



Pesticides in the Mid-South: Litigation and Regulatory Update

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Overview

- Pesticides & the ESA
- Dicamba
- Glyphosate
- Other Developments
- Final Thoughts



What's Going On?

- In 2022, EPA launched a new policy concerning its approach to ESA analysis when making decisions under FIFRA
- The change comes after multiple court opinions concluded that EPA had violated the ESA by failing to go through Section 7 analysis when registering a pesticide
- Prior to this policy change, EPA was primarily applying the FIFRA “no adverse effects” standard to analyze impacts to listed species



ESA vs. FIFRA

ESA Standard

- The ESA requires all federal agencies to analyze the impacts of their actions to listed species and, if necessary, consult with FWS and NMFS on needed mitigation
 - Referred to as Section 7 consultation
- Agencies review to determine whether their action “may affect” listed species
 - This is considered a low threshold to clear – any effect could qualify
- If an agency reaches a “may affect” finding, it considers whether the action is “likely to adversely affect” any listed species
 - If yes, then formal consultation is initiated

FIFRA Standard

- FIFRA requires EPA to ensure that a registered pesticide will not have “unreasonable adverse effects on the environment”
 - Referred to as “no unreasonable effects” standard
- “Unreasonable adverse effects on the environment” are defined as “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”
- FIFRA’s “no unreasonable effects” standard is a risk/benefit analysis



What Does EPA's New Policy Entail?

- Primarily, the policy requires EPA to “fully comply” with the ESA when registering new conventional pesticides, conducting registration review, and carrying out any other FIFRA actions
- The policy allows EPA to evaluate groups of pesticides that are “similar” to one another at the same time, and assign such pesticides the same mitigation measures
 - Pesticides are “similar” if they have similar exposure pathways, uses, and ecological risks
 - By grouping similar pesticides, EPA hopes to ensure consistency and equitability
- EPA has identified three basic strategies to help bring its FIFRA actions into ESA compliance



EPA's Three Basic Strategies

1. Use a “menu” of Interim Ecological Mitigation measures as a starting point to address pesticide risks to listed species

- EPA will decide which measures from this menu to propose based on the risks and benefits of the pesticide
- Similar pesticides may be subject to the same mitigation measures

2. Work with registrants to add language to pesticide labels directing applicators to check Bulletins Live! Two

- Bulletins Live! Two is the website where EPA publishes geographically specific pesticide use restrictions
- Some of the mitigation requirements could be as specific as a county-by-county approach – pesticide applicators may need to check Bulletins Live! Two more routinely than they currently do

3. Prioritize ESA analysis for those species that are sensitive to pesticides

- Includes initiatives to identify ESA mitigation measures for pilot species



What's on the "Menu"?

- This “menu” or “pick list” developed by EPA is meant to serve as a starting point for EPA to develop mitigation for a pesticide
 - For each registration review case, EPA will review the menu and use the mitigation measures there as a potential starting point based on the pesticide's risks and benefits – other mitigation measures may be added later
- The menu includes the following mitigation measures:
 - Surface water protection measures applicators would follow when precipitation occurs to reduce runoff
 - Conservation buffers
 - Droplet size, windspeed, and release height limits
 - Spray drift buffers from aquatic habitats and conservation areas



Ultimate Impact?

- In early 2022, EPA tested out this new policy with new labels for Enlist One and Enlist Duo
 - New labels included mitigation measures to protect the listed American burying beetle
 - The measures were implemented on a county-by-county basis, with some counties no longer able to apply either pesticide at all
- Going forward, farmers are likely to see additional application restrictions, and even application prohibitions for multiple pesticides
- Currently, EPA has court-enforceable ESA compliance deadlines for around 50 pesticides – ESA says meeting these deadlines will take it beyond 2030
 - EPA hopes that complying with the ESA on the front end will result in pesticide registration labels that hold up in court



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Dicamba Review: Where Are We?

