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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA
TUCSON DIVISION

Center for Biological Diversity, *et al.*, Plaintiffs, v. **United States Environmental Protection Agency, *et al.*,** Federal Defendants, and **Bayer CropScience LP, BASF Corp., and Syngenta Crop Protection, LLC,** Defendant-Intervenors.	No. 4:20-cv-00555-DCB **EPA'S CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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GLOSSARY OF ACRONYMS

APA	The Administrative Procedure Act
BE(s)	Biological Evaluation(s)
DT	Dicamba-tolerant
EPA	United States Environmental Protection Agency
ESA	The Endangered Species Act
FIFRA	The Federal Insecticide, Fungicide, and Rodenticide Act
FWS	United States Fish and Wildlife Service
LOC(s)	Level(s) of Concern
NAS	National Academy of Sciences
OTT	Over the Top, meaning post-emergence
SOF	EPA's Statement of Facts
USDA	United States Department of Agriculture
VRA	Volatility Reducing Agent
VSI	Visual Signs of Injury

INTRODUCTION

In 2020, the U.S. Environmental Protection Agency ("EPA" or "the Agency") issued three licenses for dicamba-based products. In 2022 and again in 2023, EPA approved amendments to those licenses. Each of those actions was supported by the information then before the Agency and was consistent with governing law. Each action, in short, was reasonable. Plaintiffs challenge EPA's actions but their claims fail, either because Plaintiffs misstate the record and the law, or because they lack standing to challenge EPA's actions. The Court should therefore enter summary judgment for EPA.

LEGAL FRAMEWORK

A. The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")

FIFRA generally prohibits the distribution or sale of any pesticide unless it is "registered" by EPA. 7 U.S.C. § 136a(a). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used in the United States. *Id.* § 136a(c)(1)(A)-(F). These terms and conditions include the specific formulation and packaging, and labeling that includes requirements for lawful use. *See id.* § 136(p); 40 C.F.R. §§ 152.115, 156.10. It is unlawful to use a registered pesticide "in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

An applicant seeking a registration or proposing an amendment to an existing registration must submit specific information to EPA, including supporting data and proposed labeling. *Id.* § 136a(c)(1); 40 C.F.R. §§ 152.44, 152.50. EPA often discusses registration or amendment applications with the applicant and may note deficiencies in the application or request additional labeling restrictions. Ultimately, however, the Agency can only grant or deny a proposed registration or amendment. 7 U.S.C. § 136a(c)(3). EPA "shall" grant an unconditional registration (or amendment) if the application is supported by sufficient data and meets statutory criteria, including that use of the pesticide will not generally cause "unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(D), "taking into account the economic, social, and environmental costs and benefits" of the pesticide's use, *id.* § 136(bb). EPA may issue a conditional registration if "data concerning

the pesticide" is "insufficient to support an unconditional" registration or amendment. *Id.* § 136a(c)(7)(B); *see also id.* § 136a(c)(7)(A) & (C). When EPA grants an application for registration or amendment, it issues a notice, which is the pesticide license.

FIFRA Section 24(c) allows states to register "additional uses" of registered pesticides "to meet special local needs." 7 U.S.C. § 136v(c)(1). A State acting under this section must notify EPA of the additional use registration. 40 C.F.R. § 162.153(h). Unless EPA disapproves the registration in 90 days, it remains effective. 7 U.S.C. § 136v(c)(2).

If it appears "that a pesticide or its labeling or other material required to be submitted does not comply with" FIFRA or "generally causes unreasonable adverse effects on the environment," EPA can issue a notice of (1) intent to cancel a registration, or (2) intent to hold a hearing to determine whether it should cancel a registration under FIFRA Section 6(b). But before it can cancel a registration over a registrant's objection, EPA must comply with requirements, which may include, at the registrant's request, a formal hearing before an administrative law judge. *See* 40 C.F.R. pt. 164. The outcome of such a proceeding is subject to administrative appeal before it becomes ripe for judicial review. 7 U.S.C. § 136d(d). Cancellation "proceedings may take one or two years to complete." *Ellis v. Housenger*, 252 F. Supp. 3d 800, 806 (N.D. Cal. 2017) (internal quotation marks omitted).

