

## **The Deal with Dicamba: Court Vacates Over-the-Top Registration**

*Brigit Rollins*

On February 6, 2024, a federal court in Arizona issued a ruling directing the Environmental Protection Agency (“EPA”) to vacate the 2020 registrations allowing over-the-top use of three dicamba-based pesticides, XtendiMax, Engenia, and Tavium. This marks the second time a court has ordered EPA to vacate a dicamba registration, following a ruling from the Ninth Circuit Court of Appeals which overturned the then-current over-the-top dicamba registration in June 2020. While the decision from the Arizona court relies on different legal arguments than the Ninth Circuit’s 2020 decision, the outcome is the same. Following the ruling, EPA has issued an order that will enable farmers to use existing stocks of dicamba directly onto crops during the 2024 growing season, but only if the pesticides were “labeled, packaged, and released for shipment” prior to February 6. After 2024, it is unclear whether dicamba will be available for over-the-top use going forward.

### **Background**

The herbicide known as dicamba has been used since the 1960s to target broadleaf plants. In recent years, dicamba has been used to combat weeds that have grown resistant to glyphosate including palmer amaranth, commonly known as pigweed. Prior to 2016, dicamba was primarily used as a pre-emergent, applied to the ground in late winter or early spring before any crops were planted. Dicamba is known for being highly volatile, meaning that it will evaporate into the air and travel off-target. This volatility is the reason why dicamba was historically used as a pre-emergent. However, in late 2016, EPA issued its first ever registration allowing dicamba to be used directly onto crops for the 2017 and 2018 growing seasons. The registration was granted to new, low-volatility forms of dicamba that were intended to be used on soybean and cotton seeds that were genetically modified to be resistant to dicamba.

The decision to approve over-the-top use of dicamba was highly controversial and quickly subject to legal challenge. Environmental plaintiffs filed a lawsuit against EPA claiming that the registration decision violated both the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) and the Endangered Species Act (“ESA”). While the lawsuit challenging the 2016 registration was ultimately dismissed by the court after the registration expired, the plaintiffs quickly refiled to challenge the 2018 dicamba registration which EPA had issued to reapprove over-the-top use for another two years. In their challenge to the 2018 registration, the plaintiffs once again claimed that EPA had violated FIFRA and the ESA by failing to ensure that the registration decision met the standards of either statute. Ultimately, the plaintiffs were successful in their challenge and the Ninth Circuit issued a decision directing EPA to vacate the over-the-top dicamba registration for three dicamba-based products, XtendiMax, Engenia, and FeXapan. The decision was issued in June 2020, leaving many farmers with questions and uncertainty in the middle of the growing season. To learn more about the Ninth Circuit’s decision, click [here](#).

Following the Ninth Circuit’s 2020 decision, EPA issued a Notice of Cancellation to formally cancel the 2018 dicamba registration. However, months later, EPA issued a new registration re-approving over-the-top use of dicamba for the 2021-2025 growing seasons. The new registration included additional use restrictions that EPA believed would resolve the issues the Ninth Circuit

found with the 2018 registration. Once again, the same environmental plaintiffs that challenged the 2016 and 2018 registrations filed suit to challenge the 2020 registration. While the plaintiffs raised the same claims in their latest lawsuit as they had in the previous two challenges, it was the novel arguments made against the 2020 registration decision that ultimately swayed the court.

## The Court's Decision

The plaintiffs in *Ctr. for Biological Diversity v. U.S. Env'tl. Agency*, No. 4:20-cv-00555 (D. Ariz. Feb. 6, 2024) raised various legal challenges against the 2020 over-the-top dicamba registration, claiming that the decision violated FIFRA and the ESA. The plaintiffs also raised procedural challenges, alleging that EPA had failed to follow mandatory notice-and-comment procedure when issuing the registration. Ultimately, the court agreed with the plaintiffs on the procedural arguments and vacated the registration without ever reaching the FIFRA and ESA claims. For an in-depth look at all the arguments raised by the plaintiffs in *Ctr. for Biological Diversity v. U.S. Env'tl. Agency*, click [here](#).

In their complaint, the plaintiffs argued that the 2020 over-the-top registration of XtendiMax, Engenia, and Tavium violated mandatory FIFRA notice-and-comment requirements. Specifically, the plaintiffs claimed that by issuing the 2020 registration decision without a period of public comment, EPA had violated FIFRA procedures for issuing a new use of a pesticide, and FIFRA procedures for “uncancelling” a pesticide use that had been formally cancelled.

Under FIFRA, EPA is directed to “publish in the Federal Register, [...] a notice of each application for registration of any pesticide if it contains any new active ingredient or *if it would entail a changed use pattern*. The notice shall provide 30 days in which any Federal agency or any other interested person may comment.” 7 U.S.C. § 136a(c)(4), (emphasis added). In other words, FIFRA allows EPA to register a changed or new use of an already-registered pesticide after a 30-day period of public comment. In this context, a “new use” is defined as “any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.” 40 C.F.R. § 152.3. The plaintiffs in *Ctr. for Biological Diversity v. U.S. Env'tl. Agency* argued that the 2020 over-the-top dicamba registration was a “new use” registration because at the time it was issued, over-the-top use was not approved for dicamba due to EPA’s formal cancellation order. Because the 2020 registration was issued without a period of public comment, the plaintiffs claim that the decision violates FIFRA’s process for registering a new use.