- Three dicamba pesticide products are currently registered for over-the-top use onto dicamba-resistant seeds
 - Bayer's XtendiMax, BASF's Engenia, Syngenta's Tavium
- The current registration was granted in 2020 and is set to expire in December 2025
 - EPA is currently in process of developing a new registration decision
- In 2021, EPA released a report which concluded that in making the 2018 dicamba registration decision, it had "varied from typical operating procedures" which contributed to the Ninth Circuit's 2020 decision
- Legal challenges to the 2020 registration are currently on-going



Here We Go Again (Maybe?)

- On April 13, plaintiffs in the lawsuit ***Ctr. for Biological Diversity v. U.S. Eenvtl. Protection Agency, No. 4:20-cv-00555 (D. Ariz.)*** filed a motion for summary judgement asking the judge to overturn the 2020 dicamba registration
- Plaintiffs in this case are the same plaintiffs that successfully petitioned the Ninth Circuit Court of Appeals to overturn the 2018 dicamba registration
- In their MSJ, plaintiffs argue that the 2020 registration violates both FIFRA and the ESA – the same arguments they raised in their earlier lawsuit against the 2018 registration
 - They also claim EPA violated mandatory rulemaking procedures



FIFRA Arguments

1. EPA failed to address the FIFRA violations identified by the Ninth Circuit in its 2020 decision

- Those violations include: approving a label so long it was almost impossible to follow (40 pages in length), failing to consider full economic cost of crops lost to drift damage, failing to consider social costs

2. EPA did not meet unconditional registration standard when making 2020 registration decision

- To register a pesticide under FIFRA, EPA must make a finding that use of the pesticide as its intended will not cause “unreasonable adverse impacts on the environment”
- An unconditional registration requires EPA to determine that no additional data is needed to register the pesticide
- Plaintiffs say neither of these standards were met



ESA Arguments

1. EPA applied the FIFRA “no unreasonable adverse effects” standard instead of the ESA “may affect” standard

- Remember: EPA has recently changed its policy so that it applies the “may affect” standard

2. EPA considered the wrong “action area”

- The ESA requires agencies to consider “all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action” when analyzing actions for impacts to species. 50 C.F.R. § 402.02.
- EPA analyzed fields where dicamba would be applied and a 57-foot buffer

3. EPA failed to consider impacts to critical habitat

- EPA limited its critical habitat analysis to fields where dicamba is applied



Procedural Violation Arguments

1. EPA violated FIFRA process for “un-cancelling” a pesticide

- When a pesticide receives a cancel order, FIFRA outlines a specific process that EPA must follow to re-register a pesticide
- Process requires EPA to make a finding that reconsideration of the cancellation decision is “warranted”
- Reconsideration may be warranted if EPA finds “substantial new evidence” that was not available at the time the cancellation decision was issued. 40 C.F.R. § 164.131.
- Plaintiffs say EPA did not make that finding

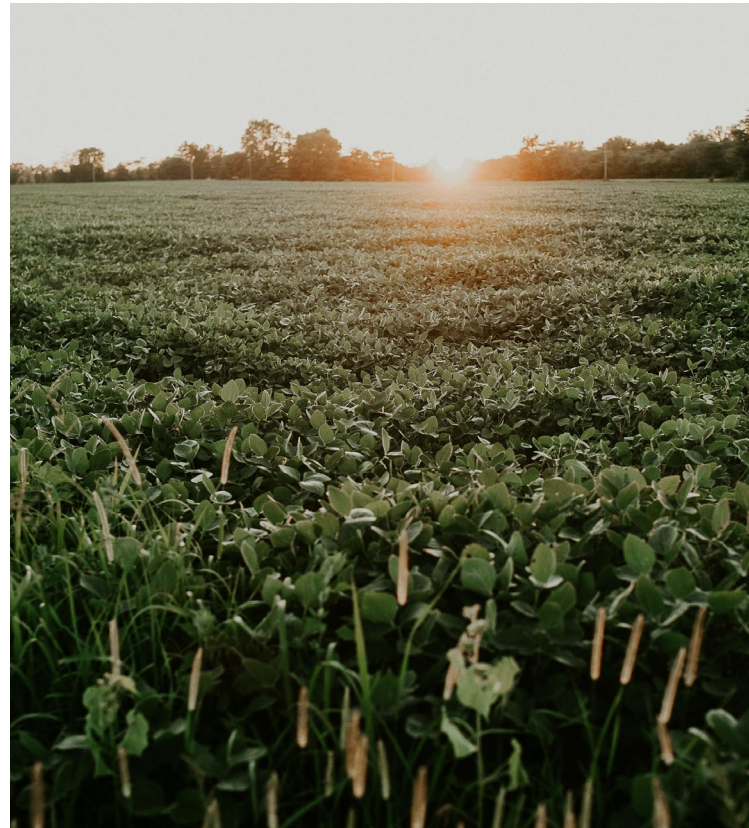
2. EPA did not go through notice-and-comment process when making 2020 registration decision

