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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Center for Biological Diversity, et al., Plaintiffs, v. United States Environmental Protection Agency, et al., Defendants, and Bayer Cropscience LP, et al., Intervenor-Defendants.	No. CV-20-00555-TUC-DCB **ORDER**

The Court finds the EPA violated FIFRA notice and comment mandates for issuing "new use" pesticide registrations for OTT dicamba for DT crops (cotton and soybean). For the reasons explained below, the Court vacates the 2020 registrations for XtendiMax, Enginia, and Tavium.

A. HISTORIC AND PROCEDURAL BACKGROUND

Plaintiffs challenge the registrations issued in 2020 and amendments made in 2022 and 2023 by the Defendant, the United States Environmental Protection Agency (EPA) for over-the-top (OTT) use of dicamba products manufactured by the Intervenor Defendants, agrochemical companies. Plaintiffs allege violations of the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), the Endangered Species Act (ESA), and the Administrative Procedures Act (APA).

Dicamba, a chemical herbicide, combats weeds and has been used for more than fifty years. Dicamba is an effective weed killer, but its toxicity is not limited to weeds; it kills broadleaf plants, generally, including desirable plants, bushes, and trees. Dicamba easily moves off-field due to wind drift during spraying and is volatile, meaning it evaporates into a gas during spraying if there is a temperature inversion[1] or even hot weather can cause it to vaporize after spraying. Either way, its volatility causes it to reach nontarget plants offsite, i.e., off-field, due to wind drift. Originally, dicamba was registered for limited use, largely, in late winter or early spring before crops were planted or in the early growing season for post-emergent use on crops, like wheat and corn, that are naturally tolerant to dicamba. *Nat'l Fam. Farm Coal. v. U.S. Env't Prot. Agency* (*NFFC) (Monsanto)*[2], 960 F.3d 1120, 1125 (9th Cir. 2020).

After many years, many weeds developed a resistance to glyphosate, the main ingredient in the original dicamba, "Round-up," products. Monsanto and other agrochemical companies developed "low-volatility" dicamba products, which in combination with deregulation in 2015 of genetically engineered dicamba-tolerant (DT) crops (cotton and soybean), opened the door for post-emergent OTT spaying during the growing season of dicamba products on DT crops (cotton and soybean). *Id.* at 1125-26.

In 2016, EPA granted three low-volatility OTT dicamba products two-year conditional registrations, as follows: Monsanto Company (now Bayer) for XtendiMax; Corteva (formerly DuPont) for FeXapan, and BASF for Enginia. In response to soring numbers of complaints about offsite damage due to dicamba drift during the 2017 growing season, Monsanto proposed, and EPA adopted by amendment a more restrictive use and corresponding label restrictions for the OTT dicamba products. The 2018 growing season saw similar complaints. *Id.* at 1126-1128.

The conditional registrations for all three OTT dicamba products were set to expire in 2018, but on October 31, 2018, the EPA approved and granted requests for extensions

[1] The earth's cooling at night cools the air near the surface, which becomes trapped there by warmer air above it. The pesticide, like any other pollutant, is trapped in the cooler air near the earth and subject to moving offsite.
[2] The Court distinguishes between cases based on Defendant Intervenors.

and issued "conditional two-year amended registrations." *Id.* at 1124. EPA imposed further use restrictions for OTT application of dicamba herbicides to DT soybeans and cotton, most importantly as follows: "(1) application was permitted only between one hour after sunrise and two hours before sunset (rather than any time between sunrise and sunset); (2) only two OTT applications were permitted per crop for soybeans, with the last application made no later than forty-five days after planting; (3) only two OTT applications were permitted per crop for cotton, with the last application made no later than sixty days after planting; (4) an omnidirectional, in-field fifty-seven-foot buffer was required in certain counties to protect listed plant species; and (5) applications could be made only by certified applicators." *Id.* at 1130.

A lawsuit followed, with Plaintiffs prevailing. The court revoked the EPA's conditional "new use" registrations for dicamba-based herbicides for post-emergent, OTT spraying of genetically modified DT soybeans and cotton. *Id.* at 1144–45. In *NFFC (Monsanto),* the court held EPA violated FIFRA six ways, *id*. at 1124, 1144 (summarizing holdings), separated into two parts: 1) EPA "substantially understated three risks it acknowledged" and 2) "also entirely failed to acknowledge three other risks." *Id*. at 1124. The court's detailed decision was also filled with factual record findings recounting catastrophic results for farmers and the environment, such as millions of acres of off-field dicamba drift, as well as damage to crops, wild plants, and native ecosystems each growing season since EPA approved OTT spraying in 2016. *Id.*

The first group of holdings in *NFFC (Monsanto)* related to costs to farmers from dicamba drift, including that the EPA understated the dicamba amount sprayed (and thus the drift harm from it), *id*. at 1124, 1136, improperly minimized the amount of under-reporting of drift damage, *id*. at 1137–38, and, despite the record evidence the registration decision "refused to quantify or estimate the amount of damage caused" by drift as an economic cost, *id.* at 1138.

The second group of violations noted in *NFFC (Monsanto)* were predicated on the court's finding that the EPA based registration on unrealistic and unanalyzed mitigation,

failed to account for the substantial non-compliance with the dicamba use instructions or grapple with the near impossibility of following the label in real-world farming conditions, and what that would mean for increased drift damage. *Id*. at 1144. In other words, the EPA improperly based its approval on the premise that the label's mitigation would be followed and, accordingly, limit off-field drift, while the record evidence showed that label instructions were "difficult if not impossible" to follow. *Id*. at 1124. The court held the EPA failed to recognize and factor in the "clear" economic cost from drift damage coercing farmers to defensively adopt dicamba-tolerant crops, and those anti-competitive, monopolistic ramifications. *Id*. EPA entirely failed to consider the social costs to farming communities from pitting neighbor against neighbor related to drift damage to crops, and trees and gardens. *Id*. at 1143.

On June 3, 2020, the United States Court of Appeals for the Ninth Circuit decided *NFFC (Monsanto)* finding that substantial evidence did not support the EPA's registration decisions because it was contrary to the record and the agency had "failed to perform a proper analysis of the risks and the resulting costs of the uses." *Id.* at 1144. Relevant here, the appellate court's jurisdiction in *NFFC (Monsanto)* hinged on its conclusion that the October 31, 2018, decision to register the three dicamba herbicides for OTT application qualified as an "order" issued by the EPA. *Id.* at 1132. Equally important, the court concluded "that the 2018 registration decision was issued by the EPA "following a public hearing," because the decision arose "from a notice-and-comment period held prior to the related 2016 registration decision." *Id., see also* 7 U.S.C. § 1326n(b) (direct appellate review following a public hearing).

The court vacated the registration decision because remand without vacatur is warranted "only in limited circumstances." *Id.* at 1144 (quoting *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015)). The court "weigh[ed] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *Id.* at1145. The court considered "the extent to which either vacating or leaving the decision in place would risk environmental harm" and "also looked at whether

the agency would likely be able to offer better reasoning or whether by complying with procedural rules, it could adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand.'" *Id.*

The court expressly addressed the practical effects of the decision, including the impact on growers who had already purchased DT soybean and cotton seeds, and "acknowledge[d] the difficulties these growers may have in finding effective and legal herbicides to protect their DT crops." *Id.* at 1145. Nevertheless, it vacated the registrations because the "fundamental flaws" in the EPA's analysis were so substantial that it was exceedingly "unlikely that the same rule would be adopted on remand." *Id.*

On June 8, 2020, EPA issued the "Final Cancellation of Three Dicamba Products" (Final Cancellation Order) for OTT use of dicamba but allowed for already purchased products to be used in the 2020 growing season. (P MSJ, SOF, Stevenson Decl., Ex. J: Final Cancellation Order (June 8, 2020) (Doc. 161-10) at 2-13.) Then within approximately four months of the June 3, 2020, *NFFC (Monsanto)* decision, on October 27, 2020, EPA again approved OTT dicamba spraying. EPA issued the three dicamba registrations at issue in this case: Bayer Defendant Intervenor's product XtendiMax (P MSJ, SOF, Ex. A13 (AR[3] A.13) (Doc. 158-8) at 2-37); BASF Defendant Intervenor's product Enginia, *id.*, Ex. A12 (AR A.12) (Doc. 158-7) at 2-39), and Syngenta Defendant Intervenor's product Tavium Plus Vapor Grip, *id.*, Ex. A05 (AR A.5) (Doc. 158-4) at 1-56). Tavium was registered in 2019 with an automatic expiration date of December 20, 2020.

All three registrations had been registered conditionally for two years but were issued in 2020, unconditionally, for five years. All three had been and remained classified as restricted use, including similar but progressively tougher restrictions to mitigate offsite drift. All the 2020 registrations, and the original 2019 Tavium registration, were issued without notice and comment. Plaintiffs filed this lawsuit.

[3] Administrative Record.

On March 15, 2022, EPA granted voluntary registrant-proposed amendments to the registrations for Iowa and Minnesota. On February 26, 2023, EPA approved registrant-proposed amendments for Illinois, Indiana, Iowa, and South Dakota, leaving the same 2022 restrictions in place for Minnesota. These amendments have added further use restrictions for OTT spraying of DT soybean and cotton crops in these states, only. Plaintiffs have twice amended the Complaint to encompass the 2022 and 2023 amendments to the registrations.

B. STANDARD OF REVIEW

1. FIFRA, ESA, and APA

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prohibits the distribution or sale to any person of any pesticide that is not registered by the EPA. 7 U.S.C. § 136a(a). "A FIFRA registration is a license establishing the terms and conditions under which a pesticide may be lawfully sold, distributed, and used." *American Soybean Association v. Regan*, 77 F.4th 873, 875 (D.C. Cir. 2023) (citing 7 U.S.C. § 136a(c)(A)-(F) (citing registration labeling requirements). "Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant . . .." 40 C.F.R § 152.3.

In registering pesticides, the EPA applies the core standard of "unreasonable adverse effects." "That is, EPA applies a cost-benefit analysis 'to ensure that there is no unreasonable risk created for people or the environment from a pesticide.'" (P MSJ (Doc. 155(R)/167(S))[4] at 16 (quoting *Pollinator*, 806 F.3d at 522–23)). Balancing benefit against risk "is supposed to take every relevant factor that the Administrator can conceive of into account." S. Rep. 838, 92d Cong. 2d Sess., reprinted in 1972 U.S.C.C.A.N. 3993, 4032. Congress defined "unreasonable adverse effects on the environment" broadly to mean: "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).

[4] R (redacted); S (sealed).

When the EPA registers a pesticide pursuant to notice and comment provisions in FIFRA for "any pesticide if it contains any new active ingredient or if it would entail a changed use pattern," 7 U.S.C. § 136a(c)(4), FIFRA provides for direct appellate review. 7 U.S.C. § 136n(b). Then, the EPA decision must be supported with "substantial evidence," *id.*, and the agency's reasoning "must also be coherent and internally consistent," *Nat. Res. Def. Council (NRDC) v. United States Env't Prot. Agency (EPA) (Nat. Assoc. Wheat Growers (NAWG))*,[5] 38 F.4th 34, 44 (9th Cir. 2022). This was the standard of review applied by the Ninth Circuit appellate court in *NFFC (Monsanto)* when it reviewed and revoked the 2016, as amended 2018 dicamba registrations. *See also,* 40 C.F.R. § 152.102.

