Ecology Law Quarterly

Volume 44 | Issue 2 Article 6

9-15-2017

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# The Silent Beehive: How the Decline of Honey Bee Populations Shifted the Environmental Protection Agency's Pesticide Policy towards Pollinators

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*When honey bee populations began to drastically decline in 2006 from what came to be known as Colony Collapse Disorder, the response from the United States Department of Agriculture was swift. As research emerged on the causes, pesticides—specifically a new and widely used class of pesticides called neonicotinoids—quickly emerged as an identifiable culprit. In reaction, the Environmental Protection Agency, as the administrator of the Federal Insecticide, Fungicide, and Rodenticide Act, began to develop a new, tiered ecological risk assessment framework to better analyze the risk that pesticides posed to honey bees and other insect pollinators. In 2012, the Environmental Protection Agency applied the new guidelines to the application for registration of a new type of neonicotinoid, sulfoxaflor. However, despite the analysis showing that sulfoxaflor posed high risks to honey bees, the Environmental Protection Agency approved the unconditional registration of sulfoxaflor. Pollinator advocates then successfully challenged the Environmental Protection Agency's registration of the neonicotinoid pesticide, sulfoxaflor in* Pollinator Stewardship Council v. EPA. *This was a victory for pollinator advocates who had been unsuccessful in challenging other pesticide registrations due to the lengthy administrative petition required.*

*This Note argues that it was the combination of honey bees' critical importance in the agricultural industry and their prevalence in popular culture that drove the quick agency action that led to the Environmental Protection Agency's creation of the Pollinator Risk Assessment guidelines. These new*

DOI: https://dx.doi.org/10.15779/Z38GQ6R199


* I would like to thank Professors Eric Biber and Robert Infelise for their guidance throughout the process of writing this Note. I would also like to profoundly thank the *Ecology Law Quarterly* editing staff, especially Emily Renda and Alex Tom, for their hard work that helped me to turn this piece into what it is. Finally, I would like to give a special thanks to my husband Eddie for all of his support and for letting me blab about bees so much this year.

*guidelines included set standards that allowed pollinator advocates to successfully challenge a registration. However, even though the Pollinator Risk Assessment guidelines have resulted in the Environmental Protection Agency applying higher scrutiny to neonicotinoids, the ability of the new guidelines to significantly impact pesticide policy is and will continue to be limited, even while honey bees continue to garner attention in popular culture.*



## INTRODUCTION

Insects, including bees, wasps, flies, butterflies, and moths, play an important role in the pollination of crops. Insects pollinate approximately 75 percent of crops, and bees are the most significant contributors.[1] Among insect pollinators, honey bees (*Apis mellifera*) are the most dominant and important commercially managed species.[2] Of the $15.12 billion in added crop value

1. Vincent Doublet et al., *Bees Under Stress: Sublethal Doses of a Neonicotinoid Pesticide and Pathogens Interact to Elevate Honey Bee Mortality Across the Life Cycle*, 17 ENVTL. MICROBIOLOGY 969, 969 (2015).
2. *Id.*

attributable to insect pollination, $11.68 billion is directly attributable to honey bees.[3] Population declines in both native and commercially managed honey bees over the past decade brought global attention to the importance of insect pollinator conservation, with a particular focus on honey bee conservation.[4]

In 2006, beekeepers noticed steep declines in their honey bee colonies.[5] Winter hive losses were a common occurrence in commercial beekeeping, but in 2006 beekeepers reported winter hive losses of 30-90 percent, a stark increase from the 15 percent losses that were common.[6] Losses occur when worker bees that are sent out to pollinate crops abandon their hives, leaving behind their brood (bees in developmental stages),[7] queen, and food reserves.[8] If too many worker bees fail to return, the queen and a brood of immature bees cannot maintain the hive and eventually die off.[9] This phenomenon, Colony Collapse Disorder (CCD), has resulted in drastic losses for beekeepers and declines in bee populations.[10]

In response to beekeepers' concerns about the high losses, the United States Department of Agriculture (USDA) sent out members of the Agricultural Research Service, the main in-house research arm of the agency.[11] Through the Agricultural Research Service, USDA led a collaborative effort to determine the causes of CCD and organized the CCD Working Team, composed of academic, private, and federal scientists, in order to quickly identify research gaps and priorities.[12] The Working Team led to the formation of the CCD Steering Committee, composed of federal program leaders, university scientists, state departments of agriculture, and private organizations, which developed an Action Plan for CCD that identified and funded critical research needs.[13] During this same period, the European Union, which was also experiencing honey bee population declines, was also conducting its own

3. POLLINATOR HEALTH TASK FORCE, POLLINATOR RESEARCH ACTION PLAN 4 (2015).

4. *See id.*

5. *CCD Overview*, U.S. DEP'T OF AGRIC., https://www.ars.usda.gov/northeast-area/beltsville-md/beltsville-agricultural-research-center/bee-research-laboratory/docs/ccd-overview/ (last modified Aug. 12, 2016).

6. Sainath Suryanarayanan & Daniel Lee Kleinman, *Perspective: Disappearing Bees and Reluctant Regulators*, 27 ISSUES IN SCI. AND TECH. 33, 33 (2011).

7. *See The Colony and Its Organization*, MID-ATL. APICULTURE RESEARCH & EXTENSION CONSORTIUM, https://agdev.anr.udel.edu/maarec/honey-bee-biology/the-colony-and-its-organization/ (last visited May 12, 2017) (the "brood" refers to honey bees in the three developmental stages before emerging as adults: egg, larva, and pupa).

8. Suryanarayanan & Kleinman, *supra* note 6, at 33.

9. Alexander Martone, *Can* Pollinator Stewardship Council v. EPA *Help Solve the Colony Collapse Disorder Crisis? Pt. I*, GEO. ENVTL. L. REV. ONLINE 1 (Sept. 2, 2014), https://gelr.org/2014/09/02/can-pollinator-stewardship-council-v-epa-help-solve-the-colony-collapse-disorder-crisis/.

10. Suryanarayanan and Kleinman, *supra* note 6, at 33.

11. *See CCD Overview*, *supra* note 5; *About ARS*, U.S. DEP'T OF AGRIC., AGRIC. RESEARCH SERV., https://www.ars.usda.gov/about-ars/ (last modified Feb. 7, 2017).

12. U.S. DEP'T OF AGRIC., CCD STEERING COMM., COLONY COLLAPSE DISORDER ACTION PLAN 4 (2007), https://www.ars.usda.gov/is/br/ccd/ccd_actionplan.pdf.

13. *Id.* at 1.

research.[14] The European Union identified multiple factors contributing to CCD and the overall decline of bee populations.[15] While identifiable contributing causes included pesticides, disease, pests (specifically the varroa mite),[16] migratory stress from long-distance transportation, and changes in habitat quality or outright habitat loss,[17] no cause emerged as the main culprit.[18] Since 2011, CCD cases have gradually declined and currently, few, if any, bee losses are directly attributable to CCD. Despite this, high bee losses continue to be a significant problem.[19] From 2013 to 2015, total annual losses rose from an average of 34.2 to 42.1 percent, in large part due to year-round losses.[20] While CCD is primarily associated with high winter losses, the current trend shows that bee colonies are suffering equally significant losses in the summer, when losses have typically been low.[21]

Though there are multiple factors leading to bee declines, researchers, beekeepers, and policy makers agree that the increased use of pesticides is more than likely playing a significant role.[22] Researchers have highlighted pesticide poisoning, particularly by neonicotinoids—a new class of systemic pesticides—as a driving reason for the decline.[23] Exposure to sublethal doses of neonicotinoids weakens honey bees' immune systems and impacts their behavior.[24] For honey bees, whose systems are already heavily compromised by the various other factors previously discussed, pesticides can exacerbate the impact of natural threats, such as pests and pathogens.[25]

The link between pesticides and bee declines quickly garnered the attention of beekeepers and conservationists, and eventually that of the U.S. government and the general public. Since 2006, scientific literature suggesting a link between neonicotinoids and bee declines has emerged.[26] Some

14. *Bee Health*, EUROPEAN FOOD SAFETY AUTH., https://www.efsa.europa.eu/en/topics/topic/bee-health (last visited May 14, 2017).

15. *Id.* (indicating that factors contributing to CCD included intensive agriculture and pesticide use, starvation and poor bee nutrition, viruses, pathogens, and invasive species, such as the Varroa mite, Asian hornet, and the small hive beetle, and environmental changes).

16. *CCD Overview*, *supra* note 5 (describing that the Varroa mite is an invasive species that continues to pose a threat to honey bees).

17. POLLINATOR HEALTH TASK FORCE, *supra* note 3, at 4.

18. *Id.*

19. *CCD Overview*, *supra* note 5.

20. Kim Kaplan, *Bee Survey: Lower Winter Losses, Higher Summer Losses, Increased Total Annual Losses*, U.S. DEP'T OF AGRIC., AGRIC. RESEARCH SERV. (May 13, 2015), https://www.ars.usda.gov/news-events/news/research-news/2015/bee-survey-lower-winter-losses-higher-summer-losses-increased-total-annual-losses/.

21. *Id.*

22. *See* Doublet et al., *supra* note 1, at 969.

23. *CCD Overview*, *supra* note 5.

24. *See* Doublet et al., *supra* note 1, at 970.

25. POLLINATOR HEALTH TASK FORCE, *supra* note 3, at 26.

26. *See, e.g.*, Doublet et al., *supra* note 1, at 969 (listing the numerous studies that originated from Europe showing sublethal effects impacting honey bee behavior, foraging success, and colony development).

beekeepers began to see neonicotinoids as the cause, linking the rise in their use in the early 2000s to the emergence of CCD.[27] But it was not until 2013, when the first published research requested by the European Commission on Honey Bee Health also suggested a link between pesticides and neonicotinoids, that action to protect bees from neonicotinoids began to gain traction in U.S. national politics.[28] That year, House Representatives John Conyers and Earl Blumenauer introduced the Saving America's Pollinators Act, a bill that would have taken neonicotinoids off the market until their safety for pollinators was more definitively proven.[29] Also that same year, the European Union issued restrictions on three neonicotinoids (clothianidin, imidacloprid, and thiamethoxam) after identifying them as harmful to European honey bee populations.[30]

In 2014, the Obama administration issued a Presidential Memorandum creating the Pollinator Health Task Force—to be co-chaired by USDA and the Environmental Protection Agency (EPA)—aimed at promoting the health of honey bees and other pollinators, clearly making honey bee health a priority by declaring it an issue of national policy.[31] Both agencies had already taken some limited steps to address honey bee health. USDA had been conducting honey bee research since 2006, but, following the Memorandum, it received a major increase in funding for honey bee and pollinator health research, as well as for habitat improvement, for the 2015 and 2016 fiscal years.[32] Prior to the Memorandum, EPA had been working to improve its regulatory process for approving pesticides for use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), focusing specifically on pesticides with potential impacts on pollinators.[33] EPA had completed a collaborative proposal for risk assessment in 2012, submitted it to the FIFRA Scientific Advisory Panel for public comment, and subsequently adopted the new proposal as the Pollinator

27. Alex Morris, *What is Killing America's Bees and What Does It Mean for Us?*, ROLLING STONE (Aug. 18, 2015), http://www.rollingstone.com/politics/news/what-is-killing-americas-bees-and-what-does-it-mean-for-us-20150818.

