects of Roundup Herbicide

I. OVERVIEW

The berries sitting on the grocery store shelf were likely treated with the chemical glyphosate before entering the supermarket.[1] Further down the aisle, the corn, soybean products, nuts, and various other vegetables, grains and fruits were probably treated with the same substance.[2] Beyond consumption, the chemical glyphosate is also used to address weed growth in parks, wildlife management areas, pastures, and is even applied before the harvest of your holiday Christmas tree.[3] As the active ingredient in Roundup Weed Killer, glyphosate has become one of the most common herbicides used by farmers in the United States.[4]

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) is tasked with registering pesticides before they are authorized for sale and distribution in the United States.[5] The EPA may authorize the registration of the

1. *See Glyphosate, Ingredients Used in Pesticide Products*, ENV'T PROT. AGENCY, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (last updated Sept. 23, 2022).
2. *See id.*
3. *Id.*
4. *Id.*
5. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a (2018).

pesticide if it determines that the pesticide does not cause "unreasonable adverse effects on the environment."[6] After a pesticide successfully registers under FIFRA, it must undergo registration review every fifteen years.[7] The EPA issued its Interim Decision to re-register glyphosate in 2020, considering both the ecological and carcinogenic effects of the chemical's application prior to reaching its determination.[8] The EPA's preliminary ecological risk assessment of glyphosate concerning its effects on "non-target organisms" determined that the chemical "may pose certain risks to mammals and birds" and "may adversely affect terrestrial and aquatic plants."[9] Despite reaching the determination that the chemical may pose a risk to the environment, the EPA did not consult with Fish and Wildlife Service (FWS) or conduct an effects test as required under the Endangered Species Act (ESA).[10]

The EPA also conducted a human-health risk assessment to determine the carcinogenic potential of the chemical.[11] Overall, the EPA determined that glyphosate was "not likely to be carcinogenic to humans."[12] The EPA reached this conclusion despite recent studies indicating that there may be a correlation between glyphosate and an increased risk of cancer, particularly non-Hodgkin's lymphoma (NHL).[13] Monsanto, the agrochemical company that created Roundup, has since lost three lawsuits where plaintiffs alleged that the chemical was responsible for their illnesses.[14]

Finally, the EPA analyzed the agricultural and economic benefits of glyphosate use, concluding "the benefits outweigh the potential ecological risks when glyphosate is used according to label directions."[15] The EPA also identified mitigation measures to lessen the ecological impact, such as imposing label changes with instructions "to reduce spray drift."[16] The EPA indicated that prior to reregistering the pesticide, the

6. *Id.* § 136a(c)(5)(C).
7. *Id.* § 136a(g)(1)(A)(iii).
8. Nat. Res. Def. Council v. U.S. Env't Prot. Agency, 38 F.4th 34, 43 (9th Cir. 2022).
9. *Id.* at 41.
10. *Id.* at 43 n.3.
11. *Id.* at 41. The agency's Office of Research and Development and Scientific Advisory Panel both criticized the studies and the conclusions drawn. *Id.* at 42.
12. *NRDC*, 38 F.4th at 42.
13. WHO Int'l Agency for Rsch. on Cancer, *Evaluations of Five Organophosphate Insecticides and Herbicides*, IARC MONOGRAPHS, Mar. 20, 2015.
14. *See, e.g.*, In re Roundup Prods. Liab. Litig., 544 F. Supp. 3d. 950 (N.D. Cal. 2021). Monsanto is also a defendant in the noted case.
15. *Nat. Res. Def. Council*, 38 F.4th at 43.
16. *Id.*

agency would complete an effects assessment on endangered and threatened species in accordance with ESA, and if necessary, consult with FWS.[17]

Following the Interim Decision, two organizations, Rural Coalition and Natural Resource Defense Council (NRDC), filed petitions for review.[18] Rural Coalition challenged the human-health portion of the decision while NRDC criticized the ecological conclusions drawn by the EPA.[19] Rural Coalition also asserted that the agency neglected to follow ESA's "procedural requirements" before reaching its decision.[20] The Ninth Circuit *held* that EPA's human-health determination was not supported by substantial evidence and issued a vacatur.[21] Additionally, the Ninth Circuit found that the Interim Decision triggered ESA consultation obligations and issued a remand without vacatur.[22] *Natural Resources Defense Council v. Environmental Protection Agency*, 38 F.4th 34 (9th Cir. 2022).