In this case, EPA did not follow the FIFRA notice-and comment provisions and issued the 2020 Decision as an "unconditional" registration, which EPA may only grant if it concludes that the pesticide (1) "will perform its intended function without unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(C), and (2) "when used in accordance with widespread and commonly recognized practice [the pesticide] will not generally cause unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(D); *see also* 40 C.F.R. § 152.112(e). Accordingly, district court review exists in this Court over this action. 7 U.S.C. § 136n(a); *see also,* (Order (Doc. 83) at 2; Order (Doc. 64) at 2 (explaining this Court's jurisdiction over this case)). Unlike the statutory directive to the appellate court, FIFRA does not expressly provide a standard of review for this Court to review registrations issued without notice and comment.

Likewise, there is no express standard of review in the Endangered Species Act (ESA), the other substantive statute relied on by Plaintiffs. Congress enacted ESA to ensure the survival and recovery of endangered species. 16 U.S.C. § 1531(b), (c). Under ESA, there is no FIFRA-like cost-benefit analysis. In ESA, Congress made a "conscious decision" and gave endangered species priority over the "primary missions" of all federal agencies. *Tennessee Valley Auth. v. Hill,* 437 U.S. 153, 185 (1978). Section 7 is ESA's "heart," and crucial to the recovery of ESA-protected species. *Karuk Tribe v. U.S. Forest*

[5] *See* n.2.

Serv., 681 F.3d 1006, 1019 (9th Cir. 2012) (*en banc*). Under section 7, the EPA, like all other federal agencies, has a substantive duty to "ensure" any authorization of a pesticide is not likely to jeopardize any species or adversely modify any critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.02. If the EPA determines that its actions, including registration decisions, "may affect" protected species or critical habitat, the EPA has a procedural duty to evaluate the registration's effects "in consultation with and with the assistance of" the wildlife agencies that Congress has designated as having endangered species expertise, here, the United States Fish and Wildlife Service (FWS). 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). In this case, the EPA made a "no effects" finding and did not consult FWS to evaluate the effects of OTT dicamba on protected species and habitat.

"'[T]he strict substantive provisions of the ESA justify more stringent enforcement of its procedural requirements, because [they] are designed to ensure compliance with the substantive provisions.'" (P MSJ (Doc. 155(R)/167(S)) at 18 (quoting *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985), abrogated on other grounds by *Cottonwood Env't Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1088–89 (9th Cir. 2015)).

Accordingly, the Court applies the standard of review applicable under the APA for the ESA claim and under FIFRA because the EPA issued the challenged registration decision without notice and comment. *See, e.g., Ctr. for Food Safety v. Regan*, 56 F.4th 648, 656 (9th Cir. 2022) (explaining that "because the ESA does not specify a standard of review, we review EPA's compliance under the [APA]"); *Ellis v. Housenger*, 252 F. Supp. 3d 800, 808 (N.D. Cal. 2017) (reviewing FIFRA challenge under 7 U.S.C. § 136n(a) under APA standards); *Friends of Animals v. EPA*, 383 F. Supp. 3d 1112, 1120 (D. Or. 2019) (holding APA standards for "other final actions" of EPA under § 136n(a)).

Plaintiffs argue that the EPA's 2020 Decision does not pass muster under either because there is "no substantive difference" between FIFRA's "substantial evidence" standard and the APA. *Ass'n of Data Processing Serv. Orgs. v. Bd. of Governors of the Fed. Reserve Sys.*, 745 F.2d 677, 683–84 (D.C. Cir. 1984). The APA standard of review,

referred to as the arbitrary and capricious test, is defined in § 706 of the APA, as follows:

> To the extent necessary to a decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—
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> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> > (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
> >
> > (B) contrary to constitutional right, power, privilege, or immunity;
> >
> > (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
> >
> > (D) without observance of procedure required by law;
> >
> > (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
> >
> > (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

The scope of APA review 5 U.S.C. § 706(2) is narrow and highly deferential, with the court presuming the agency's action to be valid. The Court must not substitute its judgment for that of the agency and only determines whether the agency has examined the relevant data and articulated a satisfactory explanation for its action including making a "rational connection between the facts found and the choice made." *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, (1962)*; Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). An action is "'arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" (P MSJ (Doc. 155(R)/167(S)) at 15-16 (quoting *Motor Vehicle Mfrs*., 463 U.S. at 43), *see also Ranchers Cattlemen Action Legal Fund v. United States Dept. of Agric.,* 499 F.3d 1108, 1115 (9th

Cir. 2007) (same). In APA review, the Court makes a "searching and careful inquiry," to ensure the agency "engaged in reasoned decision making." *NW. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1052 n.7 (9th Cir. 2008) (cleaned up).

2. Cross Motions for Summary Judgment

Federal Rule of Civil Procedure 56(a) provides for summary judgment when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Material facts are facts that may affect the outcome of the case. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). A dispute is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party on a material question of fact. *Id.* On summary judgment, the court may not weigh the evidence and must view the evidence in the light most favorable to the nonmoving party. *Id.* at 255. In short, the standard for granting summary judgment mirrors the standard for a directed verdict under Fed. R. Civ. P. 50(a): "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-252.

The party moving for summary judgment bears the initial burden of informing the court of the basis for its motion and of identifying those portions of the pleadings or materials in the record that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A moving party having the burden of proof at trial "must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party." *Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir.2007) (relying on *Celotex*, 477 U.S. at 323). Where the moving party's opponent will have the burden of proof at trial, the moving party can prevail merely by "pointing out to the district court ... that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325. If the moving party meets its initial burden, the opposing party must then set out specific facts showing a genuine issue for trial to defeat the motion. *Anderson*, 477 U.S. at 250.

Because APA review is generally limited to the administrative record, the district court is not managing a "garden variety civil suit," but rather "sits as an appellate tribunal." *Cnty of Lost Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999). The usual "genuine dispute of material fact" standard for summary judgment normally does not apply in an APA case because normally there are not disputed facts to resolve. *Occidental Eng'g Co. v. I.N.S*, 753 F.2d 7666, 769 (9th Cir. 1985). "The function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Id.; City & Cnty of San Francisco v. United States*, 130 F.3d 873, 877 (9th Cir. 1997). Here, the parties submit cross-motions for summary judgment, therefore, the Court considers each motion on its own merits to determine for each party whether judgment may be entered in accordance with Rule 56. *Fair Housing Council of Riverside County, Inc. v. Riverside Two*, 249 F.3d 1132, 1136 (9th Cir.2001).

C. PROCEDURAL VIOLATIONS: FIFRA, ESA and APA

1. Did EPA violate FIFRA Public Hearing Requirements for "New Use" and Cancelled Registrations?

While the substantive merits of whether the dicamba registrations require the Court to consider an extensive and complicated scientific record, the Court is in familiar territory when considering relevant questions of law, interpreting constitutional and statutory provisions, and determining the meaning or applicability of the terms of the EPA's action, to decide issues of alleged procedural error. 5 U.S.C. § 706(2).[6]

Plaintiff alleges that the EPA issued the 2020 dicamba registrations without complying with FIFRA notice and comment requirements for "new use" registrations. Under FIFRA: "The Administer shall 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*

[6] Under *Chevron v. Natural Resources Defense Council, Inc.* 467 U.S. 837 (1984), the Court grants APA deference to agencies on questions of law in the face of statutory ambiguity and accepts an agency's construction/interpretation of a statutory term if it has a reasonable basis in law. *Chevron* deference is currently under review by the Supreme Court but reversal or narrowing of the doctrine will not affect this case because the Court finds agency error. This Court applies *Chevron.*

would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment." 7 U.S.C. § 136a(c)(4). "New use" means, in part: "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." *Id*.; 40 C.F.R. § 152.3. It is undisputed that dicamba was previously registered for pre-emergent use. Plaintiffs are correct that the relevant FIFRA "new use" provision in this case is a changed use pattern that significantly increases in the level of exposure. Likewise, notice of cancellation or change in classification[7] must be sent to the registrant and made public, and any person adversely affected by the notice is afforded an opportunity to request a hearing. 7 U.S.C. § 136d((b).

Notice requirements ensure that agency regulations and/or decisions are tested via exposure to diverse public comment and to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and, thereby, enhance the quality of judicial review. *Cf., Am. Coke and Cal Chems. Inst. v. EPA,* 452 F.3d 930, 938 (D.C. Cir. 2006) (discussing APA notice and comment requirements). Notice and comment occur before an agency takes action to ensure that affected parties have an opportunity to participate and influence agency decision-making at an early stage when the agency is more likely to give real consideration to alternative ideas. *See Advocates for Highway and Auto Safety v. FHA*, 28 F.3d 1288, 1291-92 (D.C. Cir 1994) (stressing importance of comments being made during formative stages because this promotes a flexible and open-minded attitude and addresses the concern that an agency is not likely to be receptive to suggested changes after it puts its credibility on the line in the form of a final rule or decision).

Post hoc notice and comment cannot cure this procedural violation because such allowance would render the statutory notice-and-comment requirements meaningless. *See NRDC v. EPA (NRDC (Bayer))*, 676 F. Supp.2d 307, 314-316 (NY 2009) (finding no

[7] When registered, a pesticide is classified for general use, restricted use, or both. A change in classification requires notice and an opportunity for comment. 7 U.S.C. §§ 136a(d), 136d(b). The notice-and-comment issues in this case do not involve changed classifications. OTT dicamba has always been a "restricted use" pesticide and may only be sprayed by Certified Applicators.

distinguishable difference between FIFRA and APA notice and comment provisions; failure to abide by those unambiguous provisions in FIFRA constituted a fundamental flaw and serious deficiency). In the context of considering whether to vacate spirotetramat, a pesticide used to kill insects, the court held that it was not a matter of cancelling the registration, a procedure that is costly and time consuming, because notice and comment failures in the registration meant spirotetramat was not lawfully registered in the first place, and revocation was more appropriate. *Id.*

The jurisdictional implications for decisions issued by the EPA with or without public hearing gives special meaning to FIFRA's "public hearing" requirement, which must ensure anyone "adversely affected by a resulting order" can become "a party to the proceedings," in the appellate courts. For this to be true-- the agency must at least provide notice of its proposed action to the public and opportunity to comment. "Without public notice of the pending action, the agency's consideration of it cannot be considered a 'public' hearing—i.e., a proceeding "'[o]pen or available for all' who might wish to participate." *American Soybean Assoc*., 77 F.4th at 877.

"FIFRA 'is a comprehensive regulatory scheme aimed at controlling the use, sale, and labeling of pesticides.'" *NFFC (Dow),* 966 F.3d at 912 (quoting *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002)). Under FIFRA, registration occurs in a variety of ways. Unconditional registration, under 7 U.S.C. § 136a(c)(5), requires the EPA to "review[ ] all relevant data in [its] possession" and "determine[ ] that no additional data are necessary" to its decision. 40 C.F.R. § 152.112(b), (c). EPA can unconditionally register a pesticide only if it will "not generally cause unreasonable adverse effects on the environment" "when used in accordance with widespread and commonly recognized practice." *Id.* § 152.112(e). This balances "risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide," *NFFC (Dow),* 966 F.3d at 912-913 (quoting 7 U.S.C. § 136(bb)); *see also* 7 U.S.C. §136a(c)(3)(A) (citing 7 U.S.C. § 136a(c)(5)). Also, EPA may unconditionally register or amend a registration of a pesticide which is identical or substantially similar 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). These registrations are often called "me-too" registrations.