28. *Bee Health*, *supra* note 14.

29. Morris, *supra* note 27.

30. European Commission Press Release IP/13/457, Bee Health: EU-Wide Restrictions on Pesticide Use to Enter Into Force on 1 December (May 24, 2013).

31. Memorandum from President Barack Obama on Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators (June 20, 2014), https://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b [hereinafter Presidential Memorandum 2014].

32. POLLINATOR HEALTH TASK FORCE, NATIONAL STRATEGY TO PROMOTE THE HEALTH OF HONEY BEES AND OTHER POLLINATORS 3–4, 13–14 (2015) [hereinafter NATIONAL STRATEGY] (describing the initiation of USDA research in 2006 and showing how the USDA budget was increased from $48 million in fiscal year 2015 to $79 million fiscal year 2016).

33. *See* EPA, HEALTH CAN. PEST MGMT. REGULATORY AGENCY & CAL. DEP'T OF PESTICIDE REGULATION, WHITE PAPER IN SUPPORT OF THE PROPOSED RISK ASSESSMENT PROCESS FOR BEES 2–3 (2012) [hereinafter WHITE PAPER].

Risk Assessment Framework (PRAF) in 2014.[34] The new guidance was in line with EPA's role in the Pollinator Health Task Force, which charged it with "assess[ing] the effect of pesticides, including neonicotinoids, on bee and other pollinator health and tak[ing] action, as appropriate, to protect pollinators."[35]

The PRAF was designed to better analyze the risk posed to honey bees from a pesticide by utilizing a tiered approach for assessing risk, and setting base guidelines for when the risk to bees from a particular pesticide was too high.[36] Prior to the PRAF's implementation, rather than relying on quantitative guidelines, EPA would use its own discretionary judgment to determine what risk was too high. The PRAF's new guidelines reflected the growing importance that honey bees had gained, as it resulted from a cross-national collaboration with Canada and California and was also the result of a lengthy public comment period.[37] It also provided pollinator advocates a tool with which they could challenge the use of neonicotinoids.

Pollinator Stewardship Council, a pollinator advocacy organization, brought the first challenge under the PRAF, contesting EPA approval of a new neonicotinoid pesticide. In *Pollinator Stewardship Council v. EPA*, the Ninth Circuit handed honey bee advocates a strong win in their battle against neonicotinoids.[38] The Ninth Circuit strengthened the PRAF by holding that EPA had to follow the standards it adopted and needed sufficiently reliable data to support its decisions.[39] However, this Note argues that even though this win appeared to shift the momentum strongly against neonicotinoids, recent events show that pollinator advocates using the PRAF as a legal tool will face many limitations, and will be unlikely to prevent pesticide use.

Part I gives some background on the issue of pesticides and how their impacts on honey bees rose to prominence. While pesticides play an important role in the agricultural industry, they also pose serious risks to wildlife, and honey bees in particular. Part I then discusses how honey bees were uniquely situated to gather the industry, public, and political attention that ultimately resulted in a shift in pesticide policy within EPA. Part II examines this shift, explaining how the PRAF differs from the previous process. Part III analyzes how the PRAF changed the ability of pollinator advocates to challenge pesticides, with a particular focus on the success of advocates in *Pollinator*

34. *New Pesticide Labels Will Better Protect Bees and Other Pollinators*, EPA (Aug. 15, 2013), https://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/c186766df22b37d485257bc8005b0e64!opendocument; *see* James Aidala, *Neonicotinoids: EPA's New Get-Tough Measures*, LAW360 (Sept. 25, 2013, 6:27 PM), http://www.law360.com/articles/473923/neonicotinoids-epa-s-new-get-tough-measures.

35. Presidential Memorandum 2014, *supra* note 31.

36. EPA, HEALTH CAN. PEST MGMT. REGULATORY AGENCY & CAL. DEP'T OF PESTICIDE REGULATION, GUIDANCE FOR ASSESSING PESTICIDE RISKS TO BEES 2 (2014) [hereinafter GUIDANCE DOCUMENT].

37. *See id.*

38. Pollinator Stewardship Council v. EPA, 806 F.3d 520, 531–32 (9th Cir. 2015).

39. *Id.*

*Stewardship Council* in strengthening the application of the PRAF. Finally, Part IV discusses the persistent limitations of using the PRAF to prevent pesticides from being approved by EPA. This Note argues that the PRAF has strengthened risk assessment and characterization for honey bees, but its impact, even after *Pollinator Stewardship Council*, is limited by two main factors: (1) the language of FIFRA hampering the extent of action that EPA can take against pesticides; and (2) the PRAF's focus on honey bees and tiered structure. Lastly, this Note concludes that EPA will be unlikely to swiftly adopt similar regulations for other wildlife threats if the same honey bee combination of factors—public, economic, and political pressure—is not present.

## I. PESTICIDES AND BEES

Bees and pesticides both play an important role in agriculture, but they can be at odds with each other. It was not until the emergence of CCD that the U.S. government began to implement a policy aimed at protecting honey bees from pesticides. This Part provides the relevant statutory and factual background needed to understand EPA's role in managing pesticides and protecting honey bees. It first explains EPA's pesticide approval process under FIFRA. Then it highlights how the process has often been ineffective, focusing on the failure to protect wildlife in the Endangered Species Act (ESA) context. This Part then describes the particular risks that neonicotinoids pose to honey bees, and analyzes how the unique circumstances surrounding honey bees motivated a much swifter government response.

### *A. EPA's Authority under FIFRA to Regulate Pesticides*

EPA is the main agency that regulates the registration and use of pesticides under FIFRA.[40] FIFRA prohibits the use or sale of pesticides that have not been approved and registered by EPA.[41] FIFRA permits the EPA Administrator to approve an application for registration if the pesticide does not pose "unreasonable adverse effects."[42] Unreasonable adverse effects are "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[43] While pesticides are never risk free, EPA's goal is to determine whether the risks are reasonable.[44] Ultimately, FIFRA requires EPA to conduct a cost-

40. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136(b) (2012).
41. § 136a(a).
42. *Id.*
43. § 136(bb).
44. Leslie W. Touart & Anthony F. Maciorowski, *Information Needs for Pesticide Registration in the United States*, 7 ECOLOGICAL APPLICATIONS 1086, 1086 (1997).

benefit analysis to ensure that the pesticide does not create an unreasonable risk for people or the environment.[45]

Under FIFRA, applicants must submit extensive scientific data when they apply to register a pesticide.[46] Once EPA has received this data, it has two main ways of registering a pesticide. First, it can issue an unconditional registration after reviewing the scientific data and determining that the pesticide, "when used in accordance with widespread and commonly recognized practice[,] . . . will not generally cause unreasonable adverse effects on the environment."[47] Second, EPA may conditionally register a pesticide in situations where it determines there is insufficient data to properly assess the risk. This is limited to (1) products with composition and proposed uses identical or substantially similar to currently registered pesticides; (2) existing products with proposed new uses or methods of applying the pesticide; or (3) products with new active ingredients.[48] Conditional registrations may only be issued for a period reasonably sufficient to generate and submit required data.[49]

Even though conditional registration has limited application, in current practice, EPA registers most of its pesticides through this process.[50] For conditional approval, applicants must show that (1) there has been insufficient time to gather data; (2) the pesticide will not "cause unreasonable adverse effects" during the conditional registration; and (3) the use of the pesticide is in the public interest.[51] If approved, the registration is contingent on the applicant submitting the additional data within a certain timeframe.[52] However, if additional data reveals uncertainties, it can trigger further review.[53] Scholars and advocate groups have criticized conditional registrations for allowing pesticide use before completing rigorous human and environmental testing, and with incomplete knowledge of the risks.[54] Once approved, conditional registrations are difficult to challenge.[55]

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45. *See* Mary Jane Angelo, *Killing Fields: Reducing the Casualties in the Battle between U.S. Species Protection Law and U.S. Pesticide Law*, 32 HARV. ENVTL. L. REV. 95, 105 (2008). Briefly describing the cost-benefit analysis in the context of FIFRA.

46. MARY JANE ANGELO, THE LAW AND ECOLOGY OF PESTICIDES AND PEST MANAGEMENT 119 (Richard O. Brooks & Ross A. Virginia eds., 2013).

47. § 136a(c)(5)(D).

48. § 136a(c)(7)(A); *see* 40 C.F.R. § 152.113(c) (2016) (the Agency will not approve the conditional registration of pesticides if the new use involves food, both for humans and for animal feed).

49. § 136a(c)(7)(C).

50. Joanna Lau, Comment, *Nothing but Unconditional Love for Conditional Registrations: The Conditional Registration Loophole in the Federal Insecticide, Fungicide, and Rodenticide Act*, 44 ENVTL. L. 1177, 1184 (2014).

51. § 136a(c)(7)(C); *see* Lau, *supra* note 50, at 1183–84.

52. Lau, *supra* note 50, at 1183–84.

53. *Id.*

54. *Id.* at 1184–85.

55. *Id.* at 1192–95. A challenging party has to show that EPA granted conditional registration status without "substantial evidence" or else courts will defer to the agency's decision. *Id.* at 1194. The "substantial evidence" standard is difficult to overcome because it does not require the agency to make the decision the court would have made, or even to make the decision the agency itself would make in

### *B. Pesticide Threats to Other Wildlife: FIFRA and the Endangered Species Act*

Threats to wildlife from pesticides are not new. In 1962, Rachel Carson's *Silent Spring*[56] first exposed the dangers of the broad-spectrum pesticide dichlorodiphenyltrichloroethane (DDT), an organochlorine insecticide that at the time was the most widely used pesticide in the world.[57] DDT was preferred for its dramatic pest control results, but ironically its most effective quality—long persistence in the environment—was also its most dangerous. DDT's persistence caused it to accumulate in living tissue, with the concentration increasing further up the food chain, exposing predators to large quantities.[58] This bioaccumulation had serious effects on iconic predators such as the bald eagle and osprey, which caught the public's attention[59] and led to a ban on DDT in the United States.[60] However, overall pesticide use has not declined, with EPA maintaining approximately 20,000 registered pesticide products.[61]

More recently, there has been tension between environmental groups and EPA over the agency's failure to protect endangered and threatened species (listed species)[62] from these pesticides.[63] Listed species are protected primarily through the ESA,[64] which is administered by the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service, together referred to as "the Services."[65] Section 7 of the ESA requires that all federal agencies prioritize and conserve endangered and threatened species within their official capacity, and that agencies consult with the Services over any actions that "may affect" a listed species.[66] The "may affect" language pertains to both beneficial and detrimental effects, including the destruction or adverse modification of the critical habitat of any listed species.[67]

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light of evidence that emerges after the relevant time period. *Id.* at 1194. Rather, the "substantial evidence" is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* at 1194–95.