II. BACKGROUND

A. The Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for the regulation of pesticides to avoid "unreasonable adverse effects on the environment."[23] FIFRA maintains that no person shall sell or distribute pesticides without first acquiring registration approval from the Administrator of EPA.[24] After registration, pesticides are subject to periodic review every fifteen years.[25] Periodic review requires the submission of any new scientific data to aid the Administrator in reaching his decision whether to re-register the chemical.[26] The Administrator applies the "FIFRA safety standard," which balances unreasonable risks to human health and ecosystems against "the economic, social, and environmental costs and benefits of the use of any pesticide."[27] Under the Act, an Interim Decision is reviewed for "substantial evidence"

17. *Id.*
18. *Id.* at 44.
19. *Id.*
20. *Id.*
21. *Id.* at 51–52.
22. *Id.* 59–61 (9th Cir. 2022).
23. 7 U.S.C. § 136a(a).
24. *Id.*
25. *Id.* § 136a(g)(1)(A)(iii)(I), (II).
26. *Id.* § 136a(g)(2)(A).
27. *Id.* § 136(bb).

considering "the record as a whole," requiring that the agency's rationale be both reasonable and consistent.[28] The EPA may also issue interim registration review decisions requiring "new risk mitigation measures" to lessen the environmental impact of the chemical.[29]

B. Endangered Species Act

The Endangered Species Act (ESA) aims to preserve vulnerable species from the threat of extinction.[30] The Act's purpose is to "provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved."[31] The Act requires that agencies shall "afford first priority to the declared national policy of saving endangered species" over their other primary goals or objectives.[32] The Act further necessitates that the EPA consult with FWS before taking an action that may jeopardize the survival of endangered or threatened species or result in the destruction of designated critical habitat.[33] Consultation between agencies must occur "at the earliest possible time," when determining whether agency action affects endangered or threatened species or their habitat.[34] After receiving informal input from FWS, the EPA then makes an effects determination.[35] If the effects determination yields the possibility that agency action may harm endangered and threatened species or their habitat, then a formal consultation with FWS requiring a biological opinion is mandated under the Act.[36]

Agency decisions that violate ESA are subject to judicial review under the Administrative Procedure Act (APA). The court may vacate agency decisions under the APA when agency actions or conclusions are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[37] In deciding whether vacatur is the appropriate remedy under the circumstances, the court analyzes three factors.[38] First, the court balances the severity of the agency's errors against the negative

28. 7 U.S.C. § 136n(b).
29. *Nat. Res. Def. Council*, 38 F.4th at 40 (citing 40 C.F.R. §§ 155.23–155.58).
30. 16 U.S.C. § 1531(b).
31. *Id*.
32. *See* Tenn. Valley Auth. v. Hill, 437 U.S. 153, 185 (1978).
33. 16 U.S.C. § 1536(a)(2).
34. 50 C.F.R. § 402.14(a).
35. 16 U.S.C. § 1536.
36. *Id*.
37. 5 U.S.C. § 706.
38. *Nat. Res. Def. Council*, 38 F.4th at 51.

consequences of an interim change.[39] Next, the court determines "the extent to which either vacating or leaving the decision in place would risk environmental harm."[40] Finally, the Ninth Circuit analyzes "whether the agency would likely be able to offer better reasoning [and] . . . adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand."[41] If the court decides against vacatur, then it generally grants the agency's request for voluntary remand unless made in bad faith.[42]

III. COURT'S DECISION

A. Human Health

In the noted case, the Ninth Circuit found that the EPA's conclusion that glyphosate did not pose a risk to human health was unsupported by substantial evidence.[43] The EPA reached its determination by neglecting to follow its own "Cancer Guidelines."[44] EPA's Cancer Guidelines outline criteria for selecting epidemiological studies, identifying factors for reaching causal determinations, and providing tests or methods to decide "whether results are statistically significant."[45] Additionally, the EPA uses assessment tools that allow it to assign hazard descriptors to products indicating the pesticide's level of risk.[46] Generally, if a pesticide product is assigned a low descriptor indicating less of a risk to human health, then fewer mitigation efforts are coordinated.[47] The EPA assigned glyphosate the lowest descriptor, "not likely" carcinogenic to humans, because the Agency stated that the "animal-tumor and genotoxicity studies showed no reason for concern."[48]

Most of the EPA's human epidemiological studies revealed that exposure to the herbicide suggested "an at least somewhat increased risk of developing NHL."[49] However, the EPA argued that its epidemiological