In comparison, the EPA may "conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the [EPA] determines that [] the applicant has submitted satisfactory data pertaining to the proposed additional use and [] amending the registration in the manner proposed ... would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id.* at § 136a(c)(7)(B); 40 C.F.R. § 152.113(a). Also, EPA may "conditionally" issue "me too" registrations or amended registrations based on data as would be required to obtain unconditional registration of a similar pesticide but if such data has not yet been generated, the registration or amendment may be issued under such conditions as required not later than the time such data are required to be submitted with respect to the similar and already registered pesticide. 7 U.S.C. § 136a(c)(7)(A); 40 C.F.R. § 152.113(b).

For a conditional registration, the EPA must review "at a minimum, data needed to characterize any incremental risk that would result from approval of the application and determine that approval would not significantly increase the risk of any unreasonable adverse effect on the environment. 40 C.F.R. §152.113(a)(1-2). Conditional registration of substantially similar products and new uses issued under §152.113 require submission or citation of all data which are required for unconditional registration . . . under FIFRA 3(c)(5), but which have not yet been submitted, no later than the time such data are required to be submitted for similar pesticide products already registered." 40 C.F.R. §152.115(a).

Unconditional registrations hinge on whether the registrant-pesticide "cause[s] any unreasonable adverse effects" compared to the standard for conditional registrations which is whether it "significantly increases the risk of any unreasonable adverse effect." The differing standards reflect that conditional registration is an option only when a pesticide

or active ingredient has already been registered using the unconditional registration, causation-based standard. "The conditional registration standard is therefore best understood as limiting the scope of new evidence EPA must consider in making its registration decision." *NFFC (Dow)*, 966 F3d at 916. "EPA need only consider evidence that bears on whether the new or additional use changes EPA's original conclusion that the pesticide or active ingredient will 'not generally cause unreasonable adverse effects.'" *Id.* (quoting 7 U.S.C. § 136a(c)(7)(A)).

FIFRA's implementing regulations provide a specific approach in cases involving "'active ingredient[s]' that have already been registered as part of other 'pesticide product[s].'" *Id.* at 913 (quoting 40 C.F.R. § 152.111). "In such cases, 'the Agency will not commence a complete review of the existing data based on a given chemical in response to receipt of an application for registration.'" *Id*. "'Instead, the Agency will review the application using the criteria for conditional registration' under 7 U.S.C. § 136a(c)(7)(A) and (B)," *id.*, which as noted above requires the EPA to consider evidence relevant to show whether the new or additional use changes the original conclusion that the pesticide or active ingredient will not generally cause unreasonable adverse effects.

a. New Use Registrations

These summarized provisions are relevant in this case because dicamba is an active ingredient that was registered as part of other pesticide products, such as "Roundup," which due to its volatility and propensity to drift offsite and damage nontarget plants was used pre-emergent, generally, on baren fields before or early in the growing seasons. As noted in the historical notes herein, eventually agrochemical manufactures developed new, "lower-volatility" dicamba products and DT cotton and soybean seeds and sought to register OTT dicamba for DT crops (cotton and soybeans) for post-emergent use during the growing season. The 2016 dicamba registrations, and 2018 amendments, were undeniably for an "additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure from dicamba.

In 2016 after notice and comment, the EPA granted "new use" applications and issued two-year "conditional" registrations for three "lower volatility" OTT dicamba products for DT crops (cotton and soybean), i.e., post-emergent spraying during the growing season for XtendiMax; FeXapan, and Enginia. *NFFC (Monsanto),* 960 F.3d at 1132. All three registrations were set to automatically expire at the end of 2018. All included restrictions which were "'expected to eliminate any offsite exposures to dicamba.'" *Id.* at 1127 (quoting 2016 registration decision). When the 2017 and 2018 growing seasons reflected the contrary, dicamba manufacturers proposed, and EPA adopted by amendment in 2018, further restrictions, *id.* at 1127-1130, again to address volatility and spray drift aimed at eliminating offsite exposures and extended the conditional registrations for the three dicamba products for two more years. *Id.* at 1127.

The EPA issued "conditional" 2016 registrations, and 2018 registration amendments, under § 7 U.S.C. § 136(c)(7)(B), which allows such registration "notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." *NFFC (Monsanto),* 960 F.3d at 1133. On June 2, 2020, the Ninth Circuit Court of Appeals in *NFFC (Monsanto)* vacated the 2016 registrations, as amended in 2018, after finding that the October 31, 2018, decision upon which they were premised was not supported by substantial evidence. *Id.* at 1125.

On June 8, 2020, EPA issued the *Final Cancellation of Three Dicamba Products* (Final Cancellation Order), expressly canceled these registrations but allowed use of already purchased existing OTT dicamba stock. (P MSJ, SOF, Stevenson Decl., Ex. J: Final Cancellation Order (Doc. 161-10) at 2-13.)[8] The EPA noticed the manufacturers but did not issue a public notice regarding the cancellations.

[8] The Court takes judicial notice of this publicly available document which is a government publication. Fed. R. Evid. 201(b). It is central to the procedural question of notice and

Within four months, on October 27, 2020, without notice and comment, the EPA issued a decision to "unconditionally" register dicamba under FIFRA § 136a(c)(5) to be used post-emergent for OTT spraying, post-emergent, on DT crops (cotton and soybean) finding "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." (P MSJ, SOF, Ex. A04 (AR A.4): 2020 Decision Supporting Approval (Doc. 158-3) at 3, 1-19, 22); *see* 7 U.S.C. § 163a(c)(5)(D); 40 C.F.R. § 152.112(e). The EPA issued unconditional registrations for XtendiMax and Enginia, which had been vacated on June 2, 2020, in *NFFC (Monsanto)* and canceled by the EPA on June 8, 2020. Simultaneously, the EPA amended a 2019 registration for Tavium to extend its automatic expiration date of December 20, 2020, to December 20, 2025. Tavium had been conditionally registered on April 5, 2019, under FIFRA "me too" provisions. 7 U.S.C. § 136a(c)(7)(A). In 2020, the EPA issued an unconditional amended registration.

According to the EPA, the 2020 dicamba registrations did not fall under FIFRA "new use" provisions because "[i]n relevant part, those requirements apply to registrations of "a product containing a particular active ingredient" when: (1) there is "no product containing the active ingredient that is currently registered for that use pattern"; or (2) when the registration would authorize an "additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to that active ingredient." (EPA CMSJ (Doc. 170) at 28 (citing 40 C.F.R. § 152.3). "Neither condition applies here." *Id.* "Tavium was registered for OTT dicamba application to DT cotton and DT soybean in 34 states," and therefore "the 2020 Registrations involved the same active ingredient, applied in the same manner, to the same crops, in the same states." *Id.* "The 2020 Registrations thus did not involve a new or additional "use pattern," and 40 C.F.R. § 152.102's procedural requirements did not apply." *Id.*

EPA included this rationale in the 2020 Decision to explain the unconditional registration decision even though the Defendant Intervenors Bayer and BASF, both,

comment, and directly referenced and quoted by the parties. *See* (EPA CMSJ (Doc. 170) at 28, EPA Reply (Doc. 239) at 15).

submitted registration applications for new registrations of XtendiMax and Enginia. Syngenta submitted a request to amend Tavium's conditional registration to extend its expiration date. *See* (P MSJ, SOF, Ex. A04 (AR A.4): 2020 Decision Supporting Approval (Doc. 158-3) at 4 n. 3) (explaining "[since Tavium is currently registered for use on DT cotton and DT soybeans, none of these registrations are considered to include any new uses")).

Then and now, EPA ignores that the 2019 Tavium registration, the linchpin for the 2020 registrations, was a "me too" conditional registration. This means, Tavium was registered as being identical or substantially similar, or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, compared to the XtendiMax and Enginia dicamba products, as conditionally approved in 2016, and amended in 2018. In 2019, it was true that Tavium involved the same active ingredient, applied in the same manner, and to the same crops as approved for those XtendiMax and Enginia registrations. And, the 2019 Tavium "me too" registration did not require any additional data beyond that required by the 2016 and 2018 amendments for XtendiMax and Enginia registrations. The Tavium 2019, two-year, conditional registration did not involve a new or additional "use pattern," and FIFRA's notice and comment procedural requirements did not apply.

The same was not true in 2020 because the 2016, and 2018 amended XtendiMax and Enginia registrations were vacated and cancelled. These registrations approving the new post-emergent use of OTT dicamba for DT crops (cotton and soybeans) were vacated and cancelled because the 2016 Decision approving this new pattern of use was found to not be supported by substantial evidence. In 2020, OTT dicamba was not an approved use. It does not matter whether the Tavium registration was or was not challenged, or whether the 2019 Tavium registration should have remained in place after the XtendiMax and Enginia registrations were vacated and canceled. What matters is that the 2019 Tavium registration was issued under FIFRA "me too" provisions because it was identical or substantially similar to the then registered, and subsequently vacated and cancelled, OTT

dicamba products, XtendiMax and Enginia. EPA erred when it relied on the Tavium 2019 registration, which was premised on these vacated and cancelled XtendiMax and Enginia registrations. In 2020, just like in 2016, as amended in 2018, EPA was considering approving OTT dicamba for DT crops (cotton and soybean). This is the relevant use pattern. It was a new use in 2016, when amended in 2018, and after those decisions were vacated, it remained so when the EPA considered registering OTT dicamba products again in 2020. The EPA is wrong that the OTT dicamba applications in 2020 did not meet the "new use" definition under 40 C.F.R. § 152.3, which means: "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." Just like the 2016, as amended in 2018, registrations did, the 2020 registrations met this definition. The 2020 registrations required notice by publication in the Federal Register and public comment under FIFRA. 40 C.F.R. § 152.102.

b. Cancelled Registrations

Plaintiff argues that on June 8, 2020, when EPA cancelled the vacated 2016, as amended 2018 registrations, it triggered notice-and-comment provisions under section 6 of FIFRA. 7 U.S.C. § 136d. (P MSJ, SOF, Stevenson Decl., Ex. J: Final Cancellation Order (Doc. 161-10) at 2-13.)[9] "EPA may commence cancellation proceedings '[i]f it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment.'" *Id.* Then, EPA may either issue a notice of intent to cancel or issue a notice of intent to hold a hearing to determine whether a registration should be canceled. If the first option is chosen, the registrant may demand a hearing. 7 U.S.C. § 136d(b). Once a final decision to cancel has been made, the registrant may seek judicial review by filing a petition for review in a court of appeals. 7 U.S.C. § 136n.