B. The Endangered Species Act ("ESA")

Congress enacted the ESA to, among other things, conserve species deemed to be endangered or threatened. *See* 16 U.S.C. §§ 1531(b), 1532(6), 1532(20), 1533. The ESA requires the U.S. Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service (collectively, the "Services") to designate critical habitat for species listed as threatened and endangered, to the maximum extent prudent and determinable. *Id.* § 1533(b)(2). "[C]ritical habitat" includes areas occupied by the species that are "essential to the conservation of the species" and whose "physical or biological features . . . may require special management considerations or protection." *Id.* § 1532(5)(A)(i).

ESA Section 7(a)(2) requires federal agencies to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence

of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat. *Id*. § 1536(a)(2). To that end, Section 7 and its implementing regulations delineate a process—Section 7 consultation—for determining a proposed action's biological impacts. *Id*. § 1536; 50 C.F.R. pt. 402. Through this process, an agency proposing an action determines whether its action "may affect" a listed species or the designated critical habitat for a listed species. 50 C.F.R. § 402.14(a). If the agency determines that its proposed action will have "no effect" on listed species or designated critical habitat, Section 7 consultation is not required. *Id*. § 402.12(k)(1).

C. The Administrative Procedure Act ("APA")

Under the APA, "agencies perform their administrative functions both through rulemaking and by adjudication." *Neustar, Inc. v. FCC*, 857 F.3d 886, 893 (D.C. Cir. 2017). The APA's rulemaking procedures include public notice and an opportunity for public comment. 5 U.S.C. § 553 (b)-(c). But those notice and comment requirements do not apply to "interpretive rules and statements of policy." *Id.* § 553(d).

FACTUAL BACKGROUND

A. Pre-2020 Registrations of post-emergence dicamba products

Dicamba, an herbicide used to control broadleaf weeds, has been registered under FIFRA since 1967. EPA's Stmt. of Fact ("SOF") ¶¶ 13-15. For most of that time it has been used only to kill weeds before planting or after harvest. SOF ¶ 24. In 2015, however, the U.S. Department of Agriculture ("USDA") authorized commercial sale of genetically modified dicamba-tolerant ("DT") soybean and cotton seeds. SOF ¶¶ 22-23. And companies developed new, less volatile dicamba products for post-emergence "over-the-top" ("OTT") use on DT cotton and soybean. SOF ¶¶ 21, 25. The combination of DT seeds and OTT dicamba products allows growers to control weeds—including "especially problematic" weeds that have developed resistance to widely used herbicides like glyphosate—after crop emergence without damaging the crops themselves. A.4 at 22; SOF ¶¶ 36-41. But dicamba can damage non-target plants if it drifts offsite during application ("spray drift") or if it vaporizes and drifts offsite after application ("volatility"). SOF ¶ 20.

In 2016 and again in 2018, EPA granted three two-year conditional use registrations under FIFRA authorizing the use of three OTT dicamba products—XtendiMax, Engenia, and FeXapan—on DT soybean and cotton in 34 states (the "2016" and "2018 Registrations"). SOF ¶¶ 25-27. In 2019, EPA granted a fourth conditional use registration (until December 2020) for another OTT dicamba product, Tavium. *Id.*

The amount of dicamba applied to soybean and cotton (pre- and postemergence use) increased following the 2016 Registrations. SOF ¶¶ 58–60, 75. EPA also began to receive reports of crop injury "alleged to be caused by off-target movement" of dicamba. A.4 at 7. The number of such reports increased annually through 2019. SOF ¶¶ 76-87.

In June 2020, the Ninth Circuit vacated the 2018 Registrations, holding that EPA had understated certain risks of OTT dicamba use and failed to consider others. *Nat'l Family Farm Coal. v. EPA*, 960 F.3d 1120 (9th Cir. 2020) ("*NFFC II*").