In response, EPA claimed that the 2020 registrations were not new use registrations approved under section 136a(c)(4) of FIFRA, but were instead approved under a different FIFRA provision colloquially referred to as the “me-too” provision. Under this “me-too” provision, EPA may register or amend registration of a pesticide which is “identical or substantially similar in composition and labeling to a currently-registered pesticide [...] or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment[.]” 7 U.S.C. § 136a(c)(3)(B). Under FIFRA, “unreasonable adverse effects on the environment” is 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.” 7 U.S.C. § 136(bb). Before a pesticide may be registered for use under FIFRA, EPA must determine that when used as intended, the pesticide will not cause any unreasonable adverse effects on the environment. FIFRA’s “me-too” registration allows EPA to register a pesticide product, or amend an already registered pesticide label, so long as the new product or amended label is “substantially similar” to a currently registered pesticide and the new product or amended label would not “significantly increase” the risk of unreasonable adverse effects to the environment. EPA argued that the 2020 over-the-top registrations were “me-too” registrations because the Ninth Circuit’s decision directed EPA to cancel over-the-top use of XtendiMax, Engenia, and FeXapan. Tavium, though registered for over-the-top use in 2019 for the 2020 growing season, was not included in the Ninth Circuit’s decision. EPA claims that the 2020 re-registration of XtendiMax and Engenia were “me-too” registrations because the products were substantially similar to Tavium. Unlike “new use” registrations, “me-too” registrations do not have a notice-and-comment requirement.

Ultimately, the court agreed with the plaintiffs that the 2020 registrations of over-the-top use for XtendiMax and Engenia were “new use” registrations that were subject to notice-and-comment requirements. Crucial to the court’s decision was the fact that Tavium itself had been approved for over-the-top use as a “me-too” registration. The 2019 Tavium registration was made pursuant to FIFRA’s “me-too” provisions based on the already-registered over-the-top dicamba products XtendiMax and Engenia. According to the court, “EPA erred when it relied on the Tavium 2019 registration, which was premised on these vacated and cancelled XtendiMax and Engenia registrations.” The court determined that the 2020 registrations met the definition of “new use” and that EPA should have followed the notice-and-comment requirements for a “new use” registration.

Along with concluding that EPA failed to provide the required notice-and-comment period for registering a new use of a pesticide, the court also concluded that EPA violated FIFRA’s requirement to provide a period of notice-and-comment when re-approving a cancelled pesticide use. According to FIFRA’s implementing regulations, if EPA would like to re-approve a pesticide registration that “has been finally cancelled or suspended,” then the agency must allow “notice and hearing opportunities.” 40 C.F.R. § 160.130. The plaintiffs argued that because EPA’s 2020 registration decision re-approved a use that had been formally cancelled without a period of public notice and comment, the registration decision violated FIFRA. The court agreed with the plaintiffs, finding that EPA had twice violated FIFRA’s procedural mandates by failing to provide the notice-and-comment period required to registering a new use of a pesticide and to re-approve a cancelled use. For those reasons, the court overturned the 2020 over-the-top registrations of XtendiMax, Engenia, and Tavium. Following that decision, there are no dicamba products with an approved over-the-top use for the 2024 growing season.

## **Going Forward**

On February 14, EPA [issued an order](#) to allow existing stocks of XtendiMax, Engenia, and Tavium directly onto crops so long as the pesticides were “labeled, packaged, and released for shipment” prior to the February 6 court decision. The existing stocks order was welcomed by members of the agricultural industry who were concerned that farmers who had already purchased dicamba products for the 2024 growing season would be unable to use what they had

already purchased. The order also provides instructions for how to dispose of unwanted or unused dicamba products.

While the existing stocks order helps to clarify requirements for the upcoming growing season, it is unclear what the fate of over-the-top use of dicamba will be going forward. Currently, it is unknown whether EPA will appeal the court's decision, or how successful such an appeal would be. The district of Arizona is part of the Ninth Circuit, so any appeal would bring the question of over-the-top dicamba registration back before a court that has previously vacated a similar registration. It is also unknown whether EPA will look to re-register over-the-top use of dicamba, or what steps the agency would need to take to produce a registration capable of withstanding judicial scrutiny.

At the moment, farmers and pesticide applicators who had intended to make over-the-top applications of dicamba during the 2024 growing season have more questions than answers.