56. *See generally* RACHEL CARSON, SILENT SPRING (Anniversary ed. 2002).

57. ANGELO, *supra* note 46, at 70.

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 232.

62. Endangered Species Act, 16 U.S.C. § 1532(6) (2012) ("endangered species" is defined as "any species which is in danger of extinction throughout all or a significant portion of its range"); § 1532(20) ("The term 'threatened species' means any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.").

63. Jaclyn Lopez, *Can't We Just All Get Along: Reconciling Pesticide Use and Species Protection*, 33 VA. ENVTL. L.J. 184, 186 (2015).

64. §§ 1531–1544.

65. Lopez, *supra* note 63, at 188; *see* 50 C.F.R. § 402.01(b) (2016).

66. 16 U.S.C. § 1536(a)(1); 50 C.F.R. § 402.14(a) (2016); *see* Fla. Key Deer v. Paulison, 522 F.3d 1133, 1146 (11th Cir. 2008) (stating that "section 7(a)(1) imposes a judicially reviewable obligation upon all agencies to carry out programs for the conservation of endangered and threatened species").

67. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.02.

Pursuant to the ESA, if EPA determines during review that a pesticide "may affect" a listed species, it will refine its assessment to further determine if the pesticide "may affect, but is not likely to adversely affect" or "may affect and is likely to adversely affect."[68] The former triggers an informal consultation where the Services can concur or non-concur with EPA's conclusion,[69] while the latter triggers a formal consultation where EPA provides the Services with a detailed assessment of potential risks to review. The Services then provide a Biological Opinion based on EPA's data, delineating their own assessment and recommendations.[70] Exactly what an ESA consultation between EPA and the Services should entail has only recently been settled between the agencies.[71]

Despite registering thousands of pesticides that impact hundreds of listed species, EPA has been slow to comply with ESA requirements until forced to by third-party litigation.[72] Even after mandates from the courts, EPA remains in stalemates with the Services over the quality of data provided in risk assessments.[73] For example, FWS listed the California red-legged frog in 1996, acknowledging that the effects of pesticide run-off on the species demanded action, but consultation never occurred.[74] In 2006, following a 2002 suit by the Center for Biological Diversity challenging EPA's failure to consult,[75] EPA and the Center entered into a settlement agreement that prohibited the use of sixty-six pesticides near the core habitat of the red-legged frog until consultation was completed.[76] However, because of the agencies' disagreement over the data, consultations between EPA and FWS remained in a stalemate for six years.[77]

To address such disagreements over data quality between the agencies, in 2011, EPA, the Services, and USDA requested an independent report to evaluate the tools and assessment used to measure risks under FIFRA actions.[78] After the release of the completed report in 2013, the agencies set in motion a plan to adopt a common approach to risk assessment in consultations over

68. *Assessing Pesticides under the Endangered Species Act*, EPA, https://www.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act (last visited May 14, 2017).

69. *Id.*

70. *Id.* The Biological Opinion provides the Services' view of whether the pesticide's registered use is likely to jeopardize the continued existence of the species and, if so, describes alternatives to avoid jeopardy. *Id.* The Services can also authorize any "take" that would otherwise be prohibited, as long as measures to minimize take are implemented. *Id.*

71. Lopez, *supra* note 63, at 198–99. After much litigation, the agencies jointly asked for an independent report from the National Academy of Sciences, and used this document to guide a better collaboration. *Id.*

72. *See id.* at 195–97.

73. *See id.* at 197.

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. *Assessing Pesticides under the Endangered Species Act*, *supra* note 68.

listed species.[79] In comparison, however, pesticide risks to honey bees prompted a speedy response from EPA.

### *C. The Risks of Pesticides to Honey Bees*

Pesticide use in industrial farming has increased dramatically over the last sixty years at the expense of key pollinators like bees.[80] Every year, more than five billion pounds of pesticides (valued at almost $40 billion) are used around the world.[81] The United States accounts for 22 percent of the global usage or approximately one billion pounds (valued at around $12 billion).[82] Insect-killing pesticides (insecticides) have become necessary to prevent pest damage to important agricultural crops.[83] Many of the insecticides used are broad-spectrum pesticides, which kill both target and non-target pests.[84] These nondiscriminatory pesticides can cause population declines in beneficial insects such as bees.[85]

Since the 2000s, neonicotinoids—a new class of broad-spectrum pesticides—have become the most widely used in the world.[86] Neonicotinoids are systemic pesticides, meaning that plants can readily absorb the pesticide, through either their roots or their leaves, and distribute it systemically to various plant tissues.[87] As the pesticide spreads through the system, some residue enters the pollen and nectar.[88] In the United States, while neonicotinoids can be applied as foliar sprays or injected into the soil, they are most commonly applied to crop seeds as a coating.[89] Neonicotinoids work by attacking the central nervous system of insects, resulting in paralysis and death when consumed at high concentrations.[90] However, their general toxicity to

79. *Id.*

80. RICHARD ISENRING, PESTICIDE ACTION NETWORK EUROPE, PESTICIDES AND THE LOSS OF BIODIVERSITY: HOW INTENSIVE PESTICIDE USE AFFECTS WILDLIFE POPULATIONS AND SPECIES DIVERSITY 3 (2010), http://www.pan-europe.info/old/Resources/Briefings/Pesticides_and_the_loss_of_biodiversity.pdf.

81. ANGELO, supra note 46, at 67.

82. *Id.* at 68.

83. Pests account for 30 percent of biomass loss (biomass is material derived from living or formerly living plants), so farmers need pesticides to keep pests at bay. *Id*. at 86. However, pests eventually develop resistance to a pesticide, so farmers need to use new varieties that are more effective. *Id.* at 86–87.

84. *Id*. at 86.

85. ISENRING, *supra* note 80, at 11.

86. Dave Goulson, *An Overview of the Environmental Risks Posed by Neonicotinoid Insecticides*, 50 J. APPLIED ECOLOGY 977, 977 (2013).

87. *Id.*

88. *See* JENNIFER HOPWOOD ET AL., XERCES SOC'Y FOR INVERTEBRATE CONSERVATION, HOW NEONICOTINOIDS CAN KILL BEES: THE SCIENCE BEHIND THE ROLE THESE INSECTICIDES PLAY IN HARMING BEES 7 (2d ed. 2016).

89. Goulson, *supra* note 86, at 978 (defining foliar spray as the practice of spraying leaves, more commonly used on fruits and vegetables).

90. *Id.* at 977.

insects means that even small quantities can have an impact on bees and other insect pollinators.[91]

Pesticides affect honey bees either through acute or chronic exposure. Acute exposure is easily identified because individual honey bees or entire colonies will die within hours of contact.[92] Acute exposure occurs at certain high doses, and thus can usually be prevented by following label requirements during application.[93] In contrast, chronic pesticide exposure occurs from contact with lower dosages, which can produce long-lasting, sublethal effects.[94] Chronic exposure does not kill the bees, but it can weaken their immune systems.[95] Honey bees are exposed to a number of different stressors—pests, disease, loss of habitat, and stress from commercial migration—at any given time, making chronic effects more difficult to identify.[96] Chronic exposure affects not only the individual forager bees that are directly exposed, but also the brood and queen when the foragers carry pesticide-laced pollen into the hive.[97]

Sublethal effects from neonicotinoids gained attention as a potential cause for the sudden decline in honey bees after CCD research suggested a link.[98] Sublethal exposure to neonicotinoids not only weakens a bee's immune system, but also impairs a bee's brain function, which affects behavior, learning ability, and colony development.[99] Exposure reduces forager bees' ability to relocate the hive as well as their foraging performance.[100] Neonicotinoid exposure also increases individual honey bee mortality by making larval or adult honey bees more susceptible to pathogens.[101] Eventually, sublethal effects on individual bees result in colony-level impacts, such as insufficient brood development, poor nourishment (when forager bees fail to feed the colony), frequent queen replacement, low overwintering success, and possible colony demise.[102]

Honey bees are particularly susceptible to sublethal effects of neonicotinoids because the method they use to feed themselves routinely exposes the bees to the pesticide. Bees are one of the few pollinators that actively gather large amounts of pollen from flowers and use it as the principal food source for themselves and their brood.[103] Most other insects use only the

91. *Id.*

92. J.D. ELLIS ET AL., UNIV. OF FLA. INST. OF FOOD & AGRIC. EXTENSION, MINIMIZING HONEY BEE EXPOSURE TO PESTICIDES 5 (2013), http://edis.ifas.ufl.edu/in1027.

93. *Id.* at 2–3.

94. *Id.* at 3, 5.

95. *See* Doublet et al., *supra* note 1, at 970.

96. *See id*.

97. *See* ELLIS ET AL., *supra* note 92, at 4.

98. Doublet et al., *supra* note 1, at 970.

99. *See id.*

100. Adam J. Vanbergen & The Insect Pollinators Initiative, *Threats to an Ecosystem Service: Pressures on Pollinators*, 11 FRONTIERS IN ECOLOGY & THE ENV'T 251, 253 (2013).