[9] *Id.*

In reverse, § 6, Subpart D, 40 C.F.R. § 164.130, explains: "EPA has determined that any application under section 3 . . . to allow use of a pesticide . . . for which registration has been finally cancelled or suspended by the Administrator constitutes a petition for reconsideration of such order. . . .[and] such orders may not be reversed or modified without . . . notice and hearing opportunities, [pursuant] subpart D." Additionally, § 3, subpart F, 40 C.F.R. § 152.100, requires the Agency to "follow the procedures in this subpart for all applications for registration, except an application for registration of a pesticide that has been the subject of a previous Agency cancellation or suspension notice under FIFRA section 6" and "follow the procedures of subpart D of part 164 when "evaluating any application for registration of a pesticide involving use of the pesticide in a manner that is prohibited by a suspension or cancellation order."

"[T]he existence and content of Section 6 is strong evidence that Congress intended EPA to use Section 6," not some other enforcement action, to remove a product from the market if it determines that the product is no longer eligible for registration." *Benckiser v. Jackson*, 762 F. Supp.2d 34, 43-44 (D.C. 2011). In *Benckiser*, the court explained it would be illogical to allow EPA to bring an enforcement action for misbranding that would effectively cancel the registration because this would allow EPA to by-pass cancellation proceedings and circumvent the rigorous cancellation process Congress provided for in section 6. Congress intended applicants dissatisfied with the Secretary's action in refusing or canceling a registration to have recourse in advisory committee proceedings, public hearings, and eventually judicial review," "designed to both 'afford [] adequate protection to the public,' and 'protect [] applicants for registration from arbitrary or ill-advised action by the Department." *Id.* at 47 (citation).

Subpart D, 40 C.F.R. § 164.130, explains EPA is required to consider any application under § 3 to allow use of a pesticide where the Administrator has cancelled its registration to constitute a petition for reconsideration of such cancellation "[b]ecause of the extensive notice and hearing opportunities mandated by FIFRA . . . before a final cancellation or suspension order may be issued, EPA has determined that such orders may

not be reversed or modified without affording interested parties—who may in fact have participated in lengthy cancellation proceedings—similar notice and hearing opportunities."

It is undisputed that the EPA only sent the Final Cancellation Order to the manufacturer, and Bayer did not seek a hearing. The EPA did not afford notice, comment, or any opportunity for hearing when it issued the 2020 dicamba registrations. Arguably the purpose as stated in section 6 for requiring mirror public hearing procedures before reconsidering a cancellation order does not apply factually because no notice and comment or hearing was afforded prior to EPA's issuance of the June 8, 2020, Final Cancellation Order. Nevertheless, *Benckiser* suggests a preference to proceed under cancellation provision in section 6 rather than bypassing it.

The EPA argues that the cancellation provisions in part 164, subpart D only apply if the pesticide at issue has been the subject of a previous Agency cancellation under FIFRA section 6 (7 U.S.C. § 136d). Otherwise, part 152, subpart F applies, and it issued the 2020 cancelation under FIFRA section 3 (7 U.S.C. § 136a). (EPA Reply (Doc. 239) at 15) (citing Final Cancellation Order (June 8, 2020) at 4.)) In the Final Cancellation Order, the EPA explained that "the three registrations were vacated by court order immediately, without any opportunity for a cancelation order to be issued by EPA. Nonetheless, the Agency believes that the Court's action in vacating [] these dicamba registrations has been consistently viewed under FIFRA as equivalent to the cancellation of those registrations under FIFRA section 3 (7 U.S.C. § 136a) including any additional uses authorized under section 24(c) of FIFRA), because the vacatur is based upon the lack of substantial evidence to support the registration under section 3 of FIFRA." *Id.*

Section 3, subpart F pertains to agency review of applications and procedures to either grant or deny them. For example, EPA argued it could not take action in 2022 and 2023 except to approve or deny the voluntary-registrant amendments that were submitted for a few states subsequent to "[e]vents during the 2021 growing season [that]confounded EPA's expectations." (EPA CMSJ (Doc. 170) at 15.) EPA issued a status report, the 2021

Report, and released it to state stakeholders, who then sought further restrictions. However, in the 2020 Decision, the EPA advised that states could no longer act, as they had before pursuant to § 24(c) to impose restrictions greater than those imposed by the federal government. *See* (P MSJ, SOF, Ex. A0 (AR A.44): 2020 Decision Supporting Approval (Doc. 158-3) at 21 n.19.) Therefore, in 2022 and 2023, the states were dependent on the Intervenor Defendants seeking voluntary-registrant amendments. Which they did in this case for a few states.

The Court does not reach the Plaintiffs' charge that the EPA engaged in improper rule making, without notice and comment.[10] In the context of EPA's assertion that the Final Cancellation Order was issued pursuant to section 3, the Court rejects the assertion that EPA had no authority to cancel the 2020 registrations. Section 3 establishes the Agency's obligation to review data when it determines that it would otherwise serve the public interest, 40 C.F.R. § 152.107, and provides no substitute procedures to formal cancellation in the event such review should warrant such action. *Cf.*, 7 U.S.C. § 136a(c)(8) (providing for "Interim administrative review," [n]otwithstanding any other provision of this subchapter, and precluding Administrator from initiating a public interim administrative review process without initiating prior formal action to cancel); 7 U.S.C. § 136a(g) (requiring formal cancellation proceedings for periodic (15 year) reviews).

While section 3, 40 C.F.R. § 152 et seq, including subpart F, pertains to pesticide registration procedures, it carves out application of section 6, subpart D, 40 C.F.R. § 152.100, for "any application for registering a pesticide that has been the subject of a previous Agency cancellation notice under section 6." There are no other relevant provisions in section 3, subpart F. The Court concludes, any action to cancel a registration

[10] APA agency actions that qualify as rules must go through notice-and-comment. 5 U.S.C. §§ 553(b), (c). The APA defines "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4). Legislative rules are agency decisions that "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp Indus. Ass'n v. Drug Enforcement Admin.*, 333 F.3d 1082, 1087 (9th Cir. 2003). An agency can issue a legislative rule only by using the notice-and-comment procedure described in the APA. 5 U.S.C. § 553(b), (b)(B). In contrast, an agency need not follow the notice-and-comment procedure to issue an interpretive rule. § 553(b)(A).

whether it arises from section 3 review or otherwise is subject to section 6 cancellation provisions, including public hearing notice and comment requirements.

Section 6 of FIFRA provides: "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or cancelled under this section or section 136a []11, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter." 7 U.S.C. § 136d(a)(1).

Subsection b provides for the Administrator to cancel a pesticide if "its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Then, "the Administrator may issue a notice of the Administrator's intent either--(1) to cancel its registration . . . with the reasons (including the factual basis) for the Administrator's action, or (2) to hold a hearing to determine whether or not its registration should be canceled . . .." 7 U.S.C. § 136d(b).

It is undisputed that the Final Cancellation Order was a "stock order," issued pursuant to 7 U.S.C. § 136d(a) for "a pesticide whose registration is suspended or canceled under this section," referring to section 6. EPA expressly issued the notice as a "cancellation," an action authorized pursuant to 7 U.S.C. § 136d(b). The Court finds the Final Cancellation Order was issued under section 6. Even if the Final Cancellation Order is something other than a cancellation order issued under 7 U.S.C. § 136d, the nature of the EPA's action to cancel the 2016, as amended in 2018, OTT dicamba registrations taken on June 8, 2020, is not procedurally determinative because in this case the EPA approved a "new use" registration on October 27, 2020, and that action required notice and comment. Either way, the EPA failed to provide notice and an opportunity to be heard prior to issuing the 2020 dicamba registrations for OTT dicamba for DT crops (cotton and soybean).

[11] [136a-1] omitted (pertains to reregistration of registered pesticides).

2. Yes: EPA Violated FIFRA Hearing (Notice and Comment) Mandates

The court in *NFFC (Monsanto)* vacated the 2016, 2018 amended registrations, because they were not supported by substantial evidence in part because the EPA failed to consider certain risks and associated costs to stakeholders not using OTT dicamba, such as economic costs associated with defensive planting of DT soybeans, impacts to other seed technologies and other seed companies, social cost to farming communities from disputes between OTT and non-OTT dicamba users, etc. *NFFC*, 960 F.3d at 1142-1144. The EPA substantially understated and failed to quantify dicamba damage to specialty crops, like vegetables and orchards, vineyards, non-agricultural trees and plants, and beekeepers. *Id.* at 1138-39. EPA failed to consider non-compliance with label restrictions caused by so many limitations, such as time of day, temperature and wind restrictions, etc., that growers were unable to find any unrestricted means to use OTT dicamba. *Id.* at 1139-1141.

Given the unequivocal revocation and cancellation of the XtendiMax and Enginia registrations that authorized the "new use" of low-volatility dicamba products for post-emergent OTT spraying for DT cotton and soybean crops, the EPA's determination that the 2020 registrations were not also "new use" registrations is so implausible the Court cannot ascribe it to be a mere difference in view. It is not a product of agency expertise. The EPA erred when it relied on the 2019 Tavium registration as a jumping off point, data-wise and procedurally for the 2020 dicamba registrations because by its very definition as a "me too" registration it was premised on the vacated and cancelled XtendiMax and Enginia registrations.

EPA sidestepped the statutory mandate under FIFRA that notice and comment be afforded all stakeholders for new use registrations. The EPA denied the public its statutory right to meaningfully weigh in during the decision-making process before EPA concludes whether OTT dicamba has unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(4), 40 C.F.R. § 152.102. The Court finds a violation of the APA because the EPA's agency approval of the new use, OTT dicamba, registrations without notice and hearing,

was not in accordance with law, 5 U.S.C. § 706(2)(A), and without observance of procedure required by law, *id.* § 706(2)(D).

"If the court finds that an agency committed an error, the court must take 'due account' of 'the rule of prejudicial error.'" *NRDC (Bayer)*, 676 F. Supp. 2d at 311; 5 U.S.C. § 706 (in determining APA violations, "the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error." "'The rule of prejudicial error typically eliminates the necessity of remand following judicial review when the error that the agency has made was not prejudicial and did not impinge on fundamental rights.'" *Id.* (quoting *Green Island Power Auth. v. FERC*, 577 F.3d 148, 167 (2nd Cir. 2009). The Court finds the error of issuing the 2020 registrations without notice and comment was prejudicial and impinged on the fundamental right to be heard. This right is important because it ensures registration decisions are not made arbitrarily or capriciously. Without it, there was prejudice because not all stakeholders, especially non-OTT users at risk from OTT dicamba, were not afforded an opportunity to be heard to create a record of objections to be considered by the EPA before it issued the 2020 OTT dicamba registrations. Because the Court finds error, vacatur is required. The real question in this case is whether the Court should make an exception and remand the 2020 OTT dicamba registrations to the EPA, without vacatur.

D. REMEDY: VACATUR OR REMAND WITHOUT VACATUR

The Court should order remand without vacatur "'only in limited circumstances.'" (*NFFC (Monsanto)*, 960 F.3d at 1144 (quoting *Pollinator*, 806 F.3d at 532), "'when equity demands that we do so,'" *Ctr. for Food Safety*, 56 F.4th at 663 (quoting *Pollinator*, 806 F.3d at 532) (cleaned up). Vacatur is the presumptive remedy when an agency violates the law. 5 U.S.C. § 706(2)(A). Remand without vacatur, as a remedy, is used sparingly. *Wood v. Burwell*, 837 F.3d 969, 975-76 (9th Cir. 2016).