## **EPA Proposes Vulnerable Species Pilot Project**

*Brigit Rollins*

On June 22, 2023, the Environmental Protection Agency (“EPA”) released a draft white paper for its Vulnerable Species Pilot Project (“VSPP”), a central component of the agency’s new policy approach to meeting its Endangered Species Act (“ESA”) responsibilities when carrying out actions under the Federal Insecticide, Rodenticide, and Fungicide Act (“FIFRA”). While the draft white paper was released earlier this year, the EPA began developing the VSPP in 2021 and announced the program in 2022. The primary purpose of the VSPP is to add new restrictions to pesticide labels in order to limit exposure to species that EPA has found are highly sensitive to pesticides. Although the program has yet to be fully implemented, it is expected that the VSPP will lead to increased restrictions on pesticide applications, and possibly even prohibit applications in some areas all together.

## **Background**

According to the ESA, whenever a federal agency takes an agency action, the agency must consult with either the U.S. Fish and Wildlife Service (“FWS”) or the National Marine Fisheries Service (“NMFS”) (collectively, “the Services”) to ensure that the action will not jeopardize a species listed as threatened or endangered under the ESA. 16 U.S.C. § 1536(a)(2). In this context, an agency action is any activity that a federal agency has “authorized, funded, or carried out[.]” 50 C.F.R. § 402.02. Meanwhile, “jeopardy” refers to an action that is reasonably expected to appreciably reduce the likelihood of the survival of a listed species. 50 C.F.R. § 402.02.

Whenever a federal agency takes an agency action, it must determine whether that action “may affect” a species listed under the ESA. 50 C.F.R. § 402.14. The “may affect” standard is considered a relatively low threshold to clear as it includes any possible impacts the proposed agency action may have on a listed species. If the agency reaches a “may affect” finding, it will then reach out to the Services to determine whether the action is “likely to adversely affect” or

“not likely to adversely affect” a listed species. This is considered the first step of the consultation process, often referred to as informal consultation. If the agency reaches a “not likely to adversely affect” finding and the consulting Service agrees, then the consultation process is at an end and the agency may proceed with its action. 50 C.F.R. § 402.14(m)(3). However, if the agency finds that its proposed action is “likely to adversely affect” a listed species, then the agency must initiate formal consultation with the Services. 50 C.F.R. § 402.14. The formal consultation process requires the consulting Service to thoroughly examine the expected impacts the proposed agency action will have on listed species, and culminates in the development of a document known as a Biological Opinion or BiOp. 50 C.F.R. § 402.14(m)(1). Among other things, the BiOp will contain the consulting Service’s determination as to whether the proposed agency action will result in jeopardy to a listed species. 50 C.F.R. § 402.14(h)(1)(iv). If the consulting Service finds that the agency action is likely to result in jeopardy, the BiOp will contain recommended mitigation measures that the agency can adopt to reduce or eliminate the likelihood of jeopardy. 50 C.F.R. § 402.14(h)(2).

EPA is the federal agency responsible for administering FIFRA. In that capacity, EPA takes numerous agency actions every year. Such actions include registering a new pesticide product for use, modifying an already registered pesticide to allow for a new use or new labeling instructions, re-registering a pesticide product, and carrying out pesticide registration review. For each of these activities, FIFRA requires EPA to determine that the action will not cause “unreasonable adverse effects on the environment.” 7 U.S.C. §§ 136a(a), (c)(5)(C), (7)(A). FIFRA defines “unreasonable adverse effects on the environment” 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[.]” 7 U.S.C. § 136(bb). Unlike the ESA’s “may affect” standard which is a simple yes/no test, the “unreasonable adverse effects” standard is a balancing test that requires EPA to weigh both the costs and benefits of using a pesticide before making a final decision.

While each of the actions EPA takes under FIFRA are recognized as agency actions subject to ESA consultation, until recently EPA has primarily only engaged in ESA consultation when registering new pesticide active ingredients. For all other actions, EPA has relied on FIFRA’s “unreasonable adverse effects” standard. This practice has led to a wave of lawsuits, mostly resulting in wins for environmental plaintiffs. Currently, EPA believes that completing all of the ESA consultations for FIFRA actions that are subject to court ordered deadlines would take the agency until at least the 2040s. In an effort to more efficiently meet its ESA obligations, while also crafting pesticide labels more likely to hold up under judicial review, EPA has developed its new ESA-FIFRA Policy.

### **Vulnerable Species Pilot Program**

EPA’s new policy for satisfying its ESA responsibilities while carrying out agency actions under FIFRA employs two primary strategies. In a [work plan published by EPA in April 2022](#), and a [subsequent update published the following November](#), EPA outlined the two basic approaches the agency would pursue in an attempt to bring existing pesticide labels into ESA compliance. The first strategy involves dividing registered pesticides into similar groups – herbicides, insecticides, and rodenticides – and then identifying and implementing early mitigation measures

intended to reduce the impacts those groups of pesticides have on listed species. Currently, EPA is focusing on creating mitigation measures for herbicides. To learn more about this first strategy and what steps EPA has taken so far, click [here](#).

The second strategy EPA has developed as part of its new policy is the VSPP. Under this approach, EPA will identify threatened and endangered species that are considered highly vulnerable to pesticide use, and develop mitigation measures designed specifically to protect those species from pesticide exposure. While the VSPP is still in the process of development, a draft plan issued by EPA earlier this year outlines how the agency intends the program to function.