101. Doublet et al., *supra* note 1, at 970.

102. ELLIS ET AL., *supra* note 92, at 5.

103. Marla Spivak et al., *The Plight of Bees*, 45 ENVTL. SCI. & TECH. 34, 34 (2011).

nectar to fuel their flight, bypassing the pollen.[104] To gather pollen, honey bees move continuously and widely between flowers, which inadvertently pollinates them.[105] While this behavior makes them efficient pollinators, it leaves them vulnerable to chronic sublethal exposure to neonicotinoids present in the pollen. The neonicotinoids accumulate in their systems and affect the bees' susceptibility to other pests, and ultimately their ability to survive.[106] There is a general consensus that neonicotinoid sublethal effects have played a role in honey bee population declines, though some call for more field studies on the precise effects of neonicotinoids.[107]

### *D. Honey Bees: A Species Combining Economic and Popular Importance*

Honey bees embody an ideal combination to influence policy: they are both charismatic enough to capture public attention and vitally important to agriculture so as to alarm the industry. Honey bee losses pose ecological risks, as their disappearance threatens the survival of native plant species and the ecosystem services those plants provide.[108] However, as shown by EPA's delays regulating pesticides under the ESA, threats to wildlife and ecological impacts are not always enough to drive EPA to protect a species.[109] Because the disappearance of honey bees signified not only a threat of wildlife loss, but also a threat to profits and the capacity of the agricultural industry, the honey bee crisis prompted uncharacteristic EPA action.[110]

Honey bees are the most important pollinator species on the planet, and the only commercially managed pollinator in the world.[111] Since the 1600s, when European settlers brought them to the new world to pollinate their crops, honey bees have served as the primary pollinators for the agricultural industry.[112] Currently, in the United States, honey bee pollination supports an estimated $15 billion worth of agricultural production,[113] including more than

104. *Id.*
105. *Id.*
106. *Id.* at 36.
107. *See* Gina Retschnig et al., *Effects, but No Interactions, of Ubiquitous Pesticide and Parasite Stressors on Honey Bee (Apis Mellifera) Lifespan and Behavior in a Colony Environment*, 17 ENVT'L MICROBIOLOGY 4322, 4327 (2015) (calling for more field-realistic studies); *but see* Doublet et al., *supra* note 1, at 969 (describing the consensus of research concluding that neonicotinoids affect honey bees).
108. *See* Presidential Memorandum 2014, *supra* note 31.
109. *See id.*
110. *See id.*
111. HOPWOOD ET AL., *supra* note 88, at 3.
112. *Id.*
113. *See* Press Release, U.S. Dep't of Agric., USDA Releases Results of New Survey on Honey Bee Colony Health (May 12, 2016), https://www.usda.gov/media/press-releases/2016/05/12/usda-releases-results-new-survey-honey-bee-colony-health. USDA and EPA frequently cite $15 billion, but estimates go as high as $30 billion. *See* Press Release, U.S. Dep't of Agric., USDA and EPA Release New Report on Honey Bee Health (May 2, 2013), https://www.usda.gov/media/press-releases/2013/05/02/usda-and-epa-release-new-report-honey-bee-health.

130 fruits and vegetables critical to a nutritious diet.[114] Bees are especially important to certain specialty crops like California almonds, which only bees pollinate,[115] and which require the use of 60 percent of all the available commercial honey bees.[116] Further, the stability and profitability of commercial beekeeping relies on healthy honey bee populations.[117] While the loss of honey bees does not threaten famine, it would cause a decline in the nutritional value and variety of arguably the most enjoyable parts of the human diet—fruits, vegetables, and tree nuts.[118]

Honey bees garner special attention because of their entrenched historical and commercial value to the agricultural industry. Other pollinators that lack the same economic importance—such as monarch butterflies, leafcutter bees, and bumble bees—did not garner the same quick attention with research on these pollinator species lagging behind honey bees.[119] Native species of wild bumble bees (*Bombus*) have suffered greater population losses than honey bees for many of the same reasons, but failed to gather the same attention.[120] Even as awareness of native and wild bee declines rises, the honey bee remains the headliner of pollinator awareness because of its unique combination of characteristics.[121]

The disappearance of bees became ubiquitous in popular consciousness when CCD struck hives nationwide.[122] The decline of honey bees was adopted as an environmental cause by many prominent groups.[123] Honey bee losses even garnered the attention of the ice cream industry, which depend on foods pollinated by honey bees.[124] Honey bees and their decline have been, and continue to be, covered in a range of media including the *New York Times*,[125]

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114. *Conservation Work for Honey Bees*, U.S. DEP'T OF AGRIC., NAT. RES. CONSERVATION SERV. (May 2015), https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/plantsanimals/pollinate/?cid=stelprdb1263263.

115. *CCD Overview*, *supra* note 5 (almond crops were estimated to need about 1.5 million colonies by 2010 to pollinate).

116. Morris, *supra* note 27.

117. Presidential Memorandum 2014, *supra* note 31.

118. Spivak et al., *supra* note 103, at 34.

119. NATIONAL STRATEGY, supra note 32, at 6.

120. Spivak et al., *supra* note 103, at 34. Bumble bees belong to the same genus, *Bombus*, and there are roughly 4000 species; for the purposes of this Note, I focus on the species native to the United States. *See id.*

121. *See id.*; Presidential Memorandum 2014, *supra* note 31 (mentioning native bees, but focusing its strategy to "[p]romote the [h]ealth of *[h]oney [b]ees*") (emphasis added).

122. *See* Presidential Memorandum 2014, *supra* note 31; *see also* U.S. DEP'T OF AGRIC., *supra* note 114.

123. *See, e.g.*, NAT. RES. DEF. COUNCIL, WHY WE NEED BEES: NATURE'S TINY WORKERS PUT FOOD ON OUR TABLES (2011) 1–2, https://www.nrdc.org/sites/default/files/bees.pdf; CTR. FOR FOOD SAFETY, POLLINATORS & PESTICIDES: FACT SHEET 1–2 (2013), http://www.centerforfoodsafety.org/files/pollinatorspesticides_03498.pdf.

124. Parija B. Kavilanz, *Disappearing Bees Threaten Ice Cream Sellers*, CNN MONEY (Feb. 20, 2008, 8:25 AM), http://money.cnn.com/2008/02/17/news/companies/bees_icecream/.

125. Alexei Barrionuevo, *Bees Vanish, and Scientists Race for Reasons*, N.Y. TIMES (Apr. 24, 2007), http://www.nytimes.com/2007/04/24/science/24bees.html.

*PBS Nature*,[126] *Rolling Stone*,[127] and full-length documentaries.[128] The issue was even incorporated into an episode of *The Simpsons*.[129]

The industrial and public concern over honey bee declines translated into political attention at local, state, and federal levels. In response to the rise of CCD, the 2008 Farm Bill[130] approved more than $17 million in funding over five years for joint research projects between USDA and universities on CCD, and another $2.75 million for increased honey bee health inspections.[131] The joint research project was the first to prioritize pollinators in a Farm Bill.[132] This Farm Bill funded research that would later help to single out neonicotinoids as a contributor to bee declines.[133]

In 2014, the White House responded to honey bee declines by issuing a memorandum focused on protecting pollinators and entrusting EPA and USDA to head the effort to address the problem.[134] The following year EPA and USDA released the Pollinator Health Strategy, which outlined both agencies' research goals and plans for better protecting bees from pesticides.[135] EPA adopted three main areas of focus for pollinator health: (1) advancing science and understanding of the potential impact of pesticides on pollinators; (2) taking risk management actions based on advanced data; and (3) collaborating with domestic and international partners to advance protections.[136] The honey bees' combination of commercial and popular value thus shifted pesticide policy in favor of bee protection.

## II. EPA'S NEW POLLINATOR POLICY

EPA's response to the honey bee crisis involved a significant change in how to evaluate the risk posed to bees by pesticides, taking a more protectionist stance towards pollinators. This Part provides an outline of the shift in pesticide policy that occurred, which also serves as a comparison of the old and new approaches. It then gives a detailed description of the tiered structure of the new guidelines adopted by EPA. This Part ends by highlighting the benefits of having such guidelines in place.

126. *Silence of the Bees* (PBS: Nature broadcast Mar. 13, 2011).
127. Morris, *supra* note 27.
128. VANISHING OF THE BEES (Hive Mentality Films & Hipfuel Films Oct. 9, 2009).
129. *The Simpsons: The Burns and the Bees* (FOX television broadcast Dec. 7, 2008).
130. The Farm Bill is federal legislation that Congress renews about every five years and covers a wide variety of agricultural issues. RENEE JOHNSON & JIM MONKE, CONG. RESEARCH SERV., RS22131 WHAT IS THE FARM BILL? 1 (2017).
131. Spivak et al., *supra* note 103, at 36.
132. *Id.* at 36–37.
133. *Id.* at 36.
134. *See* Presidential Memorandum 2014, *supra* note 31.
135. POLLINATOR HEALTH TASK FORCE, *supra* note 3, at i.
136. *Id.*

### *A. EPA's Shift in Risk Assessment Policy for Pollinators under FIFRA*

In response to honey bee declines and the outpouring of political attention, EPA adapted its risk-management policy for pollinators to more rigorously consider the threats to honey bees.[137] Pesticides pose a unique ecological problem.[138] By definition, pesticides kill organisms—mainly insects—that compete with crops and thus "tilt the balance in favor of crops and humans."[139] But it is not possible to target some insects without also impacting some non-pest organisms—even beneficial ones, such as honey bees.[140] For decades, EPA mostly dealt with this dilemma by trying to ensure that a pesticide posed no acute risks if used in the manner for which it was registered.[141] EPA based its risk assessment for wildlife, including honey bees, on acute toxicity testing rather than on evidence of chronic effects, such as impacts on behavior, reproduction, or neurology.[142]

Between 1992 and 2013, EPA's Office of Pesticide Programs operated under a policy deemphasizing the requirements for field testing and emphasizing the use of laboratory-derived risk criteria for pollinators.[143] The policy embraced risk-mitigation techniques to reduce exposure,[144] such as spraying at night if an insect was active only during daytime.[145] In order to focus resources on higher-risk pesticides, pesticides deemed "safe"[146] under this policy were exempt from extensive review.[147] While this policy created a risk of false positives—a failure to identify a pesticide that is harmful—Office of Pesticide Programs determined that the risk was insufficient to warrant the large expense of requiring field studies for every pesticide.[148] In adopting this policy, Office of Pesticide Programs prioritized the speed of the approval process.[149]

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137. *See How We Assess Risks to Pollinators*, EPA, https://www.epa.gov/pollinator-protection/how-we-assess-risks-pollinators (last visited May 15, 2017); *see also* WHITE PAPER, *supra* note 33, at 2–3.

138. *See generally* Touart & Maciorowski, *supra* note 44; ANGELO, *supra* note 46, at 1–4.

139. ANGELO, *supra* note 46, at 1 (citations omitted).

140. *Id.* at 120–22.

141. *See id*.

142. *See id*. (explaining that acute toxicity testing focuses on the impacts of short-term exposure to large doses, while analysis of chronic impacts considers the effects of the accumulation of toxins over a longer timeframe).

143. Touart & Maciorowski, *supra* note 44, at 1091. A key policy decision was to "[b]ase decisions on laboratory studies with less dependence on terrestrial and aquatic studies" in the context of other fish and vertebrate species. *Id.*

144. *Id.*

145. Spivak et al., *supra* note 103, at 36.

146. Touart & Maciorowski, *supra* note 44, at 1091. Pesticides analyses are about reducing risk; "safe" means an acceptable level. *See id.*

147. *Id.*

148. *Id.*

149. *Id.* at 1091–92.