- The Ninth Circuit ruled in *Center for Food Safety v. Regan*, 56 F.4th 648 (9th Cir. 2022) that it is a FIFRA violation to re-approve a cancelled pesticide without notice-and-comment



What Next?

- The future is unclear
- EPA has not yet filed a response to the plaintiffs' MSJ
- If the district court grants plaintiffs' request and vacates 2020 registration order, it is not clear how long it would be before a new registration order is issued
 - How long would ESA compliance take? Would EPA need to resolve FIFRA violations identified by the Ninth Circuit?



Any Other Lawsuits?

- A lawsuit filed by the American Soybean Association in late 2020 asking the D.C. district court to uphold the 2020 dicamba registration is still on-going
 - Case has been under an administrative stay, but a motion to lift that stay was filed in February
- ***Bader Farms, Inc. v. BASF Corp., No. 23-1134 (8th Cir. 2023)*** is back before the appeals court, this time on damages
 - BASF argues that it should not be liable for punitive damages
 - The corporation is asking the Eighth Circuit to uphold a lower court decision which concluded that once Bader Farms had settled with Monsanto, there was no reason to continue a trial on punitive damages
- Other lawsuits involving claims of dicamba injury are still ongoing
 - At the federal level: ***In re: Dicamba Herbicides Litigation, No. 1:18-md-2820 (E.D. Mo.)***; most cases settled, but suit filed by Coy's Honey Farm, Inc. still on-going
 - At the state level: ***Texas High Plains Grape Growers v. Bayer & BASF (B-207748)***; spent much of 2022 determining venue



2025 is Closer Than You Think

- The current over-the-top dicamba registration is set to expire at the end of 2025
- EPA is already in the process of determining whether to issue another registration decision
- In 2022, EPA released both an ecological risk assessment and a human health risk assessment as part of its registration analysis for the fifteen-year registration review for dicamba – both considered over-the-top use
 - The human health risk assessment found additional restrictions added to the 2020 over-the-top registration did not limit drift damage as much as hoped
 - The ecological risk analysis found occupational inhalation “risks of concern”
 - Unclear how these findings will impact future over-the-top use registration



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Up for Review

- Glyphosate is currently undergoing registration review – the evaluation FIFRA mandates all registered pesticides to go through every fifteen years to make sure the pesticide still meets FIFRA’s “no adverse effects” standard
- As part of the registration review, EPA released an interim registration review decision in 2020
 - Included a human health risk analysis which concluded that glyphosate is unlikely to be a human carcinogen, and an ecological risk analysis which concluded that the benefits of glyphosate outweigh any potential ecological risks
- EPA withdrew the interim registration in 2022 following an opinion from the Ninth Circuit
 - A final registration decision is now not expected until 2026



Ninth Circuit Weighs In

In June 2022, the Ninth Circuit issued a ruling which vacated the human health portion of the 2020 glyphosate interim registration decision