In the draft plan, EPA identified twenty-seven species that serve as the “initial set” of pilot species addressed by the VSPP. According to EPA, these species are considered particularly sensitive to pesticides due to a combination of factors such as small population sizes, limited geographic ranges, and overall general susceptibility to environmental stressors. EPA claims that these species have a higher likelihood of receiving a “jeopardy” determination in future ESA consultations on FIFRA actions. In effort to reduce the possibility of future jeopardy determinations, EPA intends to use the VSPP to introduce “early” mitigation measures across multiple registered pesticides to protect the pilot species. These mitigations will take the form of additional restrictions on pesticide application.

Under the VSPP, EPA is proposing two broad categories of early mitigation measures – avoidance and minimization. Each mitigation is intended to apply broadly to conventional pesticides that are applied outdoors. As the name suggests, avoidance mitigation would involve prohibiting pesticide applications in certain areas, specifically those areas where one of the pilot species is most likely to occur. To identify these areas, EPA is relying on “species-specific location information,” primarily the species range and habitat description provided by FWS. For areas subject to avoidance mitigations, all pesticide applications would be prohibited unless the applicator coordinated with FWS at least three months prior to the application.

The other category of mitigation measures identified under the VSPP focuses on minimizing pesticide exposure to the twenty-seven pilot species through additional restrictions on pesticide applications that are designed to minimize pesticide spray drift, runoff, and erosion. Spray drift mitigation measures identified in the draft plan include additional buffer requirements, and prohibitions of certain application methods or droplet sizes. Proposed runoff and erosion mitigation measures include prohibitions on applications when the soil is saturated or when rain is in the forecast, and the requirement of certain land use practices designed to reduce both runoff and erosion such as contour farming, cover cropping, or grassed waterways. When any additional land use practices are required, EPA intends to allow farmers and applicators flexibility in choosing which methods to apply, noting that farmers are the most knowledgeable about the characteristics of their fields.

All of the mitigation measures identified under the VSPP, whether avoidance or minimization, will be geographically specific and based on the areas where the pilot species are located. Because of that, EPA intends to incorporate all VSPP mitigation measures into the applicable pesticide labels through bulletins rather than directly into the general label. All such bulletins

will be available through EPA's website [Bulletins Live! Two](#), and any pesticide label that contains a VSPP bulletin will include language directing the applicator to visit the website. Each bulletin will include a description of the relevant mitigation measures and the geographic area where the restrictions apply.

## **Going Forward**

When the draft plan for the VSPP was published in June, a 45-day public comment period was provided. According to EPA, the draft plan received more than 10,000 comments. In November 2023, EPA published a brief update to the VSPP addressing the categories of comments EPA received and outlining modifications EPA plans to make to the VSPP going forward. According to EPA, one of the main themes that emerged in comments on the VSPP draft plan focused on how EPA would identify the geographic areas where VSPP mitigation measures would apply. In response to concerns that EPA would take an overly broad approach, the agency states that it plans to refine the process by which those areas are identified by relying on species habitat maps over habitat descriptions and limiting areas with VSPP restrictions to only include locations that are most important for species conservation. Other modifications EPA intends to make based on the comments it received on the draft plan include clarifying potential exemptions to the VSPP, revisiting how vulnerable species are identified and selected, and developing a consistent approach for the strategies used to reduce pesticide exposure to listed species.

Currently, it is unclear when the VSPP will be fully implemented. In the June draft plan, EPA noted that it would spend the next eighteen months developing mitigation bulletins for the initial set of twenty-seven pilot species and begin posting the bulletins to the [Bulletins Live! Two](#) website when they become available. EPA also stated its intention to expand the VSPP to other vulnerable species, although currently the number of species included in the program remains at twenty-seven.

Ultimately, many questions remain as to whether the VSPP satisfies either EPA's ESA or FIFRA responsibilities. It is unclear whether the early mitigations proposed by the VSPP satisfy the ESA's consultation requirements, or meet FIFRA's "unreasonable adverse effects" standards. EPA has stated that it expects to provide further updates to the VSPP by fall 2024. The NALC will continue to follow the VSPP as the program develops.

## **EPA Draft Herbicide Strategy Open for Comment**

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October 22, 2023, is the last day to submit comments on the Environmental Protection Agency's ("EPA") Draft Herbicide Strategy Framework to Reduce Exposure of Federally Listed Endangered and Threatened Species and Designated Critical Habitats from the Use of Conventional Agricultural Herbicides ("Draft Herbicide Strategy"). The document is one component of EPA's new policy on how to satisfy its responsibilities under the Endangered Species Act ("ESA") when carrying out actions pursuant to the Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA"). The policy shift comes in part as the result of multiple lawsuits that

have been filed against EPA over the past several years by environmental groups claiming that EPA violated the ESA by failing to engage in mandatory consultation when carrying out FIFRA actions. Although the policy is still under development, the Draft Herbicide Strategy is expected to be finalized in 2024.