In May 2021, EPA's Office of Inspector General issued a report concluding that certain EPA officials had directed "changes to or omissions from scientific documents" supporting the 2018 Registrations, which left those registrations "legally vulnerable." Dkt. 161-7 ("OIG Report"). Among other findings, the report noted that senior leadership "decided to use plant height" as the sole "measure of dicamba effect on plants," rather than "visual signs of plant injury" ("VSI") as recommended by EPA's scientists, a restriction that "changed [EPA's] scientific conclusions." OIG Report at 9.

B. The 2020 Registrations of XtendiMax, Engenia, and Tavium

In July 2020, Bayer and BASF sought new registrations for XtendiMax and Engenia. SOF ¶ 29. The next month, Syngenta sought to extend the expiration date of the existing registration for Tavium, which was not challenged in *NFFC II* and was thus still active. SOF ¶ 30. In response to those applications, EPA discussed with Bayer, BASF, and Syngenta (collectively "Registrants") necessary changes to product labels to meet the FIFRA registration standard. *See generally* E.1 to E.13 and E.15 to E.19. Registrants then submitted to EPA labels with simplified formats, and with new or enhanced use restrictions intended to further minimize off-target movement, including mandatory use of volatility

reducing agents ("VRAs"), mandatory application cut-off dates of June 30 (for soybean) and July 30 (for cotton), and a 240-foot in-field downwind buffer. A.4 at 4-5.

In evaluating the 2020 registration applications, EPA considered the potential for off-field movement of OTT dicamba products and related risks to non-target organisms. It began by defining "endpoints"—threshold showings of dicamba-related effects to non-target organisms. A.9 at 47-48. EPA relied on two related apical endpoints for terrestrial plants: 5% reduction in plant height, and 10% VSI. *Id.* at 48. By considering both endpoints, EPA was able to draw on a larger dataset since many available studies "investigating plant responses to off-field dicamba exposure report measurement of VSI as the only plant endpoint." *Id*. EPA examined dozens of studies "encompass[ing] field trials, under variable environmental conditions and performed in a wide distribution of geographic locations," to determine the likely extent of drift or volatility-related off-field movement of dicamba residues in quantities sufficient to produce a 5% reduction in height or 10% VSI in non-DT soybean. In these studies, researchers applied OTT dicamba to fields of DT soybean, adhering to the 2018 labels' restrictions. *Id.* at 52. They then measured impacts on surrounding fields of non-DT soybean, isolating impacts due to spray drift and volatility, and volatility alone. *Id.* EPA had "high confidence" that the resulting "body of information provides a fuller understanding" of "what is happening in the field" than did the information on which the pre-2020 registrations were based. *Id.*

EPA used this data to develop "a probabilistic, distributional," "reasonable upper bound estimate" for the "distance to effect"—that is, the distance from a treated field at which 5% reduction in plant height or 10% VSI would be observable. *Id.* at 53. EPA concluded with 90 percent certainty that the distance to effect due to spray drift and volatility would be 240 feet or less, and the distance to effect due to volatility alone would be 110 feet or less. *Id.* at 52-54.

EPA also analyzed the use of VRAs to address risk concerns due to volatility. Its analysis showed that the "use of VRAs reduces volatility of dicamba to the point where movement of volatilized dicamba will not exceed conservative plant effects thresholds 89%

[] of the time at the very edge of the field," and would also "address[] dicamba loading to the downwind atmosphere." A.9 at 56-57. EPA concluded that "inclusion of approved VRAs (without consideration of any additional restrictions) prevents damage from volatile exposures off the treated field with a high degree" of certainty. *Id.* at 10.

