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# *Pollinator Stewardship Council v. EPA* and the Duty to Research FIFRA Applications

## INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prohibits the sale or distribution of any pesticide without prior registration and approval by the Environmental Protection Agency (EPA).<sup>1</sup> EPA may deny applications for pesticide registration when “necessary to prevent unreasonable adverse effects on the environment.”<sup>2</sup> On September 10, 2015, the Ninth Circuit found EPA did not adequately research the effects of the chemical sulfoxaflor on bee populations in *Pollinator Stewardship Council v. EPA*.<sup>3</sup> The court determined that EPA failed to follow its internal standard for data collection. Thus, the court vacated EPA’s registration, and remanded it to the agency for further review.<sup>4</sup> In Part I, this In Brief analyzes the standard for data collection affirmed in *Pollinator Stewardship*. Then, Part II explores the potential application and limitations of the Ninth Circuit’s decision for future cases and agency decisions, both generally and for bees in particular. *Pollinator Stewardship* is a narrow victory that affirms EPA’s duty to comply with its own data collection standards for pesticide regulation, but it remains unclear if this outcome will be translated to pesticides affecting other species.

## I. BACKGROUND

### A. *Bees in Peril*

Bees play an important role as the world’s primary pollinators.<sup>5</sup> In the United States, bee pollination contributes directly or indirectly to \$15 billion in crop value each year and one-third of the food we eat.<sup>6</sup> In 2006 researchers discovered Colony Collapse Disorder, a phenomenon characterized “by sudden and

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1. 7 U.S.C. § 136a(a) (2012).

2. *Id.*; *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 522 (9th Cir. 2015).

3. 806 F.3d at 522.

4. *Id.*

5. Mark J.F. Brown & Robert J. Paxton, *The Conservation of Bees: A Global Perspective*, 40 *APIDOLOGIE* 410, 410 (2009).

6. *Honey Bee Health and Colony Collapse Disorder*, AGRIC. RES. SERV., U.S. DEPT. OF AGRIC., <http://www.ars.usda.gov/News/docs.htm?docid=15572> (last modified Nov. 5, 2015).

widespread disappearances of adult honey bees from beehives.”<sup>7</sup> In 2014 and 2015 alone, U.S. bee colonies lost 42.1 percent of their total population, more than twice the 18.7 percent loss beekeepers reported as economically acceptable.<sup>8</sup>

While many stressors contribute to bee decline, multiple studies have linked bee decline to pesticide exposure.<sup>9</sup> In 2010 Dow Agrosiences sought EPA approval for new pesticides with the chemical sulfoxaflor as their main ingredient.<sup>10</sup> Sulfoxaflor interferes with a bee’s central nervous system to cause paralysis and ultimately death.<sup>11</sup> Sulfoxaflor is a “systemic” pesticide that affects all insects—including bees—when they come into direct contact with the pesticide or ingest plants that have absorbed the pesticide.<sup>12</sup>

### B. FIFRA’s Protections for Pollinators

FIFRA aims to “protect human health and the environment from harm from pesticides.”<sup>13</sup> To achieve this goal, EPA conducts a cost-benefit analysis to determine if a pesticide’s impact has “unreasonable adverse effects on the environment,” by balancing the “economic, social, and environmental costs and benefits of the use of [the] pesticide.”<sup>14</sup> There are two categories of pesticide registration under FIFRA: unconditional registration (permanent, no further testing necessary) and conditional registration (tentative, further testing necessary).<sup>15</sup> EPA unconditionally registers a pesticide when it is clear that the benefit outweighs the harm and that the pesticide performs its intended function without “unreasonable adverse effects” on the environment.<sup>16</sup> If a new pesticide’s impact is unknown, then EPA conditionally registers the pesticide “for a period reasonably sufficient for the generation and submission of required data [to determine the impact].”<sup>17</sup>

In response to rapid bee decline, EPA supplemented the normal FIFRA analysis with the Pollinator Risk Assessment Framework (PRAF).<sup>18</sup> The PRAF is a unique testing structure that requires more rigorous testing than normal for any

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7. NAT’L HONEY BEE HEALTH STAKEHOLDER CONFERENCE STEERING COMM., U.S. DEPT. OF AGRIC., REPORT ON THE NATIONAL STAKEHOLDERS CONFERENCE ON HONEY BEE HEALTH iv (2012), <http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf>.