39. *Id.*
40. *Id.* at 51–52 (quoting Nat'l Fam. Farm Coal v. U.S. Env't Prot. Agency, 960 F.3d 1120, 1144–45 (9th Cir. 2020) (internal citation omitted)).
41. *Id.* at 52.
42. *Id.* at 60 (citing Cal. Cmtys Against Toxics v. U.S. Env't Prot. Agency, 688 F.3d 989, 992 (9th Cir. 2012).
43. *Id.* at 51.
44. *Id.* at 46–47.
45. *Id.* at 45.
46. *Id.*
47. *Id.*
48. *Id.* at 46.
49. *Id.*

studies demonstrating an increased risk of NHL were possibly due to chance or by the introduction of other confounding factors, such as exposure to other pesticides.[50] The agency also gave weight to the few studies that did not identify a positive association between NHL and the herbicide, suggesting that these "contradictory results" did not allow it to arrive at a firm determination of the herbicide's carcinogenic potential.[51] In other words, the EPA said that its inability to reach a conclusion regarding glyphosate's carcinogenic potential justifies its hazard descriptor of "not likely."[52] The court disagreed with the EPA's analysis, stating that the agency's inability to reach a conclusion regarding NHL risk is inconsistent with the "not likely" descriptor.[53] The Agency justified its hazard descriptor by arguing that it did not believe its animal carcinogenicity studies resulting in tumor findings were caused by the introduction of glyphosate, or were therefore "treatment-related."[54] The EPA's determination was due to its reliance on historical-control data and "pairwise statistical significance," both conflicting with the Agency's own Cancer Guidelines.[55]

First, the court analyzed the EPA's selective use of historical-control data.[56] Historical-control data is used to demonstrate the "natural frequency of different types of tumors in an animal strain."[57] In other words, this data shows the likelihood of tumor development in different animal species, which can be offered to show that the resulting illness is unlikely to be due to chance.[58] The Cancer Guidelines suggest that the EPA uses this data to both "bolster" and "undermine" results.[59] However, in this case, the EPA only used the data to discount studies suggesting that glyphosate resulted in higher rates of NHL.[60] The EPA-commissioned Scientific Advisory Panel (SAP) indicated that there was potential for bias in the study results, because there "were numerous instances in which historical-control data could add weight to tumor findings, but EPA never used the data in that manner."[61]

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50. *Id.*
51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.* at 47.
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id* at 48.
60. *Id.*
61. *Id.*

Next, the EPA's reliance on the of "lack of pairwise statistical significance," was also found to be inconsistent with the Cancer Guidelines.[62] The EPA utilizes two types of tests to determine statistical significance, meaning that the resulting tumor is "unlikely due to chance."[63] A significant result in either the Agency's "pairwise comparison test" or "trend test" can establish that the result was not a product of chance.[64] The EPA's tests offered conflicting results regarding tumor occurrences in rodents.[65] The EPA discounted the trend test results suggesting statistical significance by relying more heavily on the pairwise comparison tests, which indicated no statistical significance.[66] The court determined that "EPA's bare assertion that a lack of pairwise statistical significance suggests that tumor results in rodent studies are not treatment-related fails to account coherently for the evidence of statistical significance from trend tests," as established by the Cancer Guidelines.[67]

Finally, the EPA argued that its "not likely" finding should be upheld because tumors indicating carcinogenic potential were only observed at high doses.[68] However, the court found that the EPA's descriptor selection conflicted with its own guidelines regarding pertinent dosage levels and appeared "contrary to the 'purpose' of the hazard assessment."[69] The court determined that in this case, multiple hazard descriptors would be more fitting with the Cancer Guidelines.[70] One option that the EPA could have considered instead of the "not likely," descriptor would be "likely to be carcinogenic above a certain dose range but not likely to be carcinogenic below that range."[71]

The court concluded that EPA failed substantial-evidence review and that vacatur was the appropriate remedy.[72] The reasoning provided by the EPA was inconsistent and "absent explanation," which the court believed was sufficient to constitute arbitrary action.[73] The Ninth Circuit believed vacatur was warranted because the Agency's error posed a

62. *Id.*
63. *Id.*
64. *Id.*
65. *Id.*
66. *Id.*
67. *Id.* at 49.
68. *Id.*
69. *Id.* at 49, 50.
70. *Id.* at 49.
71. *Id.*
72. *Id.* at 51–52.
73. *Id.* at 51.

serious threat to human health.[74] Additionally, the court reasoned that vacatur did not pose a risk to environmental harm, tipping the scale in favor of vacatur.[75] The court then vacated and remanded "the human-health portion of EPA's Interim Decision . . . for further analysis and explanation."[76]