A district court has "broad latitude in fashioning equitable relief "when necessary to remedy an established wrong," *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 936 (9th Cir. 2008), and may exercise its discretion where appropriate to order

partial, rather than complete, vacatur on remand. *See, e.g., Sierra Club v. Van Antwerp*, 719 F. Supp. 2d 77, 79-80 (D.D.C. 2010) (narrowing vacatur of permits to allow continued construction of partially-completed county road and to maintain storm water maintenance programs because these activities promoted purposes of Clean Water Act).

Two factors guide the Court in deciding whether to depart from, or limit, the presumptive remedy of vacatur: (1) the seriousness of an agency's errors; and (2) the disruptive consequences that would result from vacatur. (*NFFC (Monsanto)*, 960 F.3d at 1144 (relying on *Pollinator*, 806 F.3d at 532)). In applying these factors, the Court considers the following: 1) the extent to which vacating or leaving the decision in place would risk environmental harm, 2) looks at whether the agency would likely be able to offer better reasoning or whether complying with procedural rules, it could adopt the same registrations on remand, or 3) if the fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand. *Id.*

1. Seriousness of the Procedural Error

In this case, the EPA violated the statutory mandate in FIFRA for notice and comment for "new use" registrations and failed to determine no additional data was necessary before issuing the 2020 unconditional registrations for OTT dicamba. EPA violated FIFRA in 2020 when it issued the registrations for XtendiMax, Enginia, and Travium. The seriousness of this error is compounded by the finding in *NFFC* that the original registrations issued for OTT dicamba in 2016, amended in 2018, failed to consider risks to certain stakeholders, including those not using OTT dicamba.

In *NFFC (Monsanto)*, the court considered these factors for the 2016, as amended 2018, OTT dicamba registrations and vacated them. *Supra.* at 4 (citing *NFFC (Monsanto)*, 960 F.3d at 1144-1145). The appellate court concluded the fundamental flaws in the EPA's analysis was so substantial that it was "exceedingly unlikely that the same rule would be adopted on remand." *Id.* at 1145. In part the seriousness of the error was attributed to the EPA's failure to consider certain risks to stakeholders such as the Plaintiffs, who are non-users of OTT dicamba. *Supra.* at 25 (citing *NFFC (Monsanto)*, 960 F.3d at 1138-1144).

In *NFFC v. EPA (Dow)*, 966 F.3d 893, 929 (9th Cir. 2022), the court found far less serious errors and remanded without vacatur because one was typographical and EPA's substantial compliance with ESA mitigated the other error, which was EPA's failure to first determine whether any effect was "adverse" to the Monarch butterfly before determining whether use of Enlist Due caused adverse effects to the environment. While noting EPA's risk quotient-level methodology for determining effects has been called into question, the court deferred to the EPA given the technical nature of alleged error and concluded EPA would likely be able to offer better reasoning and adopt the same rule on remand.

In comparison to *NFFC (Monsanto),* the Ninth Circuit issued a decision in 2022 in *Ctr. for Food Safety* finding procedural errors similar to those at issue here, and remanded without vacating registrations for sulfoxaflor, an insecticide that can harm honeybees. In *Ctr. for Food Safety,* the court considered unconditional registrations issued by the EPA subsequent to a judicial vacatur of conditional registrations. Like this Court's finding here, the court in *Ctr. for Food Safety* held the registrations issued after the judicial vacatur were "new use" registrations, and the EPA failed to comply with FIFRA's notice and comment requirements. Unlike this case, the EPA in *Ctr. for Food Safety* admittedly erred and asked for remand, without vacatur. After sharply rebuking the EPA for thumbing its nose at its prior judicial decision and court directives to comply with ESA, the majority nevertheless "reluctantly" remanded without vacatur, *Ctr. for Food Safety*, 56 F.4th at 668-69, "because a vacatur may end up harming the environment more and disrupting the agricultural industry," *id.* at 652. In *Ctr. for Food Safety,* there was no alternative pesticide compared to the enhanced environment protection covered by the sulfoxaflor registration. *Id.* at 668. The court in *Ctr. for Food Safety* did not issue a blanket remand. It ordered the EPA to act "immediately," within 180 days to comply with ESA. *Ctr. for Food Safety*, 56 F.4th at 669.

In *Ctr. for Food Safety,* the record reflected several public hearing opportunities. The EPA first issued conditional new use registrations for sulfoxaflor in 2010 after notice and comment. In 2013, EPA again noticed and heard comment when it intended to issue

conditional registrations with mitigating measures pending further data development, but ultimately registered sulfoxaflor unconditionally. The 2013 decision and unconditional registrations were vacated, remanded for further study to support expanding use of sulfoxaflor. Subsequently, manufacturers amended the registration applications to add restrictions to eliminate exposure, such as including buffer zones and limiting spraying post-bloom. In 2016, EPA invited public comment to address the Ninth Circuit vacatur directive to obtain further studies and data for effects of sulfoxaflor on bees, then EPA found no need for additional data and unconditionally registered sulfoxaflor for limited uses with restrictions. In 2019, without notice and comment, EPA expanded the unconditional registrations to approve spraying on post-blooming crops from the 2014 vacated registrations and removed restrictions that were required in 2016. *Id.* at 653-656. Center for Food Safety sued the EPA.

In *Ctr. for Food Safety*, the court rejected EPA's asserted reliance on notice and comment afforded in 2014 and 2018, granted EPA's requested remand without vacatur, and imposed an "immediate" deadline for ESA compliance. *Ctr. for Food Safety*, 56 F.4th at 653-656, 660-663. Concurring with the majority findings of error, Circuit Judge Miller dissented in the remedy because he found the errors serious. "It is the EPA's job, not ours, to assess the risks of a pesticide. But it is difficult for us to know whether the EPA did so correctly when its errors obscure our view of the alternatives." *Ctr. for Food Safety*, 56 F.4th at 670 (Miller concurring and dissenting in parts). He did not share the confidence of the majority that EPA's violations could not have made a difference because without notice and comment to afford affected parties an opportunity to create an evidentiary record to support their objections, the court cannot know whether the agency made a fair assessment of all the data. *Id*. at 670-71. "Total ignorance is not necessary for vacatur; an erroneous or incomplete assessment will also do." *Id.* at 671 (citing *Pollinator*, 806 F3d at 532-33; *NRDC v. EPA (HeiQ Materials)*, 735 F.3d 873, 883-883-84 (9th Cir. 2013)). "Just because the EPA did not completely neglect the risks does not mean the agency would necessarily make the same decision if it understood them better." *Ctr. for Food Safety*, 56 F.4th at 671.

He concluded, if beekeepers were given an opportunity to be heard on remand, a different result may be reached. *Id.* Accordingly, he would have followed the ordinary course of vacating the agency action due to error. *Id.*

Judge Miller gave credit to the majority for acknowledging "the bad incentives created by remand without vacatur," and for mitigating them by imposing a time limit (180 days). *Id.* at 672. He pointed out, however, and this Court agrees, deadlines for compliance create a different set of problems because courts "generally 'may not, after determining that additional evidence is required for adequate review, proceed by dictating to the agency the methods, procedures, and time dimension of the needed inquiry.'" *Id.* (quoting *Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.*, 435 U.S. 519, 544–45 (1978)). "'The function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the [agency] for reconsideration.'" *Id.* (quoting *FPC v. Idaho Power Co.*, 344 U.S. 17, 20 (1952)). The best approach is to vacate EPA's unlawful action "and let it determine how, and at what pace, to proceed." *Id.* at 673.

Remand without vacatur incentivizes lawsuits like the one filed here where the EPA operates with a "whack-a-mole" mentality and postpones compliance with statutory mandates until sued and a court orders compliance, and sometimes waits until several judicial directives are issued. *Id.* at 659 (majority opinion). This behavior gives the EPA an unfair advantage because "'there is evidence of potentially serious disruption if a pesticide that has been registered for over [many years] can no longer be used.'" *Id.* at 668 (quoting *NFFC (Dow)*, 966 F.3d at 929-30)). For example, OTT dicamba has been used since 2016, without a registration substantially supported by the evidence. *NFFC*, 960 F.3d at 1144. *See infra* Part D.2 (describing disruptive consequences if OTT dicamba is vacated because growers have relied on its use for many years, without incident).

Both sides press the court to decide the merits of complicated scientific issues that have been statutorily relegated to the EPA, an agency with expertise to evaluate scientific and technical evidence of risks and benefits, including social and economic, for pesticides. This Court's jurisdiction is to assess whether the EPA complied with the law, including

statutory procedural requirements, considered all risks, and issued a decision that is not arbitrary and capricious. The EPA's position is that in spite of any procedural error, it got it right; the Plaintiffs argue that the EPA failed to consider all risks and, therefore, got it wrong. Both positions require the Court to look, with deference, at the technical merits of the EPA's determination that OTT dicamba use on DT crops (cotton and soybean) is not an unreasonable risk to the environment. The procedural error at issue in this case, lack of notice and hearing, upsets the delicate balance created by Congress between Agency determinations and judicial review. Accordingly, the Court finds the procedural error is very serious. This case is not like *Ctr. for Food Safety* where there were multiple public hearing opportunities, EPA admitted its errors, and sought a limited period of time to rectify them.

Here, the EPA provided notice and opportunity to comment regarding the use of OTT dicamba for DT crops (cotton and soybean) in 2016. That was the last time stakeholders whose interests are in opposition to OTT dicamba were given notice and comment for EPA consideration prior to approving an OTT dicamba registration. In *NFFC (Monsanto),* the court found the omission of risks associated with these same stakeholders in part resulted in the 2016, as amended in 2018, Decision and XtendiMax and Enginia registrations to be not substantially supported by evidence, and this fundamental flaw was then considered so substantial that it was "exceedingly unlikely that the same rule would be adopted on remand." *NFFC (Monsanto),* 660 F3d at 1145. The Court explains below why this remains true today.

Most obviously, the EPA's 2020 Decision failed to reconcile the unconditional 2020 registrations with the conditional 2019 Tavium "me too" registration, which by definition was premised on there being insufficient data for an unconditional registration and mirrored the data requirements from the 2016, as amended by 2018 dicamba XtendiMax and Enginia conditional registrations. To support an unconditional registration, the EPA must determine that no additional data are necessary relevant to determining that there is no unreasonable adverse effect to the environment.

The Court looks for evidence to support the change in 2020 to issue unconditional registrations instead of conditional registrations. The Defendant Intervenors refer the Court to scientific submissions of "new field studies" conducted by independent academic experts and registrants, including 19 registrant studies identifying efficacy of VRA (volatility reduction adjuvants) and other evidence of "new measures" to address dicamba volatility including: calendar cutoff dates restricting use to earlier in the season when temperatures are lower; reports from users regarding pesticide benefits, and increased yields. (Defendant Intervenors (D Interv. MSJ (Doc 174 (R)/197 (S)) at 20.)

The Court accepts that EPA considered "new" data subsequent to 2018, meaning data presented in the Intervenor Defendants' 2020 new use registration applications. The Court does not accept the representations that the EPA considered "new measures" in the 2020 registrations to address dicamba volatility or that there was "new data" showing VRAs significantly reduce volatility. *See* (D Interv. MSJ (Doc 174 (R)/197 (S)) at 20.)