## **Endangered Species Act**

The U.S. Fish and Wildlife Service (“FWS”) and the National Marine Fisheries Service (“NMFS”) (collectively, “the Services”) are responsible for administering the ESA. The Services work to identify species at risk of extinction and then list those species as either “threatened” or “endangered” under the ESA. Once a species is listed, it receives ESA protection. However, the Services are not the only federal agencies tasked with carrying out the ESA. All federal agencies are required to further the purposes and aims of the ESA by consulting with the Services any time they carry out an agency action to ensure that the action will not jeopardize the existence of listed species. 16 U.S.C. § 1536(a)(2).

Under the ESA, an agency action is defined as any activity that a federal agency has “authorized, funded, or carried out[.]” 16 U.S.C. § 1536(a)(2). Examples of activities that would be considered agency actions under the ESA include the promulgation of regulations; granting a license, contract, lease, or permit; or actions that directly or indirectly cause modification to the environment. 50 C.F.R. § 402.02. When a federal agency carries out an agency action, the ESA requires that agency to determine whether the action “may affect” any threatened or endangered species. 50 C.F.R. § 402.14. In general, this is regarded as a very low threshold to clear. [According to FWS](#), a “may affect” finding is appropriate when the proposed action may have consequences to any protected species. If a federal agency finds that its action “may affect” a species listed under the ESA, its next step is to reach out to the Services to determine whether the proposed agency action is likely to adversely affect any listed species. If the action is likely to adversely affect a listed species, then the agency carrying out the proposed action (known as the “action agency”) will initiate formal consultation with the Services.

During formal consultation, the Services will prepare a document known as a Biological Opinion or “BiOp.” 50 C.F.R. § 402.14(e). The goal of formal consultation is to ensure that the proposed agency action will not jeopardize the continued existence of a listed species. 16 U.S.C. § 1536(a)(2). The ESA defines “jeopardy” as “an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.” 50 C.F.R. § 402.02. If the Services find that a proposed agency action will result in jeopardy, then the BiOp will contain a selection of mitigation measures or alternative proposals that will meet the intended purpose of the proposed agency action while avoiding the likelihood of jeopardy. 50 C.F.R. § 402.02. From there, it is up to the action agency to decide how to proceed.

While there are a handful of exceptions to the ESA’s consultation requirements, the United States Supreme Court affirmed in *Nat’l Ass’n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644 (2007), that all “actions in which there is discretionary Federal involvement or control” are subject to ESA consultation.



## **Federal Insecticide, Rodenticide, and Fungicide Act**

FIFRA is the primary federal statute regulating the sale and use of pesticide products in the United States. EPA is responsible for administering FIFRA and carrying out numerous agency actions pursuant to the statute.

Under FIFRA, no pesticide product may be legally sold or used in the United States until the EPA has registered a label for that product. 7 U.S.C. § 136a(a). To register a label, EPA must determine that use of the pesticide according to its label instructions will not cause “unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(C). FIFRA defines “unreasonable adverse effects on the environment” 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.” 7 U.S.C. § 136(bb). Unlike the ESA “may affect” standard which serves as a yes/no threshold, FIFRA’s “unreasonable adverse effects” standard is a balancing test that requires EPA to weigh all expected impacts of registering the pesticide.

Along with registering new pesticide labels, FIFRA directs EPA to review all registered pesticides once every fifteen years. The registration review process can take multiple years, and may involve issuing an interim decision prior to a final decision. Additionally, EPA may take a variety of other actions under FIFRA such as adding a new use to a previously registered pesticide label, or granting an emergency use. Each of these actions is recognized as an agency action for purposes of the ESA, and is therefore subject to ESA consultation. However, up until recently, EPA has primarily only conducted ESA consultation when registering new pesticide active ingredients. For all other actions, EPA relied on FIFRA’s “unreasonable adverse effects” standard. This policy ultimately resulted in numerous lawsuits.

### **Recent Lawsuits**

Over the last several years, EPA has been subject to various lawsuits filed by different environmental groups alleging that EPA has violated the ESA by failing to engage in ESA consultation when taking agency actions under FIFRA. In some cases, such as *Ctr. for Food Safety v. U.S. Env’tl Protection Agency*, No. 1:23-cv-01633 (D. D.C., June 6, 2023), which was filed earlier this year, the plaintiffs challenge the registration of a pesticide without prior ESA consultation. More information on that case is available [here](#). In other cases, such as *Nat. Res. Def. Council v. U.S. Env’tl Prot. Agency*, No. 20-70787 (9th Cir. 2020) and *Rural Coal. v. U.S. Env’tl Prot. Agency*, No. 20-70801 (9th Cir. 2020), the plaintiffs challenged registration review decisions that were issued without consultation. More information on both of those cases is available [here](#). Still other cases, like *Farmworker Ass’n of FL v. Env’tl. Protection Agency*, No. 21-1079 (D.C. Cir. 2021) have involved challenges to EPA actions that amend a registered pesticide label by adding a new use without ESA consultation on that specific use. Information on that case is available [here](#).