Under this policy, EPA officially evaluated pesticide risks using a multi-step process, but, in practice, it almost never conducted analysis beyond the first step.[150] The first step consisted of acute contact toxicity tests on honey bees that indicated a median lethal dose (the dose that causes death to 50 percent of the exposed subjects).[151] The median lethal dose failed to capture sublethal effects.[152] EPA retained discretion to decide on a case-by-case basis when sublethal effects identified in toxicity testing merited further analysis at the second step.[153] If determined necessary by EPA, the second step required additional field studies.[154] With no formal agency guidelines in place, the agency's judgment was primarily based on qualitative reasoning that could be highly subjective, and was difficult for pollinator advocates to challenge.[155]

After the rise of CCD, EPA began to reevaluate its risk assessment policy for pollinators, coordinating with Canada's Pest Management Regulatory Agency and California's Department of Pesticide Regulation to draft a new ecological risk assessment framework.[156] The new framework adopted a quantitative method of assessing risks, which EPA saw as necessary to properly evaluate and reduce uncertainty in risk assessment decisions.[157] EPA was particularly concerned that acute toxicity tests could not fully capture the risks posed by neonicotinoids, which caused significantly different reactions than other pesticides.[158] In 2012, EPA submitted its collaborative PRAF proposal[159] to the FIFRA Scientific Advisory Panel for review and comment, and following that proposal, EPA began to incorporate the tiered assessment as part of its regulatory decision-making process for all pesticides impacting pollinators, though it did not release the guidance document until 2014.[160]

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150. Spivak et al., *supra* note 103, at 36.

151. *Id*.

152. *Id.*

153. *Id*.

154. *Id.*

155. *See id*.

156. EPA, *supra* note 137; *see generally* WHITE PAPER, *supra* note 33.

157. *Review of the Federal Coordination and Response Regarding Pollinator Health: Hearing Before the Subcomm. on Biotechnology, Horticulture & Research of the H. Comm. on Agric.*, 114th Cong. 15 (2015) (statement of Jim Jones, Assistant Administrator, Office of Safety and Pollution Prevention, EPA) [hereinafter H.R. 2015].

158. *Id.*

159. *See generally* WHITE PAPER, *supra* note 33.

160. *See* EPA, OFFICE OF PESTICIDE PROGRAMS, GUIDANCE ON EXPOSURE AND EFFECTS TESTING FOR ASSESSING RISKS TO BEES, at 4–6 (2016) (briefly describing the development of the tiered risk assessment, but leaving it unclear when EPA began to use it); *but see* H.R. 2015, *supra* note 157, at 12, 15 (statement of Jim Jones, Assistant Administrator, Office of Safety and Pollution Prevention, EPA) (discussing the tiered process and its applicability to pesticides outside of neonicotinoids); EPA, ENVIRONMENTAL FATE AND ECOLOGICAL RISK ASSESSMENT FOR SULFOXAFLOR REGISTRATION 26 (2013) (describing EPA's use of the tiered approach outlined in the 2012 FIFRA Scientific Advisory Panel meeting to estimate the exposure of honey bees to sulfoxaflor).

### *B. The Structure of the PRAF*

Similar to the previous approach, the PRAF uses a multi-tiered ecological risk assessment framework for characterizing the risks of a pesticide to honey bees and other pollinators.[161] The first tier focuses on the impacts of exposure to individual bees and is meant to serve as a screening tool to identify pesticides that do not pose a risk.[162] At the first tier, EPA compares the likely amount of environmental exposure to the amount toxic to the bee.[163] As with the original step in the previous policy, the primary data derived from studies at the first tier is the acute median lethal dose.[164] EPA then uses that figure to arrive at a risk quotient (RQ).[165] Under the PRAF, an RQ of over 0.4[166] for honey bees constitutes a "level of concern" that triggers the need for further study.[167] The process at the first tier is intended to generate "reasonably conservative" estimates of pesticide exposure to honey bees, so that the estimates are within one or two orders of magnitude higher than the "true" environmental exposure.[168] Only if the RQ calculated at the first tier exceeds the level of concern does the risk assessment process continue onto the second tier (and possibly the third tier).[169]

Studies at the second tier are considered "semi-field studies" where small colonies are enclosed in tunnels and forced to feed on pesticide-treated crops.[170] These studies focus on colony level impacts rather than individual bee toxicity.[171] Nonetheless, these studies face many limitations from the inherent difficulty of studying bees in a controlled environment versus a natural one.[172] EPA also uses studies at the second tier to identify risk-mitigation options that applicants can incorporate.[173] If EPA still finds in the second tier that

161. GUIDANCE DOCUMENT, *supra* note 36, at 6 (honey bees serve as the surrogate for other bee species).

162. Pollinator Stewardship Council v. EPA, 806 F.3d 520, 524–25 (9th Cir. 2015).

163. *Id.*

164. *Id.*; *see* 40 C.F.R. § 152.3 (2016).

165. *Pollinator Stewardship Council*, 806 F.3d at 525 (explaining that EPA determines the risk quotient by dividing the expected environmental concentrations with the acute median lethal dose).

166. *Id.* (explaining that an RQ of 0.4 is the concentration where 10 percent or more of bees would die).

167. *Id.*

168. WHITE PAPER, *supra* note 33, at 60.

169. GUIDANCE DOCUMENT, *supra* note 36, at 24.

170. *Pollinator Stewardship Council*, 806 F.3d at 525.

171. *Id.*

172. *Id.* at 525–26. One limitation of semi-field studies is the heightened stress levels of bees while they are kept in control tunnels, which can lead to higher bee death rates than in the normal environment even though the bees do not receive pesticide-treated food in the tunnels. *Id.* at 525. Also, because bees in the environment may obtain food from a mixture of treated and untreated crops, tunnel studies may overstate the effects of pesticide exposure on hives. *Id.* In addition, the studies can only last seven to ten days because of the stress the bees experience in the tunnels. *Id.* at 525–26.

173. WHITE PAPER, *supra* note 33, 36–37, 137.

additional information is needed to support a regulatory decision or understand potential risks, it can order studies at the third tier.[174]

The third tier is the highest level of scrutiny, consisting of full-field studies intended to address specific uncertainties that remain regarding the effects of a pesticide applied in accordance with label requirements by studying impacts under actual conditions.[175] Field studies confirm the safety under anticipated conditions (frequency of application, adherence to label use rate, and application method).[176] Field studies become more important when there is only a small difference between the concentration where toxicological effects occur and the potential environmental concentration.[177] These studies are also valuable to verify that mitigation measures reduce risks to acceptable levels.[178] Assessment at the third tier is meant to be used with the information gathered at the first and second tiers to fully characterize the risk.[179]

The primary benefit of the PRAF is its evaluation of the risk to bees using a quantitative method, replacing the subjectivity of the previous method with the objectivity of strict guidelines.[180] Unlike the previous assessment method, the PRAF establishes a median lethal dose that would automatically trigger further review; the PRAF does not afford the agency discretion regarding what level of risk requires further study.[181] However, the inclusion of more tiers for registration applicants to go through delays the process and makes it more expensive. Though a registrant can receive a conditional registration while it gathers data for the process, doing so limits the registrant's ability to market the pesticide.[182]

Despite implementing the PRAF into its risk assessment procedure, EPA conditionally registered sulfoxaflor, and bent the guidelines in favor of pesticide approval.[183] In 2013, EPA found itself in court after approving the registration of a new neonicotinoid and defending that approval. The next Part explains how the result strengthened the future application of the PRAF.

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174. *Id.*

175. GUIDANCE DOCUMENT, *supra* note 36, at 27.

176. Touart & Maciorowski, *supra* note 44, at 1088–89.

177. *Id.* When directly applying a product to water, field data is necessary to confirm that there are no other adverse effects to ecosystem and function, which cannot be determined by single species toxicity testing. *Id.* For honey bees, this can be important as pesticides are sprayed directly on foliage. *Id.*

178. *Id.*

179. *How We Assess Risks to Pollinators*, *supra* note 137.

180. H.R. 2015, *supra* note 157, at 15–16 (statement of Jim Jones, Assistant Administrator, Office of Safety and Pollution Prevention, EPA).

181. *See id.*

182. *Id.*

183. *See infra* Part IV.B. (describing EPA's actions in *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015)).

## III. *POLLINATOR STEWARDSHIP COUNCIL* AND THE LIMITATIONS OF THE PRAF IN PROTECTING POLLINATORS

When EPA adopted the PRAF as part of its risk assessment procedure, it made an internal policy decision to adopt a quantitative method, which created a means for pollinator advocates to challenge pesticide approval if EPA did not follow the guidelines. This Part details the difficulties that pollinator advocates faced in challenging EPA's approval of neonicotinoids prior to the PRAF due to administrative procedure requirements. This Part then summarizes the relevant facts of *Pollinator Stewardship Council v. EPA*, and details what that surprising victory meant for pollinator advocates. The Part finishes by discussing the renewed difficulty of challenging EPA's approvals after the victory.

### *A. Challenges to EPA's Approval of Neonicotinoids before the PRAF and* Pollinator Stewardship Council

Before the PRAF, pollinator advocates were in a difficult position when challenging a conditional pesticide registration. Under FIFRA, an individual must show that EPA granted a conditional registration without substantial evidence.[184] However, substantial evidence is a highly deferential standard and requires only that an agency present relevant evidence a reasonable mind might accept as adequate to support its conclusion.[185] This standard can be particularly difficult to overcome in areas like FIFRA registrations that require technical or scientific expertise.[186] Moreover, if advocates seek to cancel a registration, they have to exhaust all of their remedies in administrative proceedings before bringing their claim to court.[187] FIFRA and its implementing regulations allow anyone to file an administrative petition for EPA to cancel an existing pesticide registration,[188] but the agency has significant discretion as to how quickly it responds and whether it institutes cancellation proceedings.[189] While pollinator advocates were concerned that neonicotinoids were being registered and used without proper data through conditional registration, exhaustion and deference meant that years passed and

184. 7 U.S.C. § 136n(b) (2012).

185. *See* Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951) (finding that "[s]ubstantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.") (citations omitted).

186. *See* Lau, *supra* note 50, at 1202.

187. *See* Ellis v. Bradbury, No. C-13-1266 MMC, 2014 WL 1569271, at *6 (N.D. Cal. Apr. 18, 2014).

188. 40 C.F.R. §§ 154.1(a), 154.10 (2016).