A quick comparison between the 2018 and 2020 registrations reflects changes in control measures are better described as tightened restrictions and not "new measures." Since their inception, OTT registrations have all been similarly restricted to address off-target dicamba movement, including buffer zones, time of day or year and other application restrictions addressing windy, hot, including heat inversions, and rainy weather conditions; tank mix adjuvants; hooded spray equipment, and product labeling to ensure proper application and to address weed resistance. All these restrictions were tightened in 2018 when the 2016 registrations were amended, and again tightened in 2020.

In 2020, EPA mandated "a qualified VRA/pH buffering adjuvant in the tank for every application." (P MSJ, SOF, Ex. A04 (AR A.4): 2020 Decision Supporting Approval (Doc. 158-3) at 5.) In 2018, EPA merely advised tank mixes add a pH buffering adjuvant. Spray drift downwind buffers were expanded from 110 ft. (2018) to 240 ft (2020), with ESA downwind spray drift buffers expanded from 110 ft to 310 ft. Volatility measures remained restricted by the "limit of two OTT applications of dicamba per field per year," with applications only between one hour after sunrise and two hours before sunset. In 2018,

volatility was addressed by spray restrictions specified by crop growth. Instead in 2020, the EPA added calendar application cutoff dates (June 30 for DT soybean and July 30 for DT cotton.) For ESA areas with federally listed species, a 57 ft. omni-directional buffer existed in 2018 and remained the same in 2020. The EPA added an option to use a hooded sprayer, and correspondingly allowed a reduced buffer zone to 110 ft (FIFRA) and 240 ft (ESA). The label was improved for clarity in 2020 by including calendar cutoff dates instead of growth parameters and covered only pre and post-emergent uses for DT cotton and DT soybean crops eliminating instructions for non-DT crops. The 2018 conditional registrations ended after two years, and the unconditional 2020 registrations were for 5 years. *Id.*

Responding to Plaintiff's accusation that EPA rushed the 2020 Decision, issuing it four months after the Ninth Circuit vacated the registrations in June of 2022, the Defendant Intervenors submit new data acquisition began subsequent to the 2018 amended conditional OTT dicamba registrations. Accordingly, the Court begins with the EPA's findings in 2018.

The EPA identified a list of uncertainties associated with establishing distances to effect, such as there was no data for reproductive stage plants using yields (a more appropriate measure) and no measurements from some direction other than downwind for treatment, where downwind direction was established at the time of application. The effects on plants only evaluated non-DT soybeans, which is considered the most sensitive plant based on laboratory studies--- but "there is uncertainty as to how representative these results are for other plant species with different growth and reproduction strategies." Studies reflected volatility of dicamba increases with temperature, but only three studies were representative of warmer temperatures with sustained temperatures during the day above 90 degrees. Only one study reported the pH of the tank mixture resulting in "uncertainty as to how various tank mixtures in field studies may have depressed pH values resulting in increased volatility." EPA reported there was a limited number of large field studies for Enginia, which might not directly translate for XtendiMax. Likewise, there was

uncertainty whether results for field studies conducted primarily in areas with high levels of alleged incidents would robustly account for variability of dicamba movement and attendant effects for non-target species located across other landscapes proximal to sites of dicamba use. (P MSJ, SOF, Stevenson Decl., Ex. E, 2018 New Information and Analysis of Dicamba Use on DT Soybean and Cotton, including Updated Effects Determinations for ESA . . . § 4.6 (Doc. 161-5) at 49-50).[12]

See also id. at 80 (among other things recognizing that growth stages of listed plants in the wild will likely not always coincide with that of soybeans or other agricultural crops).

As amended in 2018, the OTT dicamba registrations were expressly conditioned on data gathering and monitoring requirements: 1) Confirmatory Data, including field studies examining offsite movement of dicamba and investigation into temperature effects on volatility, ecological effects on non-target plants, related to survival, growth and reproduction for select sensitive tree/shrub/woody perennial species, and effects of lower pH on secondary movement; and 2) Monitoring Needs for the 2019 and 2020 Growing Season, including enhanced incident reporting to aggregate potential damage to non-target vegetation and information for dicamba-resistant weeds and weed control failure, data by state for acres of sales of DT tolerant cotton and soybean seed and product used for OTT dicamba applications. (P MSJ, SOF, Ex. M168 (AR M.168): 2018 Decision for Continued Use of Dicamba on DT Cotton and Soybean (Doc. 158-33) at 20, 24.)[13] In 2018, EPA noted it was particularly important to study the impact of off-target movement from dicamba OTT applications on high-value specialty crops, as well as privately-owned gardens, landscaping, and orchards because these stakeholders, unlike cotton and soybean growers, cannot defensively use DT seed. *Id.* at 24.

In 2020, the EPA's silence (no express discussion or conclusion) regarding the need for additional data is particularly deafening because the 2020 Decision concludes that for

[12] The Court takes judicial notice of this publicly available document which is a government publication. Fed. R. Evid. 201(b). *See* (P MSJ, SOF, Ex. A04 (AR A.4): 2020 Decision Supporting Approval (Doc. 158-3) at 11 (describing the 2020 Decision as including consideration of earlier submitted relevant information, including earlier registration actions).

[13] *Id.*

a variety of sensitive crops "[q]uantification of this damage is difficult. There have been a few greenhouse studies that have attempted to follow plants with a known level of injury through maturity and harvest to quantify changes in yield or quality. These studies are currently insufficient to extrapolate to a field level to estimate an impact per acre of affected crop. Damage to plants in non-crop areas (e.g., shelterbelts, trees, residential plantings, etc.) usually lack an objective valuation that could be used to estimate overall damages." (P MSJ, SOF, Ex. A06 (AR A.6): 2020 Incidents and Impacts to Users and Non-Users (Doc. 158-5) at 47.)

EPA continued regarding risk to non-target crops, as follows:

> . . ., the damage can be bounded by examining the per-acre value of sensitive crops (USDA NASS, 2020c; calculated from yield per acre and value price per unit harvested). Soybean and cotton have a per-acre value of $410 and $510, respectively. Vegetable crops can have a value 10-fold higher (e.g., tomato, $5,900 per acre). Perennial crops can have an even higher value (e.g., peaches, $7,300 per acre). If the tree is no longer viable it would have to be replaced and the new tree would not be commercially productive for about four years. Damage to non-crop areas (shelterbelts, trees, residential plantings, etc.) is difficult to quantify.
>
> Overall, the impacts to non-users from the registration of these OTT dicamba products will depend on how well the selected control measures address the offsite movement of dicamba or reduces the potential for damage, if offsite movement does occur. Some measures only address one type of offsite movement (e.g., volatility) while others may address both volatility and spray drift (e.g., buffers). The performance of these measures depends on the efficacy of each measure separately, as well as in combination with the other required measures.
>
> For example, the calendar-based application restriction is intended to limit applications of OTT dicamba to earlier in the growing season when temperatures are cooler. This addresses offsite movement that may occur through volatility but will have limited effect on offsite movement resulting from spray drift. Additionally, if offsite movement does occur at this timing, there may be a reduced impact because sensitive plants may not yet be present in adjacent areas. If the number of incidents is reduced, state agencies will expend fewer resources.
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> These control measures should benefit non-users by addressing offsite movement. However, impacts to non-users of OTT dicamba products may still occur, if misuse occurs.

Id. at 47-48 (emphasis added).

The EPA tightened the control measures for a third time and concluded: "If all mandatory control measures on the product labels are implemented there is a high degree of certainty that these will address offsite movement." (P MSJ, SOF, Ex. A06 (AR A.6): 2020 Incidents and Impacts to Users and Non-Users (Doc. 158-5) at 41.) The EPA did not assess costs associated with risks for non-users of OTT dicamba users because "any negative impacts to non-users from OTT dicamba will be minimal. (P MSJ, SOF, Ex. A04 (AR A.4): 2020 Decision Supporting Approval (Doc. 158-3) at 18 (review of "Impacts of Registration to Non-Users of Dicamba, found "the control measures give EPA a 90% confidence that there will be no offsite movement of dicamba.")

The 2020 Decision approved OTT dicamba, summarizing its action as follows:

> EPA received studies and other information, necessary to comply with the data requirements for the uses of these products. The EPA also reviewed a large body of data and information to determine how these products have been and will be used to determine the risks and benefits. All of these evaluations informed EPA's determination that registering these products will not generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

Id. at 20.

This is conclusory boilerplate language given the unexplained incongruity between the unconditional and conditional registrations issued in such close proximity to each other. EPA relied on a circular risk analysis with all roads leading back to efficacy of the control measures because effects from the registration of OTT dicamba depends on how well the control measures address the offsite movement of dicamba and thereby reduces the potential for offsite OTT dicamba related damage. If the control measures eliminate or reduce it to "minimal," there is no risk. If there is no risk, there is no need to assess the cost of this risk. Of course, the reverse is true if the control measures are not sufficiently

effective to mitigate volatility and spray drift to eliminate damaging effects from OTT dicamba. EPA's approach is especially problematic for the ESA "no effects" determination. "[M]itigation measures that merely 'reduce,' but cannot scientifically 'eliminate' an 'effect' probably compel a 'may effect' finding." (*NFFC (Dow)*, 966 F.3d at 924 (quoting *Karuk Tribe of Calif v. EPA*, 681 F.3d 1006, 1028 (9th Cir. 2011)). Mitigation measures can cut against a "no effect" finding if they reduce but cannot eliminate the impact to threatened species. *Id.* When a failure to consult stretches over years, it is a substantial procedural violation; it is not a violation that is merely technical or de minimis. *Washington Toxics Coal. v. Env't Prot. Agency*, 413 F.3d 1024, 1034 (9th Cir. 2005) *abrogated on other grounds as recognized by Cottonwood Envtl. Law Center v. U.S. Forest Service*, 789 F.3d 1075 (9th Cir. 2015).

The Defendant Intervenors reference "new data" asserting it shows no risk from offsite movement of OTT dicamba because of control measures, as follows: the mandated VRA tank mix adjuvant in the 2020 registrations, A.9 (Doc. 188-9) at 56-57; pH buffering tank adjuvants stabilize dicamba by preventing salts from converting into dicamba acid which is prone to volatization, A.4 (Doc. 188-4) at 14, A.9 (Doc. 188-9) at 56-57; studies show when VRA is in tank mix, dicamba volatility is significantly reduced, A.4 (Doc. 188-4) at 14; five new field studies on VRAs and humidome studies show 85 to 99.9% volatility reduction if VRAs are in tank mixes, B.25 (Doc. 189-3) (S) at 1, F.85 (Doc. 189-28) (S) at 8; field studies reflect much lower dicamba volatility (89% reduction) and show volatization likely reduced with cooler air temperatures, A.4 (Doc. 188-4) at 14, and significant reduction means distances from where "dicamba produced effects are seen, A.9 (Doc. 188-9) at 56-57. (Interv. D MSJ (Doc. 174 (R)/197 (S)) at 20), SOF (Doc. 176 (R)/196 (S) ¶¶ 150-158).