Many of these cases have ended in court decisions favorable to the plaintiffs. In *Farmworker Ass’n of FL v. Env’tl. Protection Agency*, the court found that EPA had failed to undergo ESA consultation when it amended the label for the pesticide aldicarb to allow for use on orange and grapefruit trees in Florida to combat citrus greening disease. There, the court vacated the label

and sent it back to EPA for further ESA review. Without the label in place, aldicarb was unavailable for use on citrus trees. In *Ctr. for Food Safety v. Regan*, No. 19-72109 (9th Cir. 2022), the court found that EPA had unlawfully registered the pesticide sulfoxaflor without undergoing ESA consultation. While the court chose to leave the registration in place, it remanded the decision to EPA with a court-ordered timeline to complete consultation. The full decision is available [here](#).

Currently, EPA claims that completing all the ESA consultations for pesticides that are currently subject to court decisions or on-going litigation would take the agency at least until the 2040s and would represent only 5% of EPA's ESA obligations. In an effort to more efficiently meet its ESA obligations and craft stronger pesticide labels, EPA has developed its new ESA-FIFRA policy.

### **Draft Herbicide Strategy**

EPA's new policy on how to meet its ESA obligations while taking agency action under FIFRA contains a variety of different strategies. In a [work plan published by EPA in April 2022](#), and a [subsequent update published the following November](#), EPA outlined two overall strategies that it would pursue in an effort to bring existing pesticide labels into ESA compliance. The first strategy involves breaking out registered pesticides into similar groups – herbicides, insecticides, and rodenticides – and then identifying and implementing early ESA mitigation measures for those groups. The second strategy involves identifying threatened and endangered species that are considered highly vulnerable to pesticides, and developing mitigation measures to protect those species from pesticide exposure. While several of these approaches are still in the planning stage, EPA has made its Draft Herbicide Strategy available for public comment, and expects to finalize and begin implementing this part of its ESA-FIFRA policy in 2024.

Under the Draft Herbicide Strategy, EPA has identified two primary categories of mitigation measures that it expects to include on herbicide labels. The first category of mitigation measures will be targeted at reducing pesticide spray drift, while the second category will focus on reducing pesticide runoff and erosion. According to EPA, these are two of the most common ways that threatened and endangered species are exposed to herbicides. Reducing exposure is expected to reduce the likelihood that future ESA consultations will result in a finding that FIFRA actions will jeopardize the existence of listed species.

The Draft Herbicide Strategy identifies buffers in the form of windbreaks or hedgerows, hooded sprayers, and application rate reductions as mitigation measures to reduce spray drift. To reduce runoff and erosion, the Draft Herbicide Strategy identified a variety of mitigation measures, including restrictions on applications if rain is in the forecast; restrictions based on field characteristics such as soil make up and field slope; methods of application; in-field management activities designed to reduce runoff such as mulch amendment or terrace farming; management activities adjacent to sprayed fields such as establishing a buffer strip; and other activities aimed at increasing water retention. For the mitigation measures for runoff and erosion, EPA is also proposing a point-based system designed to give farmers more control over which measures to implement. Each of the previously mentioned mitigation measures would be assigned a point value based on how effective the measure is at reducing runoff or erosion. Pesticide labels will

identify how many points are necessary for the pesticide's intended use. From there, farmers can implement the mitigation measures that work best for them to achieve the number of points needed to apply the pesticide. Importantly, the Draft Herbicide Strategy notes that activities farmers are already taking to reduce runoff or erosion may be used to satisfy the point system. Currently, EPA does not appear to be recommending a similar system for implementing spray drift mitigation measures.

According to the Draft Herbicide Strategy, the proposed mitigation measures will be incorporated into pesticide labels in two primary ways. Mitigation measures that EPA finds are necessary across the contiguous 48 states will be directly included as part of the pesticide label. However, some mitigation measures are only needed in specific geographic areas. For those measures, EPA expects to increase its use of the website Bulletins Live Two ("BLT"). BLT is a website run by EPA that provides geographic-specific updates to pesticide labels. For example, if EPA determines that mitigation measures are needed to reduce runoff of a particular pesticide in the Pacific Northwest region of the country to prevent exposure to listed species only found in that area, instead of adding additional language to the pesticide label, it would direct applicators to check the BLT website. There, EPA would have language addressing geographic-specific restrictions. According to the Draft Herbicide Strategy, EPA intends to make greater use of BLT as it begins implementing its new policy, and will include additional language on pesticide labels directing applicators to check BLT prior to application.

## **Going Forward**

The Draft Herbicide Strategy represents only one aspect of EPA's new ESA-FIFRA policy. As roll out and implementation of this policy continues, farmers and pesticide applicators can expect to see additional application restrictions included on pesticide labels. As previously mentioned, some of the restrictions will be included in the labels themselves, while others will be available on the BLT website. It is currently unclear how quickly these label changes will be made. EPA's work plans and the Draft Herbicide Strategy suggest that these mitigation measures will be incorporated into labels as they come before EPA for registration and registration review.

The comment period on the Draft Herbicide Strategy will close on October 22, 2023 with a final draft expected next year. EPA also intends to release a draft of its insecticide strategy in 2024, along with drafts of the strategies aimed at protecting vulnerable species. While it is still too early to know what the ultimate outcome of this new policy will be, the Draft Herbicide Strategy offers an informative look at what is to come.