189. *See* Telecomm. Research & Action Ctr. v. FCC, 750 F.2d 70, 79 (D.C. Cir. 1984) ("[T]he threshold a litigant must pass to obtain judicial review of ongoing agency proceedings [is] a high one.") (citations omitted).

no advocacy group could either successfully challenge the initial approval of neonicotinoids or get a timely reconsideration of the conditional registration.[190]

For example, in 2012, the Center for Food Safety (CFS) and other environmental groups challenged the conditional registration of clothianidin and thiamethoxam, arguing that EPA delayed subsequent review for too long.[191] While FIFRA allows conditional registration and gives EPA discretion to grant a registrant additional time to provide satisfactory data if any is missing, EPA's regulations also require that the registrant provide new data within a reasonable time.[192] For clothianidin, EPA had originally granted a three-year extension, but at the time of CFS's complaint, EPA had extended clothianidin's conditional registration for nine years.[193] Likewise, thiamethoxam had received an extension, and its conditional registration had been in effect for eleven years.[194] Prior to the litigation, CFS had filed an unanswered emergency citizen petition ("2012 Petition") with EPA, seeking cancellation of the conditional registrations as well as other agency actions to prevent further harm.[195]

The District Court for the Northern District of California dismissed CFS's claims against conditional registrations in April 2014 for failure to exhaust administrative remedies.[196] The court explained that even where the statute does not explicitly require exhaustion, exhaustion may still apply if (1) agency expertise is necessary, (2) the action would encourage bypassing the administrative scheme, and (3) administrative review is likely to allow the agency to correct its own mistakes.[197] The court held that for these claims, all three factors favored requiring exhaustion. The court reasoned that the claims

190. *See* Lau, *supra* note 50, at 1192–95; *Ellis*, 2014 WL 1569271, at *7 (requiring exhaustion of administrative process and a final decision from EPA before plaintiffs can challenge a conditional registration).

191. First Amended Complaint for Declaratory and Injunctive Relief at ¶¶ 120–39, Ellis v. Bradbury, No. C-13-1266 MMC, 2014 WL 1569271 (N.D. Cal. Apr. 18, 2014), (No. 3:13-cv-01266-LB), 2013 WL 3063552. CFS made fourteen separate complaints relating to each involving EPA's "refusal . . . to cancel or suspend a registration or to change a classification not following a hearing, [and] . . . failure to conduct required ESA analysis and consultation," as well as "other final actions of the Administrator not committed to the discretion of the Administrator." *Id.* at ¶¶ 10-11. The claims raised issues regarding APA violations, FIFRA violations, and failure to comply with ESA. *Id.* at ¶¶ 120–67. This Note focuses on the FIFRA claims related to conditional and unconditional registration, the fifth claim through the eighth claim. *Id.* at ¶¶ 120–39.

192. *See* 40 C.F.R. §§ 152.114, 152.115 (2016); First Amended Complaint for Declaratory and Injunctive Relief, *supra* note 191, at ¶¶ 121, 125.

193. First Amended Complaint for Declaratory and Injunctive Relief, *supra* note 191, at ¶ 121.

194. *Id.* at ¶ 125.

195. *See* Emergency Citizen Petition to EPA Seeking Suspension of Registration for Clothianidin by Jeff Anderson et al., at 5 (Mar. 20, 2012) (No. EPA-HQ-OPP-2012-0334).

196. Ellis v. Bradbury, No. C-13-1266 MMC, 2014 WL 1569271, at *7 (N.D. Cal. Apr. 18, 2014).

197. *Id.* at *6 (citing United States v. Cal. Care Corp., 709 F.2d 1241, 1248 (9th Cir. 1983)). "The judicially created doctrine of exhaustion of remedies does not limit jurisdiction, it merely provides that the district courts have discretion to determine its applicability. Their discretion, however, is not unbounded; they must balance the three factors . . . ." *Cal. Care Corp.*, 709 at 1248 (citations omitted).

were rooted in the 2012 Petition, which was still pending with EPA.[198] Further, the court expressed concern that allowing the claims would give petitioners the ability to bypass the FIFRA administrative process and put the court, rather than EPA, in the position of determining when a pesticide should be cancelled.[199] Given that these decisions necessitated agency expertise, and that the administrative process afforded EPA the chance to correct any errors, challengers could not bring claims before EPA fully answered the 2012 Petition.[200] As long as EPA was making some progress on the 2012 Petition, advocates could not use the courts to force EPA to review the approval of a pesticide once new information became available.[201]

Requiring pollinator advocates to go through a potentially lengthy administrative petition process limits their ability to force EPA to respond when new information emerges indicating previously unconsidered risks from a pesticide, or if the agency neglects to enforce the terms of the conditional registration. This administrative hurdle makes it critical to aggressively enforce FIFRA requirements for initial registrations, and highlights the importance of having the PRAF and its quantitative guidelines. However, prior to the PRAF, pollinator advocates had little hope of showing that EPA's qualitative, subjective assessments of risk violated the deferential substantive evidence standard.

### *B.* Pollinator Stewardship Council *Signals Success for Pollinator Advocates*

After the implementation of the PRAF, pollinator advocates had a quantitative basis for challenging neonicotinoid registrations. Advocates could now root their claims in EPA's failure to follow its own methodology when it conditionally and then unconditionally approved a new neonicotinoid.[202] In *Pollinator Stewardship Council v. EPA*, advocates challenged EPA's final decision to unconditionally register a neonicotinoid without substantial evidence, a final decision lacking exhaustion hurdles that could be challenged directly in court, unlike EPA's delayed response to a cancellation petition.[203]

At issue in this case was Dow AgroSciences LLC's (Dow) request to EPA to approve three pesticide products with the main active ingredient

198. *Ellis*, 2014 WL 1569271, at *6.

199. *Id.* at *7.

200. *Id.*

201. *See id.*

202. Pollinator Stewardship Council v. EPA, 806 F.3d 520, 522 (9th Cir. 2015) (Pollinators claimed that EPA did not have substantial evidence to determine that the neonicotinoid did not pose "unreasonable adverse effects," but this claim was rooted in the discrepancies in the data used in the framework.).

203. *Ellis*, 2014 WL 1569271, at *14 (exhaustion is required when seeking to cancel or suspend an existing pesticide registration); *see* Def. of Wildlife v. EPA, 882 F.2d 1294, 1302 (8th Cir. 1989) (noting that plaintiffs could petition EPA under FIFRA "to cancel registrations or request other action"); *cf. Pollinator Stewardship Council*, 806 F.3d at 528 (finding judicial review appropriate under 7 U.S.C. § 136n(b)).

sulfoxaflor.[204] Sulfoxaflor was a new distinct subclass of neonicotinoid for which insects had yet to gain resistance.[205] Dow sought approval for use on a variety of plants including cotton, cucurbits, citrus, fruiting vegetables, strawberries, and wheat.[206] As required by FIFRA, Dow submitted pollinator studies, which EPA assessed using the new PRAF.[207]

Using the PRAF, EPA assessed the toxicity tests under the first tier of analysis, and used the data to determine the RQ for the proposed application rate.[208] EPA arrived at RQs for honey bees that were significantly above the 0.4 level of concern: 83 for oral exposure and 2.8 for contact exposure.[209] However, rather than moving directly to the second tier once it identified RQs above the level of concern, EPA revised its assessment. It refined its analysis to account for residue and separated RQs by different stages of bee development (adult and larvae; worker bee and queen).[210] Even after the analysis was refined, the studies still produced RQs above the 0.4 level of concern (ranging from 0.8 to 5.7), which triggered the second tier of review.[211]

In the second tier semi-field studies, the shortcomings of Dow's methodology became apparent.[212] Only one of the six studies had used the maximum proposed application rate submitted by Dow in its studies, and that study only quantified residue rather than any biological effects.[213] Further, no study had properly evaluated the impact of sulfoxaflor on brood development or long-term colony health.[214] Given the incomplete and inconclusive results of the semi-field studies, EPA determined that additional studies were required, and ordered Dow to submit new studies.[215]

While Dow produced the necessary data, EPA gave sulfoxaflor a conditional registration.[216] Though EPA was concerned with the risks posed to bees, it concluded that the use in the interim would not result in "catastrophic" losses.[217] Then, six months later, EPA decided to change sulfoxaflor's registration from conditional to unconditional after EPA added mitigation measures to the application requirements, including lowering the maximum application rate and implementing crop-specific restrictions on spraying before

204. *See Pollinator Stewardship Council*, 806 F.3d at 523.
205. *Id.*
206. *Id.* at 522.
207. *Id.*
208. *Id.* at 524.
209. *Id.* at 525.
210. *Id.*
211. *Id.*
212. *Id.* at 525–26.
213. *Id.* at 526.
214. *Id.* Brood development is a significant factor in determining colony-level risk because a honey bee colony is an interdependent superorganism that functions as an organic whole, so the effect on one type of bee can impact the entire hive. *Id.* at 529–30.
215. *Id.* at 527.
216. *Id.* at 526.
217. *Id.* at 527 (emphasis omitted).

or during bloom.[218] EPA ultimately concluded that applying sulfoxaflor in accordance with the added requirements would not cause "unreasonable adverse effects" and that "the benefits of [sulfoxaflor] compared to the registered alternatives, as well as [sulfoxaflor's] ability to control problematic target pests outweighed the costs."[219] EPA thus concluded that no additional data was needed. Pollinator Stewardship Council then challenged this final decision, asserting that EPA lacked substantial evidence because it did not properly follow the PRAF guidelines.[220]

In a surprising success, the Ninth Circuit agreed with Pollinator Stewardship Council and held that EPA did not have substantial evidence on which to base its unconditional approval because the agency had failed to follow its own guidelines by approving sulfoxaflor without conducting further semi-field studies pursuant to the PRAF.[221] In vacating EPA's decision, the Ninth Circuit strengthened the impact of the PRAF in holding that EPA must adhere to the standards it sets, even if the results are "close" to the established threshold.[222]

The Ninth Circuit relied on *Natural Resources Defense Council v. EPA*, which established that EPA had to follow its own regulations once they were adopted.[223] The Ninth Circuit emphasized that it could not alter an agency's own rule even if the agency felt that its guideline was overly conservative.[224] As such, EPA could not approve sulfoxaflor without first receiving the missing data pursuant to the PRAF guidelines.[225] In so holding, the Ninth Circuit also highlighted the need for EPA to use reliable and substantial data when analyzing the risk under the PRAF.[226]

The holding in *Pollinator Stewardship Council* strengthened the PRAF as a tool for pollinator advocates to challenge unconditional registrations. First, the Ninth Circuit made it explicit that EPA has to abide by the PRAF and the RQ standard that triggers further review.[227] Moreover, once further review is triggered, EPA has to follow the PRAF process and conduct the analysis with data from studies that meet EPA's own requirements.[228] EPA cannot justify its decisions on measurements that are "close enough" or "in the neighborhood"

218. *Id.* EPA not only added extra mitigation measures, but also lowered the maximum application rate. *Id.*

219. *Id.* at 528 (internal quotations omitted).

220. *Id.*

221. *Id.* at 532.