The Court has reviewed the "new studies" and finds that, with the exception of showing lower temperatures reduce volatility, the studies rely on tank mix adjuvants to reduce spray drift and volatility to support the unconditional 2020 OTT dicamba registrations. In 2020, EPA considered two types of adjuvants: a drift reduction adjuvant

(DRA) and a pH buffering volatility reduction adjuvant (VRA). (P MSJ, SOF, Ex. A06 (AR A.6): 2020 Incidents and Impacts to Users and Non-Users (Doc. 158-5) at 25.) DRAs reduce the number of fine droplets produced by nozzles, which are more likely to drift during application; DRAs reduce spray drift. VRAs reduce volatility by keeping the dicamba spray solution closer to a neutral pH because lower pH causes dicamba to form the more volatile dicamba acid. Both tank-mix adjuvants were recommended by Bayer in its 2020 application to register XtendiMax. (D Interv. MSJ, Ex. B16 XtendiMax Support for Registration, July 24, 2020 (Doc. 192-2) at 8.) In the end, only VRAs made it into the 2020 dicamba registrations. The EPA concluded "the requirement of both additives would increase the cost of the OTT dicamba program," and "the added cost will reduce the benefit of dicamba relative to other control [herbicide] options, . . ." "with the two adjuvants, the dicamba tolerant program would be similar in cost to the 2,4-D program" for weed control. (P MSJ, SOF, Ex. A06 (AR A.6): 2020 Incidents and Impacts to Users and Non-Users (Doc. 158-5) at 25-26.)

In reviewing the record, the studies related to DRA tank mix agents were not definitive. *Id.* at 57, *see also* Ex. A09 (AR A.9): 2020 Ecological Assessment Including Effects Determination for ESA (Doc. 158-6) at 266) (a majority (88%) of studies with a DRA tank mix agent, Intact, showed "mixed results on drift reduction,"), (DRA field studies included so many variables, such as wind speed wind direction, temperature, relative humidity, etc, during application that "it is difficult to ascertain the impact of the DRA alone" and "[l]aboratory studies in controlled environments would allow for the elimination of site-specific variables and a complete evaluation of the extent of any drift reduction that adding a DRA to a tank mix would provide.") The "EPA did not separate out the data based on whether or not a drift reducing agent [DRA] or volatility reducing agent [VRA] was included in the tank mix, as the variety of tank mix partners (i.e., with or without glyphosate) and nozzles was limited." (P MSJ, SOF, Ex. A09 (AR A.9): 2020 Ecological Assessment Including Effects Determination for ESA (Doc. 158-6) at 266.) Those studies while too few in number (45) to be applied when determining off-field

distance to effect, *id.* at 270, were considered by EPA in assessing the probability that the in-filed 57 ft omnidirectional volatility setback would prevent the offsite movement of dicamba from causing 10% VSI (visual signs of injury, with 10% VSA being treated similarly to the protective threshold of no more than 5% reduction in plant height and yield), *id.*

In 2020, the EPA recognized the limited scope played by VRAs in reducing effects and impacts. EPA reported a high level of confidence in describing the distance to effects without consideration of the mandatory control measures for near-filed zones out to between 300 to 400 feet from the field edge, but admitted this was not true for wide-area effects, unrelated to the field study applications of the herbicide. Then, the largest body of evidence came from incident reports which contained information on approximately 5600 off-target incidents (reported at various distances) for the years 2017 through 2019. EPA concluded these reports showed incidents occurring beyond the distances from treated fields, including the setback restrictions contained on earlier labeling for these products, intended to address spray drift and vapor drift routes of exposure. EPA concluded as follows:

> [It could not] definitively exclude the potential impact of vapor phase drift in the wide area zone based on an evaluation of the available large field off-field movement studies. Moreover, EPA cannot identify any single volatility control measure (e.g., volatility reducing agent, VRA) that is certain to prevent dicamba from transforming into its acid, that results in offsite volatilization."

(P MSJ, SOF, Ex. A09 (AR A.9): 2020 Ecological Assessment Including Effects Determination for ESA (Doc. 158-6) at 20). *See also* 2020 Incidents and Impacts to Users and Non-Users (Doc. 158-5)).

The other control measure, temperature, was addressed in the 2020 registrations by calendar cutoff application dates for each DT crop (cotton and soybean). In addition to being clear and easily understood, two things result from shifting application dates earlier in the season when temperatures are cooler. The likelihood of offsite movement from volatility is reduced. Also, there is less likelihood of sensitive crops being present early in

the growing season. The downside to an early cutoff date is that it precludes growers from applying dicamba if weeds emerge later in the season. The June 30 cutoff date for soybean and July 30 cutoff date for cotton accommodated two applications per growing season. The June 30 cutoff for DT soybean crops potentially prevented 55% of reported incidents and allowed approximately 45% of soybean crops to be treated twice and 84% to be treated once. The July 30 cutoff date allowed 90% of DT cotton crops to be treated twice but potentially prevented less than 5% of the reported incidents. (P MSJ, SOF, Ex. A06 (AR A.6): 2020 Incidents and Impacts to Users and Non-Users (Doc. 158-5) at 15-18.) EPA "did not assess the impact of reducing the number of applications so that impact on risk was not [] estimated, but limiting the number of applications can be expected to decrease risk, generally. In addition, fewer applications would reduce the selection pressure on dicamba resistant weeds but create concerns by users regarding season long weed control or potential need to purchase a different herbicide for season long control." *Id.* at 19 (cleaned up).

In short, EPA's circular approach to assessing risk, hinging on its high confidence that control measures will all but eliminate offsite movement, lead to its corresponding failure to assess costs from offsite movement of OTT dicamba for stakeholders that are non-OTT users. While recognizing that between 2018 and 2020, incident reports continued to be filed by such stakeholders, the EPA nevertheless issued unconditional 2020 OTT dicamba registrations, without any need for additional data.

To be clear, the Court does not include the above examples and discussions in the context of assessing whether the 2020 Decision and registrations were arbitrary or capricious. The Court considers the record to answer the question of whether remand should be with or without vacatur because it is likely or not likely that the EPA will issue the same registrations on remand if it complies with FIFRA's procedural rules requiring notice and comment to all stakeholders. In this context, the Court also considers a status report, the 2021 Report, issued by the EPA on December 15, 2021. EPA issued the 2021 Report for OTT dicamba usage, incidents and consequences of off-target movement and

impacts during the 2020 growing season under the control measures it had been highly confident would preclude any such movement or impacts. (P MSJ, SOF, Ex. UO1 (AR U.1 (S)): 2021 Report (Doc. 168-18) (S)). [14]It is relevant to the question of vacatur because incident reports reflect the type of stakeholder input EPA's procedural error precluded during its consideration of the 2020 registrations. If EPA hears from these stakeholders on remand, is it likely or not that EPA would adopt the same registrations for XtendiMax, Enginia and Tavium?

Like every year since the inception of OTT dicamba use in 2016, the EPA recorded dicamba related incidents during the 2020 growing season. In 2017, there were approximately 1,400 incidents reported, and they increased as follows: 3,000 in 2018, 3,300 in 2019, and 3,461 in 2020. (P MSJ, SOF, Ex. UO1 (AR U.1 (S)): 2021 Report (Doc. 168-18) (S) at 17-18.) In 2021, EPA cataloged incidents in 29 of the 34 states where use of dicamba on DT crops is authorized. *Id.* at 18. It issued the status report to provide transparency about incident reports and other information provided to the Agency during the 2020 growing season. *Id.* at 7. EPA continued to believe that incidents are underreported by about 25%. *Id.* at 7, 10. EPA reported social conflicts caused by dicamba continued in 2021.[15] *Id.* at 6. Essentially, "[there is no change from previous years in the number, severity, or geographic extent of incidents." *Id.* at 44. Notably there were 63 counties that have endangered species or critical habitat with at least one reported dicamba incident and a total of 290 incidents across the counties," suggesting the EPA's "no effects" conclusion sits on shaky ground because it was based on the premise that the 2020 control measures would preclude offsite movement of dicamba during the 2020 growing season. *Id.* at 25-26 ("incidents suggest the possibility that a 'take' could occur").

"Newly available data indicated incidents are more extensive than had been described and are continuing into 2021," *id.* at 24-25, referencing incidents of dicamba symptomology at landscape level at a 160,000-acre national wildlife refuge and an

[14] Objections that the 2021 Report is beyond the administrative record do not apply to the Court's consideration of it in the context of vacatur.

[15] *See NFFC*, 960 F.3d at 1142-1144 (criticizing EPA failure to consider social cost to farming communities from disputes between OTT and non-OTT dicamba users).

Audubon Arkansas study (2021) finding probable dicamba symptoms in over 20 species of trees and shrubs, *id*. at 24-25, 43. With the majority of incident reports related to non-DT soybeans, incident reports also reflected injury to other non-target crops, such as sugar beet, rice, sweet potato, peanut, grapes/vineyards, cucurbits, vegetables, fruit trees, cranberries, cotton, tree nurseries, and timber. *Id*. at 44. EPA noted the discovery of a species (snap peas) more sensitive to dicamba than soybean (non-DT soybean). *Id*. at 20-21. Survey data in 2021 reflected financial losses for specialty crop growers from herbicide drift, not necessarily dicamba, with 50% reporting losses less than $10,000 per grower, 15% reporting losses of $10,000 or more per grower, and 1% reporting losses greater than $500,000. *Id*. at 27-28.

The 2021 Report referenced "new information about dicamba resistance, *id*. at 9, that showed weed resistance was confirmed during the 2020 growing season and was becoming much more widespread, *id*. at 14, suggesting that weed resistance is not being effectively managed by current training materials that are conditions of registration, *id*. at 15. "If weed resistance to dicamba were to follow the same trajectory as glyphosate, the value of dicamba for OTT uses and for other registered dicamba uses would be effectively lost, severely jeopardizing the ability of soybean and cotton producers to control problematic broadleaf weeds." *Id*. at 15. "As dicamba resistance spreads, the benefits of the DT-crop system declines." *Id*. at 45.

"While states indicate incidents may occur due to drift, several reported landscape level injury, which indicates dicamba volatility was widespread," with some states reporting dicamba sources more than a mile away from the injured crop, and reported incidents suggesting people are being impacted for multiple years. *Id.* at 22. State agencies reported budget shortfalls and other constraints due to the number of dicamba-related incidents requiring investigation. *Id.* at 30. Many states complained about the "clarification" in the 2020 Decision that States do not have authority under FIFRA § 24(c) to impose additional restrictions on a federal registration to either make them more or less

restrictive. *Id.* The Court has not addressed the rule-making challenge to this clarification,[16] and relies on this evidence to show that states have a stake in the restrictions imposed in these registrations, especially if they may no longer use section 24(c) to tweak them in one way or the other. The Court finds State Agencies are stakeholders that were not afforded notice and comment prior to EPA's issuance of the 2020 Decision and registrations.