## **Plaintiffs & Pesticides: Failure to Warn Claims in Pesticide Litigation**

*Brigit Rollins*

Of all the claims that plaintiffs typically raise in pesticide injury lawsuits, failure to warn is currently the claim that is most likely to impact pesticide litigation going forward. Plaintiffs filing pesticide injury lawsuits almost always bring failure to warn claims. Such claims have been raised in lawsuits concerning glyphosate, chlorpyrifos, and paraquat by plaintiffs who claim

that the defendants failed to warn consumers about the risks of using their products. In response, defendants have argued that plaintiffs should not have been allowed to raise failure to warn claims because such claims are preempted by federal law. While courts have so far been split on whether failure to warn claims are preempted, one lawsuit has been appealed to the United States Supreme Court. If the Court decides to hear the case, its decision could potentially impact thousands of on-going pesticide injury lawsuits.

### **What is Failure to Warn?**

Failure to warn is a type of civil tort that is frequently raised in products liability cases. Unlike negligence and design defect, the two other claims that have so far been covered in this series, failure to warn does not argue that a product has physical faults. Instead, a plaintiff typically raises failure to warn claims to allege that a product manufacturer failed to provide adequate warnings or instructions about the safe use of a product.

In order to succeed on a failure to warn claim, a plaintiff must prove two things. First, the plaintiff must show that the manufacturer did not adequately warn consumers about a particular risk. Second, the plaintiff must show that the risk was either known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time the product was manufactured and distributed. Essentially, the manufacturer must have either known or been able to easily discover the risk, failed to warn consumers, and that failure caused the plaintiff to become injured.

### **Failure to Warn in Pesticide Lawsuits & Initial Treatment by Courts**

Failure to warn claims have become commonplace in pesticide injury lawsuits. In *Hardeman v. Monsanto Co.*, No. 4:16-cv-00525 (N.D. Cal.), one of the first lawsuits alleging that use of glyphosate caused the plaintiff to develop non-Hodgkin's lymphoma, the plaintiff argued that his injuries were in part caused by the defendant's failure to include proper warning labels on its products. The plaintiff claimed that at the time the defendant was manufacturing its glyphosate-based pesticide Roundup, it either knew or should have known that exposure to the pesticide could cause consumers to develop cancer. By failing to add a cancer warning to the Roundup label, the plaintiff argues that the defendant's products were rendered unreasonably dangerous and defective. Plaintiffs in other glyphosate lawsuits, such as *In re: Roundup Products Liability Litigation*, No. 3:16-md-02741 (N.D. Cal.), raised nearly identical failure to warn claims. There, the plaintiffs noted that the warnings the defendant did provide were inadequate to warn consumers about the potential carcinogenic risks. Failure to warn claims are a standard part of glyphosate lawsuits.

Failure to warn claims filed in other pesticide lawsuits follow similar patterns. In the chlorpyrifos-related lawsuits *Avila v. Corteva Inc.*, No. 20C-0311 (Cal. Sup. Ct.), and *Calderon de Cerda v. Corteva Inc.*, No. 20C-0250 (Cal. Sup. Ct.), the plaintiffs argue that the defendant knew or should have known that its product could cause neurological injuries to infants and children. They claim that the defendant made its product unsafe for use by failing to include appropriate warnings. Similarly, the plaintiff in *Hoffman v. Syngenta Crop Protection, LLC*, No. 17-L-517 (Ill. Cir. Ct.), argued that the defendant's product was unreasonably dangerous

because consumers were not warned that exposure to the pesticide paraquat could cause users to develop Parkinson's disease.

Like the other claims previously discussed in this series, courts have so far had a mixed response to failure to warn claims. Although thousands of plaintiffs have filed lawsuits in recent years alleging that exposure to a particular pesticide caused them to develop an injury, currently only a handful of these cases have gone to trial. All of those cases have involved glyphosate. The first three pesticide injury cases that went before a jury all resulted in favorable rulings for the plaintiffs. Juries for *Hardeman v. Monsanto Co.*, ***Pilliod v. Monsanto Co.*, No. RG17862702 (Cal. Sup. Ct.)**, and ***Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. Sup. Ct.)** all found that the plaintiffs successfully argued their failure to warn claims. However, in both ***Stephens v. Monsanto Co.*, No. CGC-20-585764 (Cal. Sup. Ct.)**, and ***Clark v. Monsanto Co.*, No. 20STCV46616 (Cal. Sup. Ct.)**, the juries found that plaintiffs had failed to prove that their injuries were the result of the defendant's failure to warn about the risk of using their product.

### **Failure to Warn & Federal Preemption**

In response to failure to warn claims, defendants in pesticide injury lawsuits argue that such claims should be dismissed because they are preempted by federal law. On appeal, courts have differed on whether failure to warn claims are preempted. The question is now on appeal to the United States Supreme Court. If the Court decides to hear the case, a ruling would have the potential to alter the landscape of pesticide injury litigation.