B. Ecology

The court then analyzed the ecological challenges to the EPA's Interim Decision. The Endangered Species Act (ESA) requires formal consultation procedures and an effects determination before an agency may reach its final decision.[77] Petitioner, Rural Coalition, argued that the Agency did not satisfy its obligations under the ESA before issuing its Interim Decision by failing to consult with FWS.[78] Monsanto countered by arguing that the EPA has since begun formal consultation procedures with FWS, therefore mooting petitioner's case.[79] The court disagreed, because the EPA was required to consult with FWS prior to "formally concluding whether and how glyphosate may be used consistent with FIFRA's safety standard, and that behavior still has not been rectified."[80]

The ESA claims also turn on whether the Interim Decision constitutes "agency action," thus triggering FWS consultation requirements under the Act.[81] The Ninth Circuit has previously held that an "agency action" consists of two factors: the agency's decision must be "(1) affirmative and (2) discretionary about whether, or under what conditions, to allow private activity to proceed."[82] With regard to the first requirement, Rural Coalition argues that the EPA's issuance of the Interim Decision meets the definition of an "affirmative act."[83] Monsanto disagrees, suggesting that the petitioner is objecting instead to "inaction," or its failure to consult, and thus not an "affirmative act."[84] The court ruled in favor of Rural Coalition, finding that the Agency's exercise of "its regulatory power" to authorize a registration review is sufficient to

74. *Id.* at 52.
75. *Id.*
76. *Id.*
77. *Id.* at 58.
78. *Id.*
79. *Id.* at 56–57.
80. *Id.* at 57.
81. *Id.* at 58.
82. *Id.* (quoting Karuk Tribe of Cal. v. U.S. Forest Serv., 681 F.3d 1006, 1011 (9th Cir. 2012)).
83. *Id.* at 58.
84. *Id.* at 58–59.

constitute an "agency action."[85] The court held that the EPA violated its ESA requirements since "the Interim Decision was an affirmative, discretionary action, [therefore] EPA had to comply with the ESA by making an effects determination before issuing the decision."[86] In other words, because the EPA did not provide an effects determination prior to its decision-making, it was in violation of the Act.[87]

The court then determined that a vacatur would eliminate the mitigation requirements imposed by the Interim Decision that seek to reduce ecological risks.[88] Although Rural Coalition argued that the current mitigation requirements are insufficient, the court refused to issue a vacatur regarding the ecological portion of the Interim Decision because the existing mitigation requirements will "likely reduce ecological risk."[89] EPA asked the court for a partial remand without vacatur to provide the agency with "flexibility" to implement the mitigation requirements.[90] Rural Coalition disagreed with this remedy, suggesting that "EPA's actions are a bad-faith attempt to avoid judicial review."[91] The court addressed this concern by imposing a deadline.[92] The Ninth Circuit "require[d] EPA to issue a new ecological portion by the October 2022 FIFRA deadline."[93] In this case, the court used its "broad discretion" to authorize a partial remand of the EPA's Interim Decision without vacatur.[94]

IV. ANALYSIS

Here, the court's decision to remand the ecological portion of the interim decision without vacatur was consistent with precedent of the Ninth Circuit. Despite the court's consistency in deciding similar issues, petitioner Rural Coalition argues that this remedy allows the EPA to avoid judicial review of its decision.[95] When an agency decision is remanded without vacatur, the agency may decide to only address the defects identified by the reviewing court instead of addressing the core issues. Additionally, the agency may suggest a different rationale to

85. *Id.* at 59.
86. *Id.*
87. *Id.*
88. *Id.* at 60.
89. *Id.*
90. *Id.* at 61.
91. *Id.*
92. *Id.*
93. *Id.*
94. *Id.* at 60–61.
95. *Id.* at 61.

accommodate its decision. Thus, if the court decides to vacate with remand, the agency may issue the same rule but provide a different reasoning to push its agenda.

Recent caselaw indicates that the court's reasoning reflects current trends in the Ninth Circuit. *Center for Biological Diversity v. EPA* involved similar fact patterns as the noted case.[96] In that case, the EPA reregistered a pesticide's active ingredients before consulting with FWS as required by the ESA.[97] The court held that "the reregistration of an individual pesticide product is its own triggering action," reflecting the Ninth Circuit's determination that chemical reregistration triggers a duty to consult under ESA because it meets the definition of "agency action."[98]

Additionally, *Center for Environmental Health v. Wheeler* addressed Monsanto's argument that since the EPA has begun consultation procedures with FWS, the ESA claims are now moot.[99] *Wheeler* suggests that "ESA does not simply require the EPA to initiate consultation, however, but rather, to consult with FWS. Until the consultation process is concluded, that obligation continues."[100] *Wheeler* reiterates that the EPA's procedural duties under ESA are not satisfied despite initiating consultation.[101]

Finally, the D.C. Circuit has provided an in-depth analysis examining whether to remand without vacatur when the EPA registers pesticides under FIFRA in violation of ESA. In the case *Center for Biological Diversity v. EPA*, the Agency registered the chemical cyantraniliprole (CTP) under FIFRA after failing to make an effects determination and consult with the necessary wildlife services.[102] Petitioners in *Center for Biological Diversity* sought to protect Satyr butterflies and their habitat.[103] The court reasoned that "[t]he decision whether to vacate an order pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) depends on the seriousness of the order's deficiencies and, thus, the extent of doubt whether the agency chose correctly, and the disruptive consequences of an interim change that may itself be changed."[104] In determining the court's remedy, the court

96. *See* Ctr. for Biological Diversity v. U.S. Env't Prot. Agency, 847 F.3d 1075 (9th Cir. 2017).

97. *Id.* at 1092.

98. *Id.*

99. Ctr. for Env't Health v. Wheeler, 429 F. Supp. 3d 702, 717–18 (N.D. Cal. 2019).

100. *Id.* at 718.

101. *See id.*

102. *See* Ctr. for Biological Diversity v. Env't Prot. Agency, 861 F.3d 174 (D.C. Cir. 2017).

103. *Id.* at 179–180.

104. *Id.* at 188.

rationalized that a decision to vacate "would at least temporarily defeat . . . the enhanced protection of the environmental values covered by [the EPA rule at issue]."[105]

Additionally, the D.C. Circuit found that the Agency "did not register CTP in total disregard of the pesticide's potential deleterious effects," because "the Conservation Groups themselves rely heavily on the EPA's 'Ecological Risk Assessment for the Registration of the New Chemical Cyantraniliprole.'"[106] Further, the Agency classified the CTP pesticide as "reduced risk" because it is generally less toxic toward animals than the leading alternatives.[107] Therefore, the court held that remand without vacatur would be justified because it would allow the "EPA's CTP registration order to remain in effect until it is replaced by an order consistent with our opinion" and "will maintain 'enhanced protection of the environmental values.'"[108] Similarly to the noted case, since there was some benefit allocated from the mitigation requirements that the EPA issued in its Interim Decision, the court decided to remand without vacatur to preserve possible ecological benefits afforded by the mitigation requirements.

So, was Rural Coalition's concerns regarding EPA's interest in avoiding judicial review justified? Potentially. According to the recent statement released by the EPA in September 2022, the Agency maintains that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, remain the same."[109] Instead of issuing a new decision to cancel the registration of glyphosate, the agency "intends to revisit and better explain its evaluation of the carcinogenic potential of glyphosate and to consider whether to do so for other aspects of its human health analysis."[110] Since the Interim Decision was partially vacated, the EPA had until October 2022 to issue a new decision. However, due to the time needed to satisfy formal consultation requirements and fulfill notice and comment obligations, the EPA was unable to meet the court-imposed deadline.[111] As for its ecological analysis, the agency will "consider whether additional or different risk mitigation may be necessary based on the

105. *Id.* (quoting N.C. v. Env't Prot. Agency, 550 F.3d 1176, 1178 (D.C. Cir. 2008).

106. *Id.*

107. *Id.* at 189.

108. *Id.*

109. U.S. Env't Prot. Agency, Memo on Withdrawal of Glyphosate Interim Registration Review Decision (Sept. 21, 2022), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-14447.

110. *Id.*

111. *Id.*

outcome of ESA consultation for glyphosate, prepare an analysis of in-field effects of glyphosate on monarch butterfly habitat, consider whether there are other aspects of its analysis of ecological risks and costs to revisit, and consider what risk mitigation measures may be necessary to reduce potential risk following completion of analyses left outstanding in the ID."[112] As of November 2022, the EPA has not released an updated analysis or any potential risk mitigation measures may be implemented to reduce the herbicide's ecological effects.

V. CONCLUSION

In *NRDC v. EPA*, the Ninth Circuit used its discretion to arrive at a judgment consistent with prior precedent. It applied the appropriate standard and utilized reasoning that mirrored its previous decisions; however, the decision to remand and vacate in part and not to vacate in part may yield the same decision by the EPA, only citing different rationales. In other words, despite the NRDC litigation challenging the agency's Interim Decision to re-register glyphosate under FIFRA, the berries sitting on your grocery market shelf will likely be treated with the same chemicals. But does this elevate your cancer risk? According to the EPA, uncertainty in glyphosate's carcinogenic potential is insufficient to outweigh the economic and agricultural benefits of the chemical's application.[113]

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112. *Id.*

113. *Nat. Res. Def. Council*, 38 F.4th at 43.

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