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***Pollinator Stewardship Council v. United States Environmental Protection Agency*, 800 F.3d 1176 (9th Cir. 2015)**

Hallie E. Bishop

Pollinator Stewardship Council v. United States Environmental Protection Agency assures us that the bees will still be buzzing until proper EPA studies have been conducted on the sulfoxaflor pesticide. The Ninth Circuit's decision struck down the EPA's approval of a pesticide containing sulfoxaflor due to its effects on honey bees. *Pollinator Stewardship Council* affirms the EPA's process for ensuring chemical safety; however, the EPA failed to follow that process when they approved the sulfoxaflor pesticide that has been linked to the declining honey bee population. The concurrence agreed with the majority opinion that the EPA failed to meet its burden, but analyzed the EPA's decision under an arbitrary and capricious standard, a lower bar than the majority's substantial evidence standard.

I. INTRODUCTION

At issue in *Pollinator Stewardship Council v. United States Environmental Protection Agency* was whether the Environmental Protection Agency's ("EPA") decision to unconditionally register a pesticide with sulfoxaflor was based on flawed and limited data.¹ The Pollinator Stewardship Council, along with many other honey bee associations, argued that the EPA initially registered the pesticide as conditional pending more data, but then registered the pesticide as unconditional without completing the additional studies to collect more data.² The EPA sought to defend its unconditional registration decision by arguing that despite the studies' shortcomings, the EPA nonetheless used sufficient data to support its decision to register the pesticide.³ Despite the EPA's arguments that it retained the flexibility to determine the type of data to support registration of pesticides,⁴ the United States Court of Appeals for the Ninth Circuit held that the EPA had not collected substantial evidence through studies to satisfy its own risk assessment.⁵ In holding so, the pesticide is no longer allowed to be used on crops until the EPA can obtain proper and

¹ *Pollinator Stewardship Council v. U.S. Env'tl. Prot. Agency*, 800 F.3d 1176, 1177 (9th Cir. 2015), *amended by*, *superseded by*, No. 13-72346, 2015 WL 7003600 (9th Cir. Nov. 12, 2015) (panel reh'g) The panel granted respondent's petition for rehearing and issued an amended order. *Pollinator Stewardship Council*, 2015 WL 7003600, at *1. The amended order adopted in full the panel's first order while changing only two sentences; neither of which bore on the dispositive issues or the decision of the court. *See Id.* at *1, *1-18).

² *Id.* at 1182.

³ *Id.* at 1183.

⁴ *Id.*

⁵ *Id.* at 1177.

complete studies of the pesticide's effects on honey bees, and then it must re-evaluate the pesticide's safety based on those new studies.⁶

II. FACTUAL AND PROCEDURAL HISTORY

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") prohibits the sale of pesticides that lack approval and registration by the EPA.⁷ The FIFRA allows the EPA to deny registration when "necessary to prevent unreasonable adverse effects."⁸ "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 [the] pesticide."⁹ Essentially, the FIFRA requires a cost-benefit analysis by the EPA.¹⁰

The EPA may either conditionally or unconditionally register a pesticide.¹¹ The EPA's conditional registration of a pesticide occurs when there is insufficient data to fully evaluate the unreasonable adverse effects, and therefore may only be used under specific conditions.¹² The EPA's unconditional registration of a pesticide requires sufficient data to evaluate all environmental risks.¹³ In order to register a new pesticide, a manufacturer must submit an application detailing a pesticide's uses, benefits, ingredients, and the studies and test results of the pesticide's health, safety, and environmental effects.¹⁴ In 2010, Intervenor Dow AgroSciences LLC ("Dow") submitted an application with the EPA for approval and registration of pesticides containing sulfoxaflor.¹⁵ Pursuant to the FIFRA, the EPA analyzed the application and studies by Dow using its pollinator risk assessment framework to determine the effect sulfoxaflor would have on bees.¹⁶

A. The Pollinator Risk Assessment Framework

The Pollinator Risk Assessment Framework is a multi-tiered evaluation.¹⁷ The first tier, the preliminary or screening level ("Tier 1"), is intended to identify if potential risks to bees exist.¹⁸ If Tier 1 is answered in the

⁶ *Pollinator Stewardship Council*, 2015 WL 7003600, at *1.

⁷ *Pollinator Stewardship Council*, 800 F.3d at 1177 (citing 7 U.S.C. § 136a(a) (2012)).

⁸ *Id.* at 1178 (quoting 7 U.S.C. § 136a(a)).

⁹ *Id.* (quoting 7 U.S.C. § 136(bb)).