"In 2020, the Agency assessed the practicality of, and likely compliance with, individual control measures of the 2020 label" and found compliance with application cutoff dates likely improved by recordkeeping requirements, however, compliance was also influenced by crop progress, weed pressure, and weather. (P MSJ, SOF, Ex. UO1 (AR U.1 (S)): 2021 Report (Doc. 168-18) (S) at 33.) "At the time of the 2020 Decision, the Agency did not have information about the current availability of the required buffering agents and was not able to estimate compliance with requirements to add buffering agents." *Id.* Subsequently EPA "found that the complexity of determining the appropriate buffer (varying distances dependent on county, wind direction, adjacent sensitive crops or other plants) suggested noncompliance was likely." *Id.* Summarizing what EPA heard from states and academics regarding product usability pursuant to the 2020 label restriction, it concluded many factors contribute to incidents. *Id.* at 38. Some states reported applicators are applying OTT dicamba according to label restrictions and the buffering agents are not sufficiently reducing volatility to keep OTT dicamba from moving off fields; others opined applicators struggle with the label requirements and some blatantly ignore the restrictions. *Id.* at 38. Either way, OTT dicamba can move offsite and damage non-target plants.

The 2021 Report supports the Ninth Circuit's conclusion in *NFFC* that the EPA failed to consider whether restrictions were too limited in allowances for application times and conditions for growers to use OTT dicamba if they used it in substantial compliance with such restrictions. In *NFFC*, the court held the EPA failed to consider the risk of substantial non-compliance and corresponding dicamba damage. (*NFFC (Monsanto)*, 960 F.3d at 1139-1142 (criticizing restrictions such as wind speed and temperature inversion

[16] *See* n. 10.

limitations that allowed only 44 hours of application time in 2016 or only 47 hours and two days in June for application in 2018). "A week after the 2020 Registrations, farmers across the United States, including soybean farmers in the Upper Midwest and cotton farmers in the South, filed suit in D.D.C., alleging that EPA's new application restrictions were now too restrictive." (D Interv. MSJ (Doc 174 (R)/197 (S)) at 16.)

The Court finds that the administrative record for the 2020 Decision and registrations and the 2021 Report reflect the EPA is unlikely to issue the same registrations on remand if it follows FIFRA procedures for notice and comment and hears from all stakeholders, especially those who have from the inception of OTT dicamba use been subjected to the risks of OTT dicamba offsite movement. While the EPA has been highly confident control measures would eliminate any such risk to only a minimal effect, the incident reports filed year after year complaining of offsite movement of OTT dicamba reflect otherwise. Yet, this dichotomy has not caused the EPA to seek additional data to establish these associated costs that have flowed from OTT dicamba for the past approximately seven years that OTT dicamba has been used in the United States. Like Judge Miller believed hearing from beekeepers was likely to change the sulfoxaflor pesticide decision on remand, this Court believes hearing from all stakeholders is likely to change the OTT dicamba registrations at least from unconditional to conditional, with data gathering requirements reinstated. Hearing from non-users of OTT dicamba may change the EPA's circular approach to assessing costs for risks from OTT dicamba offsite movement. Instead of simply concluding there is no risk and, therefore, no costs to these stakeholders, EPA is likely to include the costs to these stakeholders when balancing the risks and benefits for OTT dicamba. Accordingly, the Court finds the EPA's procedural error to unconditionally issue the "new use" 2020 dicamba registration, without notice and comment, was serious. The Court turns to the disruptive consequences of vacatur.

2. Disruptive Consequences of Vacatur

The EPA and Intervenor Defendants ask the Court to remand without vacatur, if it finds error. Both submit the economic importance for using OTT dicamba for DT crops

(soybean and cotton) post-emergent during growing seasons to control weeds, outweighs any risk to the environment, endangered species or critical habitat. They contend OTT dicamba has been used for many years, and the Plaintiffs fail to produce any evidence that offsite dicamba movement has caused any harm. There is zero evidence of potential risks to endangered species or protected habitat. (D. Interv. Reply (Doc. 241) at 15-16.) The burden, however, is not on Plaintiffs but on Defendants. *See, Alliance for the Wild Rockies v. U.S. Forest Serv*., 907 F.3d 1105, 1121-22 (9th Cir. 2018) (explaining presumption of vacatur under the APA must be overcome by the party seeking remand without vacatur).

The Court accepts that there are substantial benefits from OTT dicamba for DT crops (cotton and soybean) for weed control, especially for controlling weeds that are resistant to other herbicides or when there is no herbicide resistance, OTT dicamba affords flexibility in herbicide choices for rotating or mixing herbicides to manage weed resistance. (P MSJ, SOF, Ex. UO1 (AR U.1 (S)): 2021 Report (Doc. 168-18) (S) at 10.) By 2020 about three-quarters percent of cotton acreage used DT seed and about two-thirds percent of soybean acreage used DT seed. *Id.* at 12. Defendants submit evidence that the cost of herbicide resistant weeds on U.S. agriculture is more than 2 billion dollars, with 52% potential loss in yield in soybean production due to weeds and $392 million dollars loss possible in one year due to decrease cotton yields. (D Interv. Reply (Doc. 241) at 18 (citing experts Griffin Decl. at 25 and Sunding Decl. at 66-67). The Defendant Intervenors argue: "The Ninth Circuit has previously explicitly considered such effects when deciding not to vacate." *Id.* (citing *Ctr. for Food Safety*, 56 F.4th at 668 (considering "disruption to the agricultural industry" and "serious disruption if a pesticide that has been registered for [many years] can no longer be used").

Defendants ignore that likewise the Ninth Circuit in *NFFC (Monsanto)* previously explicitly considered such effects and decided to vacate these OTT dicamba registrations. "Being aware of the practical effects" of vacatur and "difficulties these growers may have in finding effective and legal herbicides to protect their DT crops" due to vacatur," the court nevertheless found the seriousness of the agency error, including in part its failure to

assess risks and costs for non-users of OTT dicamba compelled vacatur. *NFFC (Monsanto)*, 960 F.3d at 1145. There is no evidence before the Court that the ramifications of vacatur of these registrations on growers or the environment is more dire now than it was in 2020 when the Ninth Circuit vacated the 2016, as amended in 2018, OTT dicamba registrations. There is some evidence the benefits for OTT dicamba is waning due to weed resistance. (P MSJ, SOF, Ex. UO1 (AR U.1 (S)): 2021 Report (Doc. 168-18) (S) at 8-10, 44.)

In considering *Ctr. for Food Safety*, the Court finds that unlike sufloxefor, where growers had no other pesticide options, growers do have options for OTT dicamba because they can switch to using the OTT 2,4-D system. (P MSJ, SOF, Ex. UO1 (AR U.1 (S)): 2021 Report (Doc. 168-18) (S) at 7). The Court notes that in response to vacatur of the 2016, as amended in 2018, OTT dicamba registrations, the EPA cancelled the registrations but allowed use of existing stock. Vacating the registrations poses no greater risk to the environment than leaving it in place because other similar herbicide options are available to replace it in the interim. Threats of noncompliance or that growers will use more dangerous non-OTT dicamba products if these registrations are vacated are weakened by concerns reflected in the 2021 Report that such noncompliance already occurs.

Recently the Ninth Circuit considered *Ctr. for Food Safety* in *Migrant Clinicians Network v. U.S. Env't Prot. Agency*, 88 F.4th 830, 847–49 (9th Cir. 2023) (citing FIFRA prohibition to unconditionally approve or amend a registration until it has "reviewed all relevant data" and "determined that no additional data are necessary." 40 C.F.R. § 152.112(b)–(c)). In *Network*, the court discussed the reluctant remand without vacatur of the pesticide registration issued in *Ctr. for Food Safety*, and the 180-day mandate for immediate compliance. *Network*, 88 F.4th at 848. In *Network* as here, the EPA attempted to downplay the seriousness of its noncompliance by arguing that its FIFRA analysis was sufficient to demonstrate that streptomycin use on citrus is unlikely to threaten any endangered species or its habitat, therefore, it would, after complying with the ESA, still "adopt the same rule on remand." *Id.* (quoting *Pollinator*, 806 F.3d at 532) Similarly, EPA

argues that its FIFRA analysis here was sufficient to demonstrate OTT dicamba poses no unreasonable risk to the environment or threat to endangered species or critical habitat. EPA argues that vacatur would have considerable disruptive consequences for growers who have few alternatives for weed management; in *Network*, growers needed streptomycin to manage HLB and citrus canker.

In *Network*, the court denied remand without vacatur because such "a blank check remand without vacatur would not be an appropriate remedy given the seriousness of the EPA's failures. *Id.* "[A]ny remand without vacatur would at least require as a condition a mandatory timetable for compliance similar to the 180-day deadline that [was] imposed in *Center for Food Safety*." *Id.* (citing *Ctr. for Food Safety,* at 669). In *Network*, the EPA failed to explain how the equities there would justify a more lenient remand than ordered in *Ctr. for Food Safety*. *Id.* at 849. EPA fails similarly here.

At most, *Ctr. for Food Safety* provides for a narrow reprieve of 180 days. Under the existing registrations, EPA has continued to gather incident data and generated the 2021 Report for the purpose of determining if changes to these registrations are warranted. The Court understands the EPA has moved forward with new ESA effects assessments for all dicamba products, including OTT dicamba. Nevertheless, the EPA does not submit that if the Court finds error it can immediately (within 280 days) correct such error.

The Court follows *Network* and finds that remand without vacatur would not be a sensible remedy. The Court follows *NFFC (Monsanto)* in concluding that growers, through no fault of their own, will be placed in the difficult position of finding effective and legal herbicides to protect their DT crops if these registrations are vacated. Nevertheless, the Court finds vacatur is compelled given the seriousness of EPA's procedural error in failing to afford notice and comment for the 2020 "new use" OTT dicamba registrations.

Accordingly,

IT IS ORDERED that the question of procedural error was determined based on the administrative record and express statutory provisions under FIFRA, not on any evidence outside the administrative record, therefore, the motions asking the Court to

expand the administrative record relevant to issues not reached herein (D Interv. (Docs. 104 (R); 122 (S) and Plaintiffs' (Doc. 108) are DENIED AS MOOT.

IT IS FURTHER ORDERED that the Motion to Strike (Doc. 173) Plaintiffs' Statement of Material Facts (Docs. 156 (R); 167 (S)) is DENIED; Defendants had ample opportunity to and did object by way of filing controverting statements of facts to their dispositive motions. The Court has designated the evidentiary record herein upon which it relied, which falls well beyond any objectionable statements of fact; the findings in *NFFC (Monsanto),* 960 F.3d 1120 (9th Cir. 2020) speak for themselves. *See* (P Resp. (Doc. 210) (providing reasons to deny motion to strike).

IT IS FURTHER ORDERED that the Crossmotion for Summary Judgment (Docs. 170 (R); 198 (S)) filed by the EPA is DENIED.

IT IS FURTHER ORDERED that the Motion for Summary Judgment (Docs. 174 (R); 197 (S)) filed by Intervenor Defendants is DENIED.

IT IS FURTHER ORDERED that the Motion for Summary Judgment (Docs. 155 (R); 167 (S)) filed by Plaintiffs is GRANTED.

IT FURTHER ORDERED that 2020 registrations for XtendiMax, Enginia, and Tavium are VACATED.

IT IS FURTHER ORDERED that the Clerk of the Court shall enter Judgment accordingly.

Dated this 5th day of February, 2024.

Honorable David C. Bury
United States District Judge