The Ninth Circuit determined that EPA's conclusion that glyphosate was "not likely" to cause cancer was inconsistent with other statements made in the human health risk analysis

- Under FIFRA, EPA must support its conclusion with "substantial evidence," and its reasoning must be "coherent and internally consistent." 7 U.S.C. § 136n(b).
- In the human health analysis, EPA made a statement that it was unable to reach a conclusion regarding the connection between glyphosate and non-Hodgkin's lymphoma – the Ninth Circuit found this directly contradicted EPA's "not likely" conclusion



Ninth Circuit Weighs In, Cont.

The court also found that EPA had violated the ESA by failing to conduct required ESA analysis when issuing the interim decision, but declined to grant relief



EPA was given a court-ordered deadline of October 1, 2022, to correct flaws in human health risk analysis



Because EPA could not meet that deadline, it pulled the entire interim registration decision



Glyphosate and the ESA

- As part of the registration review, EPA has initiated an ESA analysis for glyphosate
- A final biological evaluation was published in November 2021 a year after a draft version was made available for public comment
 - EPA reached a “may affect” finding for each one of the 1,795 listed species and 792 designated critical habitats examined
 - A “likely to adverse effect” determination was made for 1,676 species and 759 critical habitats
- EPA has initiated formal review with the Fish and Wildlife Service and the National Marine Fisheries Service
- It is currently unclear what, if any, mitigation measures could be required



Preemption Issue Refresh

- In 2021, Bayer appealed the glyphosate lawsuit *Hardeman v. Monsanto* to the United States Supreme Court
- The issue on appeal involves federal preemption, FIFRA, and state law failure to warn claims
- Outcome has potential to affect not only glyphosate lawsuits, but all on-going and future pesticide product liability suits



Issue on Appeal

- Bayer is specifically appealing Hardeman’s failure to warn claim, arguing that it is preempted by FIFRA
- Preemption occurs when a “higher” level of government reduces or eliminates the authority of a “lower” level of government
- Because federal law comes from a “higher” level of government than state law, federal law can preempt state law
- Failure to warn is a common law claim that derives from state law
- FIFRA is the federal statute governing pesticide labeling and regulation



FIFRA Preemption

- State authority under FIFRA:
 - (a) A state may regulate the sale or use of any federal registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
 - (b) Such State shall not impose or continue in effect any requirements for labeling or packaging *in addition to or different from* those required under this subchapter.
 - 7 U.S.C. § 136v.
- Supreme Court in *Bates v. Dow Agrosciences* established preemption test:
 - “For a particular state rule to be pre-empted, it must satisfy two conditions. First, it must be a requirement ‘*for labeling or packaging*’[.] Second, it must impose a labeling or packaging requirement that is ‘*in addition to or different from* those required under this subchapter.’”
 - This can include common law requirements that affect labeling or packaging of pesticides



FIFRA Misbranding & Failure to Warn

- Misbranded:

A pesticide is misbranded if [...] the labeling accompanying it does not contain directions for use which [...] are adequate to protect health and the environment. 7 U.S.C. § 136(q)(1)(F).

- Unlawful acts:

It shall be unlawful for any person in any State to distribute or sell to any person [...] any pesticide which is adulterated or misbranded. 7 U.S.C. § 136j(a)(1)(E).

- Failure to warn claims:

- To prove failure to warn, plaintiff must show that the manufacturer did not adequately warn of a particular risk, and that the risk was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution



The Two Main Arguments

FIFRA Preempts Failure to Warn Claims

State law failure to warn claims would require a new warning to be added to the glyphosate label that is *different from* or *in addition to* the federally registered label.

Preemption under 7 U.S.C. § 136v.

FIFRA misbranding requirement is broader than state law failure to warn claims, so preemption does not occur.

No preemption if FIFRA requirements are parallel to state law requirements.

FIFRA Does **NOT** Preempt Failure to Warn Claims



Visit to the High Court?