¹⁰ *Id.* (citing *Wash. Toxics Coal. v. Env'tl. Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005)).

¹¹ *Id.* (citing 7 U.S.C. § 136a(c)(5), (7)(C)).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* (citing 7 U.S.C. § 136a(c)).

¹⁵ *Id.* at 1178.

¹⁶ *Id.* at 1179.

¹⁷ *Id.*

¹⁸ *Id.*

affirmative, then second tier is intended to pinpoint when and where the risks exist and the extent of their risk to the bee population (“Tier 2”).¹⁹

In Tier 1, the EPA reviewed the studies submitted by Dow and determined the acute median lethal dose. The acute median lethal dose is the dose at which half of the individual bees that are tested, both when the chemical is sprayed onto the bees (contact dose) and when the bees orally consume the chemical, die from that dose.²⁰ The EPA determined that the acute median lethal dose for the contact doses was .13 micrograms, and .052 micrograms for the oral doses.²¹ Based on these determinations, the EPA categorized sulfoxaflor as “extremely toxic” to honey bees.²² The EPA also compared those median lethal doses with the concentration of the pesticide that bees would likely encounter in the environment (the risk quotient) and found that the .4 risk quotient set by the EPA, representing circumstances where ten-percent or more of bees would be killed in an environment, was far lower than the calculated risk quotient for bees’ exposure to sulfoxaflor.²³ Therefore, the EPA needed to conduct further studies and it continued on to Tier 2.²⁴

Tier 2 analysis aims to evaluate the pesticide’s effect on a colony of bees in the environment.²⁵ Dow submitted six “tunnel semi-field” studies, but only one of the studies used pesticide application rates at Dow’s proposed application rate of .133 pounds of active ingredient per acre.²⁶ The sixth study (“Ythier 2012”) only used Dow’s proposed application rates in two of seven applications and tested on cotton, which may have skewed the results because cotton is not a good source of pollen.²⁷ The EPA conceded the Ythier 2012 study only provided “limited biological effects information.”²⁸ The EPA concluded, that based on these Tier 2 results and the limitations of the studies that had been conducted, additional data was needed before allowing use of sulfoxaflor.²⁹

B. EPA’s Condition and Unconditional Registrations

The EPA initially proposed to give sulfoxaflor conditional approval while it collected more data.³⁰ Under this conditional approval, the EPA proposed mitigation measures like restricting its use to specific crops at specific times and reducing sulfoxaflor’s maximum single application rate.³¹ Additionally, the EPA

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.* at 1180.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* at 1181.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.* at 1181-82.

requested that Dow conduct more studies about the pesticide's harmful effects in accordance with the Organization for Economic Coordination and Development ("OECD") guidelines.³² The EPA announced its decision for conditional approval in January 2013, but then unconditionally registered sulfoxaflor in May 2013.³³ The court found no indication that Dow ever completed the additional studies requested by the EPA.³⁴ The EPA justified the unconditional registration by highlighting additional required mitigation measures.³⁵ Thus, the EPA concluded that despite the potential hazard to bees, that hazard would be properly mitigated by reducing application rates to .09 pounds per square acre, increasing the time between application intervals, and requiring warning labels.³⁶

After the EPA approved the unconditional registration for sulfoxaflor, petitioners sued, arguing that the EPA's decision to unconditionally register sulfoxaflor was not supported by substantial evidence.³⁷

III. ANALYSIS

For a court to uphold the EPA's decision to register a new pesticide under the FIFRA, the EPA's decision must be "supported by substantial evidence" based on the whole record.³⁸ The Ninth Circuit focused on the limitations and deficiencies in Tier 2 of the risk assessment performed by the EPA.³⁹ The court determined that the EPA's decision to unconditionally register sulfoxaflor was not supported by substantial evidence.⁴⁰ The court began by highlighting the deficiencies of the EPA's conclusion after noting that the Dow studies did not support unconditional registration.⁴¹ The court focuses on the EPA's argument that the mitigating measures that accompanied the unconditional registration supports the EPA's decision.⁴²

The EPA decided to conditionally register sulfoxaflor pending additional studies, but then approved unconditional registration with mitigating measures five months later.⁴³ However, the court found that the EPA lacked data from studies to support the mitigation measures, such as the impact of applying the pesticide at a reduced rate of .09 pounds of active ingredient per acre.⁴⁴ As the court stated, the EPA initially concluded that there were limited studies at the .09 application rate, and there were no studies done on brood development and

³² *Id.* at 1182.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* at 1182-83.

³⁷ *Id.* at 1183.

³⁸ *Id.* (citing 7 U.S.C. § 136n(b) (2012)).