8. Kim Kaplan, *Bee Survey: Lower Winter Losses, Higher Summer Losses, Increased Total Annual Losses*, AGRIC. RES. SERV. (May 13, 2015), <http://www.ars.usda.gov/is/pr/2015/150513.htm>.

9. Brown & Paxton, *supra* note 5, at 413.

10. Pollinator Stewardship Council v. EPA, 806 F.3d 520, 523 (9th Cir. 2015).

11. *Id.*

12. *Id.*

13. Headwaters, Inc. v. Talent Irrigation Dist., 243 F.3d 526, 531 (9th Cir. 2001).

14. 7 U.S.C. § 136(bb) (2012).

15. 7 U.S.C. § 136a(c)(5), (7) (2012); See *Pesticide Registration Manual: Unconditional/Conditional Registration*, EPA, <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#unconditional> (last updated Jan. 4, 2016).

16. § 136a(c)(5)(C)–(D).

17. § 136a(c)(7)(C).

18. Pollinator Stewardship Council v. EPA, 806 F.3d 520, 524 (9th Cir. 2015).

pesticide that may impact bee populations.<sup>19</sup> This heightened testing structure involves multiple tiered studies designed to identify different degrees of risk for bees.<sup>20</sup> Tier 1 studies determine how much risk there is for individual bees, while Tier 2 and 3 studies determine the extent of the risk for entire colonies.<sup>21</sup>

Tier 1 studies determine the presence of risk by exposing individual bees to concentrated doses of pesticides in a laboratory enclosure.<sup>22</sup> The result of the Tier 1 studies is the “risk quotient,” a ratio of maximum expected exposure to the amount of pesticide necessary to kill half the bees tested.<sup>23</sup> The EPA must conduct Tier 2 and 3 studies if the risk quotient exceeds the “level of concern,” meaning the point where 10 percent of bees tested die.<sup>24</sup> Tier 2 studies are “semi-field studies,” in which researchers place bees in a tunnel enclosure and feed them pesticide-treated crops to simulate a real-world colony environment.<sup>25</sup> Tier 3 studies are “full field studies” in which researchers observe bees treated with the pesticide in a natural environment.<sup>26</sup> Tier 2 and 3 studies guide the FIFRA cost-benefit analysis by more clearly observing the “biological effects” of pesticide use on an entire colony.<sup>27</sup>

### C. *The Fight to Protect the Colony*

In 2013 the Pollinator Stewardship Council, commercial beekeepers, and beekeeping organizations sued EPA to contest the agency’s unconditional registration of pesticides containing sulfoxaflor.<sup>28</sup> The pollinators claimed that EPA failed to follow internal standards for data collection after initial studies submitted by Dow “showed [sulfoxaflor is] highly toxic to honey bees.”<sup>29</sup>

The Ninth Circuit reviewed the Tier 1 studies provided by Dow and found the risk quotient for sulfoxaflor ranged from 0.8 to 5.7, well above the PRAF’s 0.4 level of concern.<sup>30</sup> Since the risk quotient surpassed the level of concern, further Tier 2 and 3 studies were necessary.<sup>31</sup> The court found Dow’s Tier 2 studies

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19. *Id.*

20. *Id.*

21. OFFICE OF PESTICIDE PROGRAMS, EPA, GUIDANCE FOR ASSESSING PESTICIDE RISKS TO BEES 6 (2014), [http://www.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](http://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf).

22. *Id.* at 7.

23. OFFICE OF PESTICIDE PROGRAMS, EPA, WHITE PAPER IN SUPPORT OF THE PROPOSED RISK ASSESSMENT PROCESS FOR BEES 5 (2012), [http://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/epa\\_whitepaper.pdf](http://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/epa_whitepaper.pdf).

24. *Pollinator Stewardship*, 806 F.3d at 525.

25. *Id.*

26. OFFICE OF PESTICIDE PROGRAMS, *supra* note 21 at 30.

27. *Pollinator Stewardship*, 806 F.3d at 525–26.

28. Petitioner’s Opening Brief at 1, *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015) (No. 13-72346).

29. *Pollinator Stewardship*, 806 F.3d at 522.

30. *Id.* at 525.