So far, the Supreme Court has declined to take up either of the two glyphosate preemption cases that asked for certiorari

- *Hardeman v. Monsanto Co.*, No. 19-16636 (9th Cir. May 14, 2021)
- *Carson v. Monsanto Co.*, No. 21-10994 (11th Cir. 2023)

The Eleventh Circuit has agreed to an *en banc* review of *Carson v. Monsanto Co.*

- Specifically, the court will rehear arguments on the issue of preemption
 - Oral argument has been scheduled for June 13, 2023

If a circuit split occurs, it is possible that the Supreme Court could decide to hear the issue



Injury Lawsuits Continue

- Despite settling numerous glyphosate injury lawsuits, trials and new filings continue
- Bayer has won seven trials in a row. Most recent victory granted in May 2023 when a jury issued a verdict in favor of Bayer in a lawsuit brought by a woman who claimed that using Roundup caused her to develop lymphoma
 - At trial, Bayer stressed that no national regulatory agency has banned glyphosate



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Sulfoxaflor

On December 22, 2022, the Ninth Circuit issued an opinion in ***Ctr. for Food Safety v. Regan*, No. 19-72109 (9th Cir. 2022)** which found that EPA's 2019 decision to reapprove the insecticide sulfoxaflor violated both FIFRA and the ESA

- Comes after a similar decision from the Ninth Circuit in 2015 which found that the 2013 approval of sulfoxaflor also violated the ESA
- Court criticized EPA for deploying a “whack-a-mole strategy” for ESA compliance, and EPA's claims that it “lacks the resources” for more thorough compliance



Sulfoxaflor, Cont.

While the court declined to vacate the registration, it did order EPA to complete ESA analysis within 180 days

- Although EPA interpreted the court's order as directing the Agency to begin ESA analysis within 180 days, the plaintiffs argue that the court directed EPA to complete analysis by that deadline
- The parties have asked the Ninth Circuit to clarify the timeline for ESA review – full ESA consultation typically takes a year or more to complete
- Plaintiffs have asked court to rehear the case *en banc* and vacate the registration
- A biological evaluation released by EPA in March found that sulfoxaflor is “likely to adversely affect” 581 listed species and 73 critical habitats



Paraquat

- In December 2022, the Ninth Circuit agreed to pause the lawsuit *California Rural Legal Assistance Found. v. U.S. Evtl. Protection Agency, No. 21-71287 (9th Cir. 2022)* which challenged EPA's 2021 interim registration review decision for the pesticide paraquat
 - The plaintiffs argued that the decision violated FIFRA, specifically claiming that EPA failed to consider the alleged link between paraquat and Parkinson's disease
- The court granted the stay to allow EPA time to revisit the paraquat interim registration decision to address the plaintiffs' substantive claims
 - Currently, EPA is planning to make new documents available for public comment in January 2024
- A multi-district litigation of plaintiffs alleging that exposure to paraquat caused them to develop Parkinson's disease is also on-going



Chlorpyrifos

The Eighth Circuit Court of Appeals heard oral argument in ***RRVSG Assoc. v. EPA*, No. 22-1422 (8th Cir. 2022)** on December 15, 2022

The lawsuit challenged EPA's decision to issue a cancel order for chlorpyrifos uses on food crops following a Ninth Circuit decision that ordered EPA to withdraw the food tolerances for chlorpyrifos

The plaintiffs in *RRVSG Assoc. v. EPA* are farm groups who allege that EPA's cancel order contradicted findings made by EPA in 2020

An opinion has yet to be issued



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Final Thoughts

- EPA's new approach to ESA consultation is likely to result in further pesticide use restrictions
 - Not currently clear what those will be
 - This is largely due to multiple court opinions finding EPA had violated the ESA
- Litigation over dicamba registration is not over
 - Unclear what registration will look like after 2025
- The Supreme Court may still hear the preemption issue – a ruling either way could impact numerous ongoing lawsuits