The German pharmaceutical company Bayer bought Monsanto Corporation ("Monsanto") in 2018. At that time, Bayer took over as defendant for Monsanto in all of its currently on-going pesticide lawsuits. When the juries in *Hardeman v. Monsanto Co.*, *Pilliod v. Monsanto Co.*, and *Johnson v. Monsanto Co.* returned verdicts that were favorable to the plaintiff, Bayer appealed. Among other things, Bayer argued that the failure to warn claims filed by the plaintiffs should have been dismissed before trial because they are preempted by federal law.

Preemption is a legal doctrine that refers to the idea that a "higher" form of government will displace the authority of a "lower" form of government when the two conflict. When federal and state law conflict, federal law will preempt state law because it is a "higher" form of government. Bayer has argued that the state law failure to warn claims raised by plaintiffs in pesticide injury lawsuits are preempted by labeling requirements in the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

FIFRA is the primary federal statute regulating pesticide use in the United States. Under FIFRA, a pesticide may not be legally sold or used until it has been registered by the Environmental Protection Agency ("EPA") and has an approved label. The label contains all necessary instructions and warnings needed to use the pesticide safely and effectively.

In order to register a pesticide under FIFRA, EPA must make a finding that using the pesticide according to its label will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). FIFRA goes on to define "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account economic, social, and

environmental costs and benefits of the use of any pesticide[.]” 7 U.S.C. § 136(bb). Violating a registered pesticide label is considered a violation of FIFRA. While FIFRA does grant states the authority to “regulate the sale or use of any federally registered pesticide,” it also prohibits states from adopting “any requirements for labeling or packaging in addition to or different from” those required under FIFRA. 7 U.S.C. § 136v(a), (b). In other words, while states may adopt state requirements affecting pesticide sale and usage, they may not adopt regulations that would change the text of a registered pesticide label.

Bayer argues that the plaintiffs’ state law failure to warn claims are preempted by FIFRA because in order to avoid liability under those claims, Bayer would need to affix a cancer warning to the label or packaging of the glyphosate it sells in states where it has been sued. Doing so would amount to a state law imposing a label requirement that is either in addition to or different from the federally registered label for Roundup which does not contain a cancer warning. Because requiring such a warning would be a violation of FIFRA, Bayer argues that failure to warn claims should always be dismissed in pesticide injury lawsuits.

The plaintiffs have argued that the failure to warn claims are not preempted by FIFRA because of the statute’s prohibitions against misbranding. Under FIFRA, it is unlawful to sell or distribute any pesticide that is “misbranded.” 7 U.S.C. § 136j(a)(1)(E). A pesticide is considered misbranded if “the labeling does not contain a warning or caution statement which may be necessary [...] to protect health and the environment[.]” 7 U.S.C. § 136(q)(1)(G). The plaintiffs assert that their failure to warn claims are not preempted by FIFRA because if a pesticide manufacturer failed to warn consumers about the health risks of using their pesticides, then the pesticide was misbranded and should not have been sold without a proper warning. According to the plaintiffs, the failure to warn claims are “parallel” with FIFRA’s misbranding prohibitions. This means that if the defendant has violated its state law failure to warn requirements than it has also violated the FIFRA misbranding requirements. Because the claims are parallel, failure to warn cannot be preempted by FIFRA.

Courts have been split over this issue. In *Stephens v. Monsanto Co.*, a California state court agreed with the defendant that the plaintiff’s failure to warn claims were preempted by FIFRA and dismissed the claims before trial. However, both the Ninth Circuit Court of Appeals, and another California state court agreed with the plaintiffs that their failure to warn claims were not preempted because the claims were parallel to FIFRA’s prohibition on misbranding. Bayer has appealed the Ninth Circuit’s ruling to the United States Supreme Court. Should the Supreme Court take up the case, a ruling could have consequences for thousands of on-going pesticide injury lawsuits, as well as any pesticide injury lawsuits filed in the future. Failure to warn claims have become commonplace in pesticide injury litigation. If the Supreme Court finds that those claims are preempted by FIFRA, it could change the landscape of pesticide litigation.

**UPDATE 6/22/2022:** The Supreme Court has officially determined that it will not hear review in *Hardeman v. Monsanto*. This means that the Ninth Circuit’s decision finding that the plaintiff’s state law failure to warn claims are not preempted by FIFRA will stand. Although this is the end of the road for the *Hardeman v. Monsanto* lawsuit, it is possible that this issue will come before the Supreme Court again. However, as of this update, plaintiffs throughout the United States may continue to file failure to warn claims when bringing pesticide injury lawsuits.

## **Conclusion**

At the moment, it is unclear what the future of failure to warn claims in pesticide injury lawsuits will be, and how that future will impact other claims typically raised in such lawsuits. If the Supreme Court concludes that failure to warn claims are not preempted by FIFRA, then plaintiffs are likely to continue raising those claims in pesticide cases. If the Supreme Court finds that failure to warn claims are preempted by FIFRA, courts will likely dismiss those claims in on-going pesticide cases, and future plaintiffs will likely rely on other claims when filing lawsuits.