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* at 1184-85.

⁴² *Id.* at 1184.

⁴³ *Id.*

⁴⁴ *Id.*

colony health at this application rate.⁴⁵ The court concluded that the EPA's unconditional approval of application rates at .09 was not supported by Dow's limited studies, and the EPA's conditional approval requiring more studies.⁴⁶ Therefore, the court determined that the EPA lacked substantial evidence that sulfoxaflor, even if applied at the lower amount, would not have unreasonable adverse effects on the environment as required by the FIFRA.⁴⁷

Next, the EPA and Dow argued that since the studies were inconclusive, the studies affirmatively prove that sulfoxaflor does not cause adverse effects on the environment.⁴⁸ The court held that an agency cannot rely on ambiguous studies as evidence of a conclusion that the studies do not support.⁴⁹ The EPA also argued that, despite conducting Tier 2 studies, it was not required to do so because few residue measurements for application rate of sulfoxaflor were high enough to trigger the level of concern requiring Tier 2 studies.⁵⁰ The court concluded that some of the measurements do exceed the level of concern at the .09 sulfoxaflor application rate, and therefore the EPA was required, and indeed acted in accordance with its regulations when it moved on to Tier 2 assessment.⁵¹

The court held that the EPA cannot be allowed to avoid its own regulations when actual or close data trigger risk concerns.⁵² The EPA chose the requisite level of concern and the court cannot alter that level.⁵³ The court found that Tier 2 required more studies to substantiate the EPA's unconditional registration because that decision was not supported by substantial evidence through sufficient data documenting the risk to honey bees.⁵⁴ Since the EPA lacked sufficient data, the court found it could not decide whether sulfoxaflor would cause unreasonable adverse effects on bees under FIFRA's requirements.⁵⁵ Accordingly, the EPA's decision to register sulfoxaflor unconditionally could not be justified, and the court held the EPA's decision could not be upheld due to lack of sufficient data.

The court then turned to the decision of whether to remand or vacate the EPA's decision.⁵⁶ When determining whether to vacate the EPA's decision, a court may leave the faulty rule in place if vacating could result in possible

⁴⁵ *Id.* at 1185.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* at 1186-87.

⁴⁹ *Id.* at 1186. (citing *Tucson Herpetological Soc. v. Salazar*, 556 F.3d 870, 879 (9th Cir. 2009)).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.* (citing *Natural Res. Def. Council v. Env'tl. Prot. Agency*, 735 F.3d 873, 883-84 (9th Cir. 2013)).

⁵³ *Id.*

⁵⁴ *Id.* at 1187.

⁵⁵ *Id.*

⁵⁶ *Id.*

environmental harm.⁵⁷ The court decided that allowing the EPA's decision to remain in place created greater risks of potential harm to the bee population than vacating the decision.⁵⁸ The court remanded the case for the EPA to reevaluate its registration of sulfoxaflor after additional studies are conducted by Dow.⁵⁹ The court concluded that vacating and remanding the EPA's decision would be the most effective and environmentally safe remedy.⁶⁰

The concurrence, written by Circuit Judge N. Randy Smith, argued that the EPA's decision was not supported by evidence that would even meet the lower bar of the arbitrary and capricious standard because the EPA attempted to support its decision retroactively with studies it had previously found inadequate.⁶¹ Judge Smith asked the EPA to "explain the analysis it conducted, the data it reviewed, and how the EPA relied on the data in making its final decision."⁶² Here, the Judge did not ask the EPA to explain every scientific action, but rather that the EPA articulate a satisfactory explanation for its decision to unconditionally register sulfoxaflor.⁶³

IV. CONCLUSION

It is clear the EPA's argument that it had properly followed its own rules did not fly with this court.⁶⁴ The court held that the EPA's decision to unconditionally register sulfoxaflor was not supported by substantial evidence, despite having issued mitigating measures.⁶⁵ The court required the EPA to follow the rules it has set for itself and here, the EPA did not follow its rules because it did not support its decision with adequate data.⁶⁶ The Ninth Circuit granted the respondent's petition for a panel rehearing, adopting in full its previous opinion, while correcting two sentences; neither baring on the dispositive issues or decision of the court.⁶⁷

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.* at 1189-91 (Smith, J., concurring).

⁶² *Id.* at 1189.

⁶³ *Id.* at 1193.

⁶⁴ *Id.* at 1186 (majority opinion).

⁶⁵ *Id.* at 1183.

⁶⁶ *Id.* at 1186.

⁶⁷ *See Pollinator Stewardship Council* 2015 WL 7003600.