31. *Id.*

“inconclusive” for the following two reasons.<sup>32</sup> First, the majority of the Tier 2 studies did not provide useful information because they used less sulfoxaflor than the application rate proposed by Dow.<sup>33</sup> Second, the limited number of Tier 2 studies that used Dow’s proposed application rate examined how long sulfoxaflor residue remained on plants after application, but failed to examine the pesticide’s toxicity for bee colonies.<sup>34</sup> While Dow’s Tier 1 sulfoxaflor studies demonstrated a risk for bees, its Tier 2 studies failed to reveal the magnitude of the risk.<sup>35</sup>

The inadequacy of these studies made EPA’s decision to unconditionally register sulfoxaflor unacceptable to the court.<sup>36</sup> Initially, EPA conditionally registered sulfoxaflor while it waited to obtain new data.<sup>37</sup> As part of the conditional registration, EPA imposed a new lower maximum application rate and other minor mitigation measures.<sup>38</sup> However, four months later, without supplementary studies or new data, EPA decided to unconditionally register sulfoxaflor.<sup>39</sup> EPA justified the unconditional registration with additional mitigation measures, but did not make any changes to the application rate.<sup>40</sup> However, the few studies that examined the proposed application rate were limited in their analysis and did not show the impact on colony health.<sup>41</sup> While EPA took steps to protect bees, the effect on the colony remained unknown at the proposed application rate.<sup>42</sup>

In *Pollinator Stewardship*, the Ninth Circuit vacated and remanded EPA’s unconditional registration of sulfoxaflor because the registration was not supported by “substantial evidence.”<sup>43</sup> The court determined that “given the precariousness of bee populations, leaving EPA’s registration of sulfoxaflor in place risk[ed] more potential environmental harm than vacating [the registration].”<sup>44</sup>

## II. ANALYSIS

### A. *The Pollinator Stewardship Standard*

In *Pollinator Stewardship*, the Ninth Circuit found that EPA lacked sufficient scientific basis for its unconditional registration because the agency failed to

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32. *Id.* at 526.

33. *Id.*

34. *Id.* at 529.

35. *Id.* at 525–26.

36. *See id.* at 527.

37. *Id.* at 526–27.

38. *Id.*

39. *Id.* at 527.

40. *Id.*

41. *Id.* at 529.

42. *Id.*

43. *Id.* at 532.

44. *Id.*

follow its own rules for assessing the impact of pesticides on bees.<sup>45</sup> EPA originally decided Dow needed to provide additional data in its conditional registration of sulfoxaflor.<sup>46</sup> Then, EPA changed course and unconditionally registered sulfoxaflor without completing new studies.<sup>47</sup> The agency based this change on the unsupported assumption that a lower application rate and other mitigation measures would protect bees, even though the relevant Tier 1 and 2 studies did not study the proposed application rate.<sup>48</sup> The court vacated the unconditional registration because EPA failed to acquire new data or provide evidence to support its decision,<sup>49</sup> affirming that EPA must adhere to its own regulations.<sup>50</sup>

The Ninth Circuit relied heavily on precedent in deciding *Pollinator Stewardship*. The court rejected EPA's argument that Dow's inconclusive studies proved sulfoxaflor did not pose an unreasonable risk to bees.<sup>51</sup> This aligned with Ninth Circuit precedent, holding that ambiguous evidence, or a lack of evidence, in an agency decision is not considered scientific proof of viability for a threatened species.<sup>52</sup> Additionally, the court rejected EPA's argument that Dow used an application rate "close enough" to the unconditional application rate.<sup>53</sup> The court's decision aligned with precedent from *Natural Resources Defense Council v. EPA*, where the Ninth Circuit found a close-enough argument irrelevant from a legal standpoint, even if it made sense from a practical standpoint.<sup>54</sup> Ultimately, the Ninth Circuit vacated EPA's decision because EPA's decision was not grounded in data.<sup>55</sup> Judge Smith's concurring opinion clearly stated EPA need only "support [its] beliefs, knowledge, and judgment with evidence."<sup>56</sup>

Yet, it is important to recognize that the court did not independently assess the risk posed by sulfoxaflor.<sup>57</sup> Rather, the court rejected the *method* EPA used to arrive at its unconditional registration decision.<sup>58</sup> Furthermore, in keeping with fundamental principles of administrative law, the court did not compel a particular outcome; it only required adherence to process.<sup>59</sup>

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45. *See id.*

46. *Id.* at 527.

47. *Id.*

48. *Id.* at 525, 527–28.

49. *Id.* at 532.

50. *Id.* at 531.

51. *Id.*

52. *See Tucson Herpetological Soc'y v. Salazar*, 566 F.3d 870, 879 (9th Cir. 2009) (finding the Secretary of the Interior erred when he affirmatively relied on ambiguous and inconclusive studies to support a conclusion about the persistence of lizard populations).

53. *Pollinator Stewardship*, 806 F.3d at 531–32.

54. *Natural Resources Defense Council v. EPA*, 735 F.3d 873, 884 (9th Cir. 2013).

55. *Pollinator Stewardship*, 806 F.3d at 538.

56. *Pollinator Stewardship*, 806 F.3d at 538 (Smith, J., concurring).

57. *See id.* at 532.

58. *See id.*

59. *See, e.g.,* CHRISTINE B. HARRINGTON & LIEF H. CARTER, ADMINISTRATIVE LAW AND POLITICS: CASES AND COMMENTS 25 (5th ed. 2015) ("Administrative law deals not primarily with the substance, or content, of policy outcomes but with the process of making policies.").

### B. Pollinator Stewardship Expanded and Limited

It is important not to overstate the impact of *Pollinator Stewardship*. EPA still holds substantial power over pesticide registrations. Courts rarely vacate agency decisions, and the Ninth Circuit is likely to defer to EPA in future cases, especially those involving “substantial agency expertise.”<sup>60</sup> This expectation aligns with the standard of deference for reviewing EPA’s pesticide registrations demonstrated by the D.C. Circuit.<sup>61</sup> EPA will prevail in future challenges like *Pollinator Stewardship* if the agency can “articulate a satisfactory explanation for its action.”<sup>62</sup> The path for EPA is clear: in a future challenge, the court would likely uphold EPA’s decision if the agency could provide data showing mitigation measures, including lower application rates, are sufficiently protective.

However, *Pollinator Stewardship* also raises an important question: is the result transferable to pesticides affecting other species? The answer to this question must recognize that the court did not use an ordinary FIFRA analysis in *Pollinator Stewardship*; instead the EPA used the unique PRAF model to provide a heightened level of testing for a pesticide that harmed bees.<sup>63</sup> Future cases where PRAF does not apply will not face this same heightened standard for data collection.<sup>64</sup> When an agency is not required to follow explicit or rigorous standards, courts are more likely to defer to the agency’s expertise in performing general cost-benefit analyses.<sup>65</sup> Thus, from a legal perspective, the impact of *Pollinator Stewardship* may be limited.

Furthermore, the importance and peril of bee populations was a driving factor for the Ninth Circuit in *Pollinator Stewardship*.<sup>66</sup> First, bees have a significant impact on a profitable agricultural industry and—through pollination—contribute to much of the food we eat.<sup>67</sup> While courts focus on protectionist measures for bees, they may provide less scrutiny for species that garner little economic benefit or public attention. Bees had the pollination industry in their corner, but not all species are so lucky. The result from *Pollinator Stewardship* may only transfer to other species that garner significant public attention through an economic purpose or other avenue. The plight of less visible species may continue to go unnoticed.

Finally, the specter of Colony Collapse Disorder may have heightened the Ninth Circuit’s sensitivity towards dubious agency processes and decisions. The Ninth Circuit’s concern for a vulnerable species in *Pollinator Stewardship* is

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60. See *Pollinator Stewardship*, 806 F.3d at 538 (Smith, J., concurring) (citing *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 376–77 (1989)).

61. See *Nat’l Corn Growers Ass’n v. EPA*, 613 F.3d 266, 271 (D.C. Cir. 2010).

62. See *Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983).

63. See *Pollinator Stewardship*, 806 F.3d at 524 (noting that EPA utilized a new framework to analyze sulfoxaflo).

64. See *id.*

65. See *id.* at 534 (Smith, J., concurring) (explaining that even unclear agency decisions deserve deference if the agency’s reasoning can be recognized).

66. *Id.* at 522.

67. See AGRIC. RES. SERV., *supra* note 6 (noting that bee pollination is responsible for \$15 billion in commercial agriculture and approximately one-third of the U.S. diet).

consistent with concern the court has shown for endangered species generally.<sup>68</sup> When applying the FIFRA balancing test in other cases, the Ninth Circuit has afforded endangered species “the ‘highest of priorities’ in assessing risks and benefits.”<sup>69</sup>

*Pollinator Stewardship*’s result is already attracting other cases, but it remains unclear if the result will be the same.<sup>70</sup> Courts may follow this protectionist pattern for bees and other highly profitable or endangered species, but may be reluctant to question EPA’s judgment in cases involving less vulnerable species.

### C. Moving Forward

On November 12, 2015, EPA issued a final cancellation notice for all pesticide products containing sulfoxaflor, ending production of sulfoxaflor while allowing end-users to exhaust their existing stocks.<sup>71</sup> Because the court vacated the registrations on remand, EPA issued its cancellation orders restricting the distribution or sale of all previously registered sulfoxaflor.<sup>72</sup> Dow did not seek rehearing, but continued to fight the ruling by submitting new labels for EPA consideration in November 2015.<sup>73</sup> Further, Dow vowed to work with EPA and provide data to meet the agency’s standard for registration in the future.<sup>74</sup>

Even though the Ninth Circuit’s review of EPA decisions is usually limited to procedure, *Pollinator Stewardship* may have a significant impact on EPA’s approach to future registrations. Since EPA’s enhanced PRAF regulations increased its vulnerability to judicial review, the agency may be reluctant to establish similar heightened testing standards to protect other species. Alternatively, *Pollinator Stewardship* may push EPA to be more critical of future pesticide registrations and ensure more comprehensive data collection going forward. EPA’s February 2016 notice of intent to cancel flubendiamide—a pesticide that harms aquatic species—may point toward the EPA being cautious in

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68. See *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) (finding EPA must consider the weight of the Endangered Species Act when evaluating the impact on salmon and steelhead in the Pacific Northwest).

69. *Id.* (quoting *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 174 (1978)).

70. See Tiffany Stecker, *Pesticides: Appeals Court to Hear Case on EPA Role in Bee Die-off*, GREENWIRE (March 2, 2015), <http://www.eenews.net/stories/1060014285> (“Other recent challenges include two separate suits filed by Earthjustice and the Natural Resources Defense Council over the agency’s approval of the herbicide Enlist Duo and the weedkiller glyphosate that was also developed by Dow.”).

71. EPA, *Sulfoxaflor—Final Cancellation Order*, PESTICIDE REGISTRATION 1 (2015), [http://www.epa.gov/sites/production/files/2015-11/documents/final\\_cancellation\\_order-sulfoxaflor.pdf](http://www.epa.gov/sites/production/files/2015-11/documents/final_cancellation_order-sulfoxaflor.pdf); See 7 U.S.C. § 136(d) (Nov. 12, 2012) (authorizing EPA to cancel pesticide registrations).

72. EPA, *supra* note 71, at 1.

73. See SDSU Extension, *EPA Decision: Insecticide Active Ingredient Sulfoxaflor*, AGWEEK (Dec. 22, 2015, 3:56 PM), <http://www.agweek.com/policy-and-politics/3909630-epa-decision-insecticide-active-ingredient-sulfoxaflor>.

74. See *Dow AgroSciences to Work Diligently to Support Renewed U.S. EPA Sulfoxaflor Registrations*, DOW AGROSCIENCES (Nov. 13, 2015, 3:45 PM), <https://www.dowagro.com/en-us/newsroom/pressreleases/2015/11/sulfox-epa-decision#.VrQ9VbIrKM8>.

its future pesticide approvals.<sup>75</sup> In the past, pesticide manufacturers used conditional registrations as a loophole to sidestep meaningful agency review.<sup>76</sup> However, *Pollinator Stewardship* and the flubendiamide cancellation provide hope for a more rigorous review process in the future.

#### CONCLUSION

FIFRA gives EPA the authority to regulate pesticides. However, *Pollinator Stewardship* clarifies that EPA must abide by its own rules. While the court's ruling against EPA did not come as a surprise, neither did the court's reluctance to overturn an agency decision. The Ninth Circuit provided a clear road forward for EPA: the agency can avoid unfavorable outcomes in the future by adhering to its standards or even lowering testing standards.

*Pollinator Stewardship* is an outlier in judicial review of FIFRA applications. The Pollinator Stewardship Council and its allies had a clear advantage: bees are economically important and clearly in danger. Future cases will likely extend protections for bees, but the impact for other species may be limited without similar circumstances. In *Pollinator Stewardship*, bees benefitted from a perfect storm where a needy and necessary client got help from some powerful, personally-invested friends.

*Alex Trabolsi*

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75. See Flubendiamide; Notice of Intent to Cancel Pesticide Registrations, 81 Fed. Reg. 11558 (Mar. 4, 2016).

76. See NRDC Report: *More than 10,000 Pesticides Approved by Flawed EPA Process*, NRDC (March 27, 2013), <http://www.nrdc.org/media/2013/130327.asp>.

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