222. *Id.* at 531–32. The Ninth Circuit also rejected EPA's argument that because only a few of the first tier studies at the adjusted lower application rate of 0.09 had a risk quotient high above the level of concern, and because the level of concern was overly conservative, second tier studies were not necessary. *Id.*

223. *Id.* at 531.

224. *Id.* at 531–32.

225. *Id.* at 532.

226. *Id.* at 530.

227. *Id.* at 531.

228. *Id.*

because they are "irrelevant as a legal matter."[229] Further, EPA is precluded from revising the "level of concern" set in the PRAF guidelines for an individual application, in a manner that would favor pesticide registration.[230] The Ninth Circuit reasoned that permitting EPA to change the standards would undermine the careful process and input that went into developing the PRAF.[231] *Pollinator Stewardship Council* strengthened the future application of the PRAF by rejecting EPA's attempts to flex and adapt standards to favor a pesticide during the registration process.[232]

### *C. Recent Actions in the Wake of the* Pollinator Stewardship Council *Holding*

Following the holding in *Pollinator Stewardship Council*, EPA shifted its position on neonicotinoids, announcing that it would scrutinize them more. In response to the Ninth Circuit's decision, EPA issued a cancellation order for sulfoxaflor, preventing the further sale and distribution of the product.[233] It also shifted its position in regards to neonicotinoids, focusing on the need to properly evaluate the risks that neonicotinoids pose to essential pollinators like honey bees.[234] As part of this shift, EPA put a hold on its approval of new registrations for products containing other prevalent neonicotinoids—imidacloprid, dinotefuran, clothianidin, and thiamethoxam—stating that it would not be in the position to approve new uses of the neonicotinoids until new bee data was submitted and the PRAF process was completed.[235] As part of its revised approach to neonicotinoids, EPA started the review process for all four of the pesticides named, utilizing the PRAF.[236] Preliminary pollinator risk assessments released by EPA summarized first tier analyses that exceeded the RQ level of concern for bees and triggered the second tier of review.[237] For pollinator advocates, this was an important victory that signified EPA's acknowledgment that neonicotinoids pose a high risk to bees.[238]

However, the increased rigor of the PRAF review process has not yet resulted in the limits on neonicotinoid approvals that pollinator advocates would like to see. Most recently, in January of 2017, EPA released its initial

229. *Id.*

230. *Id.*

231. *See id.* at 532–33.

232. *See id.*

233. EPA, SULFOXAFLOR – FINAL CANCELLATION ORDER 1 (2015), https://www.epa.gov/sites/production/files/2015-11/documents/final_cancellation_order-sulfoxaflor.pdf.

234. *See generally* POLLINATOR HEALTH TASK FORCE, *supra* note 3.

235. Letter from Jack Housenger, Director, Office of Pesticide Programs, EPA, to Registrants of Nitroguanidine Neonicotinoid Products, at 1–2 (Apr. 2, 2015), https://www.epa.gov/sites/production/files/2015-04/documents/neonicotinoid-new-use.pdf.

236. *Id.*

237. *See* Memorandum from Justin Housenger et al. to Kelly Ballard et al. on Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid at 20–22 (Jan. 4, 2016).

238. *See* Tom Philpott, *The EPA Finally Admitted That the World's Most Popular Pesticide Kills Bees—20 Years Too Late*, MOTHER JONES (Jan.7, 2016, 3:08 PM), http://www.motherjones.com/tom-philpott/2016/01/epa-finds-major-pesticide-toxic-bees.

analysis for the four neonicotinoids under evaluation, and in its press release announced that the studies showed that the most approved uses "do not pose significant risks to bee colonies."[239] EPA came to the same conclusion in regard to sulfoxaflor late in 2016, approving the pesticide so long as it was used within the strict guidelines.[240] Pollinator advocates could claim a victory in that sulfoxaflor was approved with stricter requirements and limited uses.[241] Ultimately, while the PRAF will require EPA take a closer look at neonicotinoids and likely limit their approved uses, pollinator advocates have yet to convince the agency that neonicotinoids are too risky to approve.[242]

## IV. THE LIMITED IMPACT OF THE PRAF EVEN AFTER *POLLINATOR STEWARDSHIP COUNCIL*

Despite the Ninth Circuit's holding forcing the stricter application of the PRAF, the impact of the decision will be limited. These limitations primarily come from FIFRA's statutory language and the limited applicability of the PRAF itself.[243] EPA cannot do as much as pollinator advocates would like them to because FIFRA's statutory language limits EPA's role in managing pesticides with a cost-benefit analysis and lack of enforcement authority.[244] Further, even when the PRAF is applicable, it will not be able to limit pesticide use to the extent pollinator advocates desire because the PRAF is calibrated to be used with honey bees as surrogates to other pollinators, even though other pollinator species may have substantially different social and life histories.[245] As such, while the scrutiny used by EPA for neonicotinoids has strengthened, and use of the pesticide is more limited, these changes will not be able to halt the use of neonicotinoids completely.[246]

### *A. Inherent Limitations in FIFRA*

The statutory language of FIFRA limits EPA efforts to regulate pesticides because it requires EPA to consider costs and benefits of pesticide

239. *EPA Releases Four Neonicotinoid Risk Assessments for Public Comment*, EPA (Jan. 12, 2017), https://www.epa.gov/pesticides/epa-releases-four-neonicotinoid-risk-assessments-public-comment.

240. *Decision to Register the Insecticide Sulfoxaflor with Limited Uses and Pollinator Protective Requirements*, EPA, https://www.epa.gov/ingredients-used-pesticide-products/decision-registerinsecticide-sulfoxaflor-limited-uses-and (last visited May 17, 2017).

241. *See id.*; *EPA Requires Stronger Standards for Applying the Riskiest Pesticides*, EPA (Dec. 12, 2016), https://www.epa.gov/pesticides/epa-requires-stronger-standards-applying-riskiest-pesticides.

242. *See Decision to Register the Insecticide Sulfoxaflor*, *supra* note 240; *EPA Requires Stronger Standards for Applying the Riskiest Pesticides*, *supra* note 241.

243. *See* Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2012); ANGELO, *supra* 46, at 117–19.

244. *See* ANGELO, *supra* 46, at 117-119.

245. WHITE PAPER, *supra* note 33, at 3.

246. *See EPA Requires Stronger Standards for Applying the Riskiest Pesticides*, *supra* note 241; *EPA Releases Four Neonicotinoid Risk Assessments for Public Comment*, *supra* note 239.

applications.[247] The statute ensures that the benefits of pesticides, which play an important role in agriculture, weigh heavily against any risks posed to wildlife, including pollinators.[248] In applying FIFRA, EPA must conduct risk assessments to determine the costs associated with a pesticide, but there is no equivalent process for determining benefits.[249] EPA simply assumes that the benefits exist and will accrue.[250] It can do so because FIFRA does not require that EPA show that a given pesticide will actually provide a benefit, whether it be economic, social, or commercial, as part of the balancing.[251]

The outsourcing of enforcement to state agricultural agencies also limits EPA's ability to regulate pesticides.[252] EPA has the exclusive authority to register and cancel pesticides, and it periodically reviews approvals and sets the label requirements that describe how users must apply a pesticide.[253] The legally binding label requirements set the guidelines for enforcement.[254] However, actual enforcement falls to state agriculture departments, except in California and New York, where the state environmental agency handles pesticides.[255]

This dislocation of enforcement power affords states primacy in enforcement, meaning that pollinator advocacy efforts against EPA are best focused on using the PRAF to pressure EPA to refuse registration of new pesticides and limit pesticide application. Once the pesticide is in use, advocates deal with the states directly.[256] EPA cannot intervene to correct lacking state enforcement until it follows an administrative procedure and finds that the state has not fulfilled its responsibilities.[257] Moreover, EPA must allow

247. ANGELO, *supra* 46, at 117-119.

248. *Id.*

249. *Id.* at 119.

250. *Id.* at 118–19.

251. *Id.* FIFRA authorizes EPA to waive all data requirements pertaining to efficacy. 40 C.F.R. § 158.640(b)(1) (2016); *see* Bates v. Dow AgroSciences LLC, 544 U.S. 431, 440 (2005) (noting that FIFRA authorizes EPA to waive data requirements pertaining to efficacy, "*thus permitting the agency to register a pesticide without confirming the efficacy claims made on its label*.") (emphasis added) (citations omitted).

252. H.R. 2015, *supra* note 157, at 20 (statement of Jim Jones, Assistant Administrator, Office of Safety and Pollution Prevention, EPA).

253. ANGELO, *supra* note 46, at 231–32.

254. *Id.*; Petitioners' Opening Brief at 7, 16–17, Pollinator Stewardship Council v. EPA, 806 F.3d 520 (9th Cir. 2015) (No. 13-72346) (noting that EPA uses these labels as mitigation measures, like identifying the best hours to spray and limiting spray after bloom when bees are most active).

255. H.R. 2015, *supra* note 157, at 20 (statement of Jim Jones, Assistant Administrator, Office of Safety and Pollution Prevention, EPA).

256. *See id.*

257. 7 U.S.C. § 136w-2(b) (2012); 40 C.F.R. § 173.3 (2016); *see* Letter from Paul H. Achitoff, Managing Attorney, Earthjustice, to Gina McCarthy, Administrator, EPA, & Kathleen Johnson, Director, EPA, at 2 (Aug. 4, 2016), http://earthjustice.org/sites/default/files/files/2016-8-4-complaint-EPA-rescind-HDOA-primacy.pdf ("Re: Complaint Under Sections 26 and 27 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136w-2, and 40 C.F.R. Part 173").

the state ninety days to correct the deficiencies before intervening directly.[258] The inability to enforce the regulations results in uneven pollinator protection across the country.[259]

EPA's capacity also constrains its ability to manage pesticides. EPA makes a large number of regulatory decisions regarding pesticides every year and maintains over 20,000 registered products.[260] At the same time, various interest groups pressure EPA over its pesticide decisions.[261] These include pollinator advocates (who have become a leading voice in pesticide matters), agencies worried about endangered species (such as the Services), and the agricultural industry (who want pesticides approved quickly and need them to protect their crops).[262] Managing the concerns from a variety of stakeholders can make it difficult for EPA to consider risks fully while still ensuring it is approving pesticides necessary to maintain a large and prominent agriculture industry in the United States.[263]

### *B. Limitations of the PRAF*

The limited impact of the *Pollinator Stewardship Council* decision also stems from limitations of the PRAF itself. First, the PRAF's ability to protect pollinators is limited by its focus on honey bees over other pollinators. Second, the PRAF works as a tool only when EPA is evaluating a pesticide for registration. Further, the usefulness of the PRAF remains contingent on the ability of the scientific data to identify and quantify sublethal effects. Finally, the PRAF is currently only a guideline and not a regulation, which makes it vulnerable to change, especially in the current political climate.

While honey bees are the most important commercial pollinator, they are not the only species threatened by neonicotinoids or other insecticides.[264] The

258. § 136w-2(b); 40 C.F.R. § 173.3; *see* Letter from Paul H. Achitoff to Gina McCarthy & Kathleen Johnson, *supra* note 257, at 2.

259. *See* H.R. 2015, *supra* note 157, at 20 (statement of Jim Jones, Assistant Administrator, Office of Safety and Pollution Prevention, EPA).

260. ANGELO, *supra* note 46, at 232.

261. *See* Charles Franklin, *FIFRA v. the Courts: Redefining Federal Pesticide Policy, One Case at a Time*, NAT. RES. & ENV'T, Summer 2011, at 18, 18–22 (describing common conflicts that have arisen with FIFRA).

262. *See* Nichelle Harriott, *Sowing Seeds of Doubt*, PESTICIDES & YOU, Spring 2015, at 9–11 (responding to industry claims that neonicotinoids are necessary and not to blame for bee declines on behalf of Beyond Pesticides); CENTER FOR FOOD SAFETY, HEAVY COSTS: WEIGHING THE VALUE OF NEONICOTINOID INSECTICIDES IN AGRICULTURE (2014), http://www.centerforfoodsafety.org/files/neonic-efficacy_digital_29226.pdf (promoting the suspension of neonicotinoid use in agriculture pending further study). *But see* AGINFOMATICS, THE VALUE OF NEONICOTINOIDS IN NORTH AMERICAN AGRICULTURE: A CASE STUDY OF NEONICOTINOID USE IN MID-SOUTH COTTON 2–6 (2014), http://www.aginfomatics.com/uploads/3/4/2/2/34223974/case_study_neonicotinoid_use_cotton.pdf (making the case for the necessity of neonicotinoids for growing cotton); Steve Davies, *Neonic-Coated Seeds Get Boost From Court Ruling*, AGRI-PULSE (Nov. 22, 2016, 4:40 PM) (praising the dismissal of the neonicotinoid seed complaint as a victory for agriculture).

263. *See* Franklin, supra note 261, at 18–22; ANGELO, *supra* note 46, at 232.

264. *See* Spivak et al., *supra* note 103, at 34.

PRAF focuses on honey bees and uses them as surrogates for other pollinator species, which can mean other important wild and native species are left outside of the reach of the PRAF's standards.[265] EPA finds that for logistical reasons—relative ease of study and well-documented individual and colony-level behavior—honey bees are a good surrogate for other insect pollinators even though many have substantially different behavior.[266] USDA has focused on honey bees for similar reasons.[267] Though EPA regulations provide for analysis of data from non-honey bee species, they only require consideration of such data when it is available.[268] As noted in EPA's collaborative PRAF Proposal, the use of honey bees limits the ability of the PRAF to examine risks to other insect pollinators, which can leave more sensitive insects vulnerable to neonicotinoid impacts.[269]

Up to 95 percent of the land area treated with neonicotinoid pesticides is treated via pesticide-coated seeds, but this application method is exempted from the FIFRA registration process, and not subject to the PRAF's greater scrutiny.[270] In 2016, CFS challenged this exemption and sought to have seed coating considered as an act of manufacturing a pesticide, which would require its own FIFRA label and registration approval.[271] The court ruled against CFS, holding that it was within EPA's discretion to exclude chemical-coated seeds from pesticide rules when the compounds used were already covered by FIFRA in another context.[272] This loss highlights that the PRAF is not a useful tool beyond the initial review process.[273] Though disappointed, pollinator advocates noted that the loss derived from an administrative law question, not from the question of whether the seed coatings were harming the bees, and thus continue to insist that EPA must address the risk from seed coatings.[274]

Further, the PRAF's ability to prevent pesticide registrations will likely be limited to neonicotinoids and other systemic pesticides that can trigger further review under the PRAF's tiered structure. With the PRAF, EPA intended to replace the qualitative method it had historically used with quantitative risk assessment by using RQs.[275] The first tier screening is meant to be conservative

265. WHITE PAPER, *supra* note 33, at 3.

266. *Id.* at 3.

267. *Id.* at 24.

268. *Id.* at 26.

269. *See id.* at 3, *see also* Spivak, *supra* note 103, at 36.

270. Complaint for Declaratory and Injunctive Relief at 1, Anderson v. McCarthy, No. C 16-00068 WHA, 2016 WL 6834215 (N.D. Cal. Jan. 6, 2016).

271. *Id.*; *see* Davies, *supra* note 262.

272. Anderson v. McCarthy, No. C 16-00068 WHA, 2016 WL 6834215, at *7, *9 (N.D. Cal. Nov. 21, 2016) (holding that use of 2013 Guidance to exclude pesticide-treated seeds was not a final agency action and was therefore not subject to review under the APA).

273. Complaint for Declaratory and Injunctive Relief, *supra* note 270, at 1.

274. *See* Davies, *supra* note 262; Geoffrey Mohan, *Court's Rejection of a Lawsuit over Pesticides in Seed Coatings is a Setback to Beekeepers*, L.A. TIMES (Nov. 22, 2016, 6:50 PM), http://www.latimes.com/business/la-fi-pesticide-seeds-20161122-story.html.

275. WHITE PAPER, *supra* note 33 at 2, 5.

in its estimates, but is also designed to be a screening tool for which pesticides should receive stricter review.[276] Because of the difficulty of characterizing sublethal effects at all tiers, but especially at the first tier, where the acute toxicity data utilized does not properly characterize sublethal effects, the PRAF will still fail to screen some pesticides with serious chronic impacts.[277] Pesticides that do not show acute effects will not face higher scrutiny even if they might be contributing to the sublethal effects felt by honey bees and other insect pollinators.[278]

Lastly, as a guideline rather than a regulation, the PRAF is vulnerable to shifts in policy, such as the ones that occur at the change of an administration. Despite its vulnerability to shifts in policy, the PRAF has had an impact on how EPA handles pesticide registrations. The PRAF signified to EPA that it must follow the stringent method incorporated into the guidelines.[279] EPA accepted this rigidity for pollinators and declared that it would be subjecting neonicotinoids to higher scrutiny.[280] However, the willingness to adopt strict guidelines for honey bees was due to the strong public and industry attention the issued received, and it has continued to play a major role because of the continuous political focus from the Pollinator Health Task Force.[281] As seen in the ESA context, overwhelming outside pressure motivates swift EPA response to pesticide harms.[282] In the absence of such pressure, EPA is unlikely to develop frameworks that will limit its own discretion. The chilling effect might be more apparent in an administration that does not want to see its hands tied by strict guidelines such as the PRAF.[283] At the least, *Pollinator Stewardship Council* will likely discourage the development of other methodologies similar to the PRAF's framework, unless the wildlife or ecological resources under threat also possess the honey bee's combination of factors.[284]

## CONCLUSION

Pesticides have always posed a complicated ecological problem for regulatory agencies. The rise of neonicotinoids and the decline of bees is this decade's pesticide problem, and the debate over the impact of this new class of

276. *Id.* at 4.
277. *Id.* at 5, 27–29.
278. *See id.* at 5.
279. *See id.*
280. *EPA Requires Stronger Standards for Applying the Riskiest Pesticides*, *supra* note 241.
281. *See generally* POLLINATOR HEALTH TASK FORCE, *supra* note 3.
282. *Supra* Part I.B.
283. *See* Presidential Memorandum 2014, *supra* note 31; *but see* Delay of Effective Date for 30 Final Regulations Published by the Environmental Protection Agency Between October 28, 2016 and January 17, 2017, 82 Fed. Reg. 8499-02 (Jan. 26, 2017) (to be codified at 40 C.F.R. pts. 22, 51, 52, 61, 68, 80, 81, 124, 147, 171, 239, 259, 300, 770); Tim Devaney, *Trump Delays Dozens of EPA Regs*, THE HILL (Jan. 25, 2017, 11:08 AM), http://thehill.com/regulation/316049-trump-delays-dozens-of-epa-regs.
284. *See* Pollinator Stewardship Council v. EPA, 806 F.3d 520, 528 (9th Cir. 2015).

pesticides continues.[285] EPA developed the PRAF at the height of the CCD crisis, just as pesticides—and specifically neonicotinoids—were being identified as a threat to honey bees.[286] The implementation of the PRAF, the neonicotinoid ban in Europe, and the Presidential Memorandum on Pollinator Health appeared to signal a shift in pesticide policy that favored honey bees and other pollinators over liberal approval of new pesticides. The Ninth Circuit's holding in *Pollinator Stewardship Council*, a victory for pollinator advocates, continued the trend of pollinator protection and resulted in further actions by EPA in regard to neonicotinoids.[287] And while neonicotinoids are being approved in a more limited way than their uses when CCD first appeared, recent developments appear to favor the use of neonicotinoids.[288]

These developments show that PRAF's impact has been limited and will continue to be. While the PRAF has resulted in EPA applying scrutiny to neonicotinoids, the PRAF was ultimately not able to stop the approval of neonicotinoid products. It is also unclear if other non-neonicotinoid pesticides will be subjected to the same scrutiny if they do not pose the same risk of acute effects that would trigger review beyond the first tier of the PRAF. CFS's loss on the issue of pesticide-coated seeds further highlighted that many neonicotinoid applications remain outside of the scope of the PRAF. With the arrival of a new administration that is more averse to regulations, it is unlikely that EPA will develop similar guidance that would limit EPA's deferential decision-making capacity within FIFRA.[289] There is also a risk that the PRAF could be modified to relax its requirements. While honey bees will likely continue to influence pesticide policy because of public, political, and industry interest, it seems unlikely that other threats to wildlife or even to human health could drive a similar shift in policy without having the same combination of characteristics.

285. *See* David Schultz, *Polarized Neonicotinoid Debate a Distraction from Addressing Bee Peril, Scientists Say*, CHEMICAL REGULATION REPORTER (Apr. 3, 2015), https://www.bna.com/polarized-neonicotinoid-debate-n17179925032/.

286. *See* WHITE PAPER, *supra* note 33, at 2–3.

287. *See supra* Parts III.B–III.C.

288. *See EPA Releases Four Neonicotinoid Risk Assessments for Public Comment*, *supra* note 239.

289. Steven Mufson, *Trump Wants to Scrap Two Regulations for Each New One Adopted*, WASHINGTON POST (Jan. 30, 2017), https://www.washingtonpost.com/news/energy-environment/wp/2017/01/30/trump-wants-to-cut-two-regulations-on-businesses-for-every-new-one-imposed/?utm_term=.31f34e6d0b71.