To assess the mitigation potential of June 30 and July 30 application cut-offs, EPA examined the link between air temperature and volatility and found, based on laboratory studies, that volatility and distance to effect increased with increases in temperature. A.9 at 311-17. Data from incident reports were consistent with that finding. Of the reports documenting alleged dicamba injury more than 50 feet from sites of suspected dicamba application, 94% and 82% occurred at temperatures above 75°F and 80°F, respectively. SOF ¶¶ 79-85. EPA then reviewed temperature data to determine the extent to which the proposed labels' calendar-based cut-off dates would prohibit dicamba application at or above those temperatures. Results varied due to climactic differences across states. SOF ¶¶ 55, 71. But "in no state was the probability of avoiding a threshold temperature on the day of application zero." A.4 at 14. And calendar restrictions of June 30 and July 30 also shifted dicamba application to earlier periods when "nearby non-target crops are less likely to be at vulnerable growth stages." *Id.* at 20. For these reasons, EPA concluded that calendar cut-offs provided additional protection against volatility-related injury, including on the area-wide "scales suggested by available incident data." A.9 at 57.

Taking all this together, EPA forecasted that "new control measures addressing drift and volatility," in concert with other label restrictions, would likely "ensure dicamba stays on the treated field, addressing offsite movement and therefore likelihood of damage," and rendering "minimal" any likely "negative impacts to non-users." A.4 at 17.

Under FIFRA, EPA was required to assess the proposed registrations' reasonably foreseeable benefits, as well as risks. *See* 7 U.S.C. §§ 136a(c)(5), 136(bb). As EPA noted, cotton and soybean are important agricultural commodities that are valued at a combined $46.6 billion and that support hundreds of thousands of jobs. SOF ¶¶ 1-12. Growers of both crops experience losses from herbicide-resistant weeds, which can be substantial. SOF

¶¶ 36-40. While other "weed control programs [are] currently available for the control of problematic broadleaf weeds in cotton and soybeans," the "number of postemergence herbicide options" is currently limited. A.4 at 16. OTT dicamba thus "gives many growers increased flexibility" and, relatedly, provides "an additional tool to delay the further development of herbicide resistance" to the limited postemergence herbicides now available. A.7 at 3. OTT dicamba can also reduce growers' costs as compared to other OTT herbicides. SOF ¶¶ 47-48, 62-63. And the availability of OTT dicamba reduces the likelihood that growers of DT cotton and soybean will misuse higher volatility dicamba products by applying those products post-emergence. A.6 at 46.

In sum, OTT dicamba formulations confer significant benefits. And when EPA weighed those benefits against the risk of off-field movement (as mitigated by the proposed label requirements), it concluded that the registration applications satisfied FIFRA's standard of not generally causing unreasonable adverse effects. Accordingly, after fulfilling its obligations under the ESA (*see infra* pp. 8-9), the Agency registered the use of XtendiMax, Engenia, and Tavium on DT cotton and soybean in 34 states through the 2025 growing season ("the 2020 Registrations"). A.4 at 3.

C. The 2022 and 2023 Amendments to the 2020 Registrations

Events during the 2021 growing season confounded EPA's expectations. That year, the number of reports of alleged dicamba-related damage to non-target plants increased slightly relative to 2019, as EPA noted in a December 2021 report ("2021 Report") that it issued "to inform growers, state legislatures, and state pesticide regulators as they make decisions about the 2022 growing season." U.1 at 6.

Following EPA's release of the 2021 Report, the States of Iowa and Minnesota worked with Registrants to develop new restrictions on OTT dicamba application. Registrants proposed those new restrictions as voluntary amendments, and EPA approved them on March 15, 2022 ("2022 Amendments"). SOF ¶¶ 31-33. The 2022 Amendments set earlier dicamba application cut-off dates of June 20 for Iowa and June 12 for areas of Minnesota south of Interstate 94. *Id*. The amendments also prohibit applications in

Minnesota at air temperatures over 85°F. *Id.* In approving those amendments, EPA cited the link between temperature and volatility, and noted that earlier cut-off dates would likely reduce use during temperatures favoring volatility. Q.9 at 1-2; R.9 at 1-2; S.1 at 1-2.

After the 2022 growing season, and following conversation with several states, Registrants proposed additional voluntary amendments, which established June 12 application cut-off dates in Iowa, Illinois, and Indiana, and a June 20 cut-off date in South Dakota. W.1 at 1-2; X.1 at 1-2; Y.25 at 1-2. EPA approved those amendments on February 16, 2023 ("2023 Amendments"), again noting the link between calendar dates, air temperature, and volatility. *Id.*

D. EPA's analysis of the 2020 Registrations under the ESA

Before granting the 2020 Registrations, EPA conducted a careful and extensive scientific analysis to assess direct and indirect effects to listed species from the use of dicamba. A.9 at 63-112. It did so by applying a screening methodology outlined in its 2004 "Overview of the Ecological Risk Assessment Process" ("Overview"), https://www.epa.gov/sites/default/files/2014-11/documents/ecorisk-overview.pdf, at 31-37; *see also* SOF ¶ 88. That assessment uses conservative assumptions and input parameters to establish toxicological thresholds and estimated environmental concentrations for the pesticide being evaluated. SOF ¶ 89. EPA then derived a "risk quotient" for individual species by dividing estimated dicamba exposure levels by established acute and chronic toxicity levels for specific classes of plants and animals. SOF ¶ 91. EPA next compared the risk quotients to "levels of concern" ("LOC"), which indicate when a pesticide, used as directed, has the potential to impact non-target organisms. SOF ¶ 93. If the screening level assessment shows risk quotients that do not exceed the LOCs, EPA makes a no effect determination and concludes its analysis. SOF ¶ 94. But if the screening level assessment does not rule out potential effects (exceedances of the LOC), based on the conservative analysis, EPA then identifies species that may be located where the pesticide may be used and conducts a more refined species-specific assessment. SOF ¶ 95. Applying that method here, EPA concluded that the 2020 Registrations would have

"no effect" on listed species except for the Eskimo curlew.[1] SOF ¶ 96.

EPA also conducted a separate analysis of dicamba's potential effects on areas designated as critical habitat before concluding that OTT dicamba use would not destroy or adversely modify critical habitat. SOF ¶ 98. EPA determined whether use of dicamba may destroy or adversely modify any physical biological feature associated with the critical habitat. Overview at 50-51.

In reaching the no effect determinations for the 2020 Registrations, EPA considered the proposed actions with the use restrictions (use of VRAs, application cut-off dates, and a 240-foot downwind buffer) found to be necessary under FIFRA, and determined that several additional measures were necessary to protect ESA-listed species located in 287 counties. SOF ¶ 99. These measures include the 57-foot omnidirectional buffer (the same distance as the 2018 Registrations) and an expanded downwind buffer of 310 feet (collectively, "ESA Buffers"). SOF ¶ 100. The ESA Buffers apply in areas of overlap between a soybean or cotton field and a listed species or its designated critical habitat. SOF ¶ 101. To determine overlap, EPA relied on publicly available species location data published by the expert wildlife agency, FWS, to identify counties with greater than one percent overlap of a species' range or critical habitat with a soybean or cotton field. SOF ¶ 102. If a potential soybean or cotton field and a listed species overlapped in the same county, the ESA Buffers apply to use of the registered products in that county. SOF ¶ 103.

STANDARD OF REVIEW

"Where," as with FIFRA and the ESA, "a federal statute providing for judicial review of an agency's action does not itself provide a standard of review, the general standard of review of agency action established in the [APA] applies." *Ellis*, 252 F. Supp. 3d at 808 (internal quotation marks omitted). Thus, all of Plaintiffs' claims are subject to the APA standard. This standard "is highly deferential, presuming the agency action to be valid . . . if a reasonable basis exists for its decision." *Ctr. for Biological Diversity v. BLM*,

[1] EPA consulted with FWS as to the Eskimo curlew. FWS concurred that the 2020 Registrations may affect, but were not likely to adversely affect, that species. SOF ¶ 97.

833 F.3d 1136, 1146 (9th Cir. 2016) (internal quotation marks omitted). An agency action may be set aside as "arbitrary and capricious" only if the agency "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 of the product of agency expertise." *Motor Vehicle. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

ARGUMENT

This case concerns nine final actions, falling into three categories: (1) EPA's approvals of the 2020 Registrations for XtendiMax, Engenia, and Tavium; (2) EPA's approvals of the 2022 Amendments to those three registrations; and (3) EPA's approvals of the 2023 Amendments to those three registrations. Plaintiffs must have standing to challenge each action that they ask the Court to set aside. And to prevail on the merits, Plaintiffs must show that EPA acted unreasonably based on information available to it when it took each of the challenged actions. Plaintiffs fail to carry their burdens. Their challenge to the 2020 Registrations fails because it rests on post-decision information and on arguments that misread FIFRA, the record, and precedent. Plaintiffs lack standing to challenge the 2022 and 2023 Amendments both because they were not injured by those actions and because a successful challenge to those actions would not redress their alleged harms. In any case, Plaintiffs have not shown that EPA erred in approving the 2022 and 2023 Amendments and so their merits arguments would fail even if they had standing.

Plaintiffs' ESA arguments fail as well. The Court should affirm EPA's "no effects" determinations, which were reasonable and consistent with the ESA and circuit precedent. Plaintiffs' counterarguments rely on misunderstandings of the facts and law—including the same flawed ESA mantra that they have unsuccessfully been presenting since 2015: that the LOC/risk quotient methodology is somehow unreasonable. Plaintiffs also improperly rely on extra-record documents post-dating the 2020 Registrations that were not, and could not have been, considered by the agency.

I. The 2020 Registrations Were Reasonable.

EPA explained, at length, why the benefits of the 2020 Registrations outweighed the costs and thus why the risk of "adverse effects" was not "unreasonable." 7 U.S.C. § 136a(c)(5); *see supra* pp. 4-7. That kind of highly technical predictive judgment is entitled to deference. *Ranchers Cattlemen Action Legal Fund v. USDA*, 415 F.3d 1078, 1093 (9th Cir. 2005). The question is not whether that assessment was proven correct, but whether EPA acted "within the bounds of reasoned decisionmaking" in making it. *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 105 (1983). The Agency met that standard.

Plaintiffs do not acknowledge, let alone rebut, the analysis on which EPA based the 2020 Registrations. Instead they argue: (1) that incidents from the 2021 growing season retroactively render the 2020 Registrations unreasonable; (2) that the 2020 Registrations contain the same flaws as the 2018 Registrations; (3) that EPA failed to consider certain risks when it issued the 2020 Registrations; (4) that EPA erred in granting unconditional, rather than conditional, registrations; and (5) that the 2020 Registrations were procedurally improper. These arguments are meritless.

A. Post-decision evidence cannot overturn the 2020 Registrations.

Throughout their brief, Plaintiffs rely on information from the 2021 growing season to attack the 2020 Registrations. *See, e.g.*, Pls.' Br. 7, 14, 22-23. But review of agency action is limited to the record "in existence at the time of the decision." *Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996). Post-decision documents, like the 2021 Report, "may not be advanced as a new rationalization either for sustaining or attacking an agency's decision." *Tri-Valley CAREs v. U.S. Dep't of Energy*, 671 F.3d 1113, 1130-31 (9th Cir. 2012) (internal quotation marks omitted). So far as the 2020 Registrations are concerned, then, 2021 incident reports are legally irrelevant.

B. EPA corrected the flaws of the 2018 Registrations.

Plaintiffs claim that EPA repeated mistakes that the Ninth Circuit identified in *NFFC II*. But that decision was based on EPA's record for the 2018 Registrations. In relying on *NFFC II* here, Plaintiffs mischaracterize the record for the 2020 Registrations.

1. EPA considered risks of label noncompliance.

EPA discussed risks of noncompliance with each requirement on the 2020 labels, A.6 at 13-26, directly addressing the Ninth Circuit's criticism in *NFFC II* that, in 2018, EPA had "entirely failed to acknowledge" the risk that growers would fail to abide by label restrictions, 960 F.3d at 1139. EPA also sought to minimize noncompliance risk by requiring Registrants to substantially revise the 2020 labels. For instance, while prior labels included application instructions for non-DT crops, the 2020 labels are limited to DT cotton and soybean, a narrowed focus that reduced label length from 40 to just 16 pages. A.4 at 21; *see, e.g.*, A.13 at 20-36. And the information on those 16 pages appears in a simplified format, including a one-page checklist summarizing each use restriction. A.13 at 23. More still, EPA insisted on simplified use restrictions. Most notably, the 2020 labels replace field-specific growth-stage application cut-offs with nationally uniform calendar-based cut-offs. E.7 at 4. Before approving that change, EPA considered mitigation benefits and impacts on product usability. A.6 at 13-17. And it concluded that the selected dates struck an appropriate balance between providing added protection against temperature-induced volatility and allowing most growers to make two OTT applications in a growing season. *Id.*; SOF ¶¶ 53-54, 68-70. *NFFC II* demands nothing more.

Plaintiffs' counterarguments rest on cherry-picked complaints about compliance burdens that are subjective and imprecise. Take, for example, the claim that the 2020 labels were the "biggest, gnarliest label[s] ever," Pls.' Ex.-R 5 at 10, which Plaintiffs cite twice. Pls.' Br. 22, 23. For one thing, that quote—like much else in Plaintiffs' brief—comes from a document that is not part of the record, is not judicially noticeable, and thus is not properly before the Court. Even setting that aside, however, the phrase "biggest, gnarliest label ever" takes up less than one line in twelve single-spaced pages of meeting minutes, which also contain countervailing views, like that of a state regulator who "had not heard of any difficulty in following the label." Pls.' Ex.-R 5 at 4. The description of the 2020 labels as the "biggest, gnarliest label[s] ever seen" is also misleading. In fact, the 2020 labels are

less than a tenth the length of the label for glyphosate,[2] which is also registered for OTT application on cotton and soybean and is also subject to use restrictions related to wind speed and temperature inversion. Plaintiffs thus exaggerate when they claim that the 2020 Registrations were "unlike any other farmers have ever seen." *Id.* at 23.

Plaintiffs also exaggerate when they claim that the restrictions in the 2020 labels make OTT dicamba application "impossible, on a consistent basis in the real world." Pls.' Br. 14. To be sure, the 2020 labels' weather-related restrictions narrowed application windows, as documented in studies reviewing meteorological conditions over two-week periods in June 2020 (Minnesota) and July 2020 (Iowa). A.6 at 20. But even so, there remained during each of those two-week periods an average of roughly 40 hours when application was possible in conformance with all label restrictions—and this despite unusually windy conditions in Minnesota. *Id.*; *see also* M.56 at 6-7. The restrictions in the 2020 Registrations thus do not reflect a "contrived, hypothetical, laboratory scenario" or a "weather/wind 'fairy tale.'" Pls.' Br. 23. Plaintiffs offer nothing to prove that post-emergence application is "impossible" in the time available under use restrictions in the 2020 Registrations. EPA considered the relevant data and reached the opposite conclusion. EPA's conclusion is entitled to deference.

2. EPA considered other risks identified in NFFC II.

Contrary to Plaintiffs' claims, and consistent with *NFFC II*, EPA estimated the amount of damage caused by OTT dicamba application, assessed the risk of "defensive planting" of DT seeds, and considered harm to the social fabric of farming communities. 960 F.3d at 1138, 1143-44.

To quantify or estimate the scope of dicamba-related injury, the Agency drew on multiple sources, including incident reports and a "special tabulation" of soybean grower survey data that USDA prepared at EPA's request. A.6 at 26-31. Among other things, it

[2] EPA's notice of registration, which includes the glyphosate label, is available here: https://www3.epa.gov/pesticides/chem_search/ppls/000524-00659-20200317.pdf. Wind-speed and temperature inversion restrictions are on page 43 of the label.

found that in 2018, injury consistent with dicamba exposure was observed on roughly four percent of soybean fields. SOF ¶ 87. EPA also examined harms to research programs, noting that roughly half of soybean research plots had seen some dicamba-related injury, and that about a third of those (~15% overall) had reported monetary losses due to that injury. A.6 at 40-41. Finally, EPA noted dicamba-related risks to organic crops, other high-value crops, and other plantings, and it acknowledged that it could not reliably extrapolate monetary impacts from damage reports given the impossibility of reliably inferring yield reductions from reported plant injury and the lack of objective valuations for certain plants. *Id.* at 42, 46-47; SOF ¶¶ 76-78. But *NFFC II* called on EPA to "quantify or estimate" amounts of dicamba-related plant injury, not to "calculate[] with precision the reduction in yield caused by the damage." 960 F.3d. at 1138. EPA complied with that directive. Plaintiffs' claim that "*nowhere* in the 2020 Decision documents" did EPA estimate dicamba-related damage is belied by the record. Pls.' Br. 14.

So too is Plaintiffs' claim that EPA failed to consider economic costs of defensive planting or "social cost" of dicamba use. Regarding the former, EPA found that available data were ambiguous but suggestive of some defensive planting of DT seed, and that the costs of any such defensive planting would vary based on the extent to which DT seed varietals were higher-cost or lower-yield than the foregone alternatives for a given farmer. A.6 at 43-45; SOF ¶¶ 42-45. EPA concluded, however, that "there is little to no ability for firms offering DT technology to exert monopoly power" given "the expanding number competing herbicide tolerant options" and "limited levels" of defensive planting. A.6 at 45. Regarding "social costs" of dicamba use, EPA noted reports of dicamba-related conflict, *id.* at 45-46, and acknowledged that such conflicts would likely continue absent "appropriate controls" on OTT dicamba use, A.4 at 17. But EPA concluded that the controls in the 2020 Registrations would minimize off-target movement and thus minimize the risk of additional conflict. *Id*. While Plaintiffs dispute that conclusion with the benefit of hindsight, they do not demonstrate that EPA reached it unreasonably.

C. EPA considered other risks when it issued the 2020 Registrations.

Plaintiffs next contend that EPA did not "consider and weigh" risks of: (1) dicamba in runoff; (2) dicamba in rainfall; (3) wide-area dicamba injury; and (4) dicamba-inflicted harm to trees. Pls.' Br. 16. The record shows that EPA considered each of these issues.

First, in considering the risk of dicamba runoff, EPA examined field studies and modeling simulations to assess the likely intensity, duration, and extent of off-field damage due to dicamba in runoff. A.9 at 61-62; 297-98. Results varied widely based on soil condition, field size, rainfall amount, and temporal proximity between dicamba application and precipitation. *Id.* That variability precluded EPA from predicting with certainty the scope of off-field runoff. *Id.* But it is not true that EPA "*failed to mitigate*" runoff risks. Pls.' Br. 17. The 2020 Registrations prohibit dicamba application when conditions are most conducive to runoff, such as 48 hours before a rainfall event likely to over-saturate a field, or when soil is already saturated. A.13 at 22. And contrary to Plaintiffs' claim (Pls.' Br. 17), EPA did not previously state that growers were incapable of abiding by those restrictions. Rather, a guidance document that EPA did not author noted that most growers (and state regulators) lacked instrumentation to make "continuous environmental measurements" of soil moisture. M.37ag at 8. Which is not to say that growers, whose livelihoods depend on understanding soil conditions, will be unable to tell when their fields are saturated; EPA could reasonably assume that they would. Plaintiffs are also wrong to insist that EPA had to eliminate, rather than mitigate, any risk of runoff before approving the 2020 Registrations. Pls.' Br. 17. It is true that EPA had evidence of dicamba in runoff "*up to ten days* after spraying." *Id.* But the Agency never claimed that the prohibition on dicamba application 48 hours before rainfall would prevent all runoff. A.9 at 62. Rather, it concluded that the 48-hour cut-off would reduce the risk of runoff-related harm to a level that, when weighed in FIFRA's all-things-considered balance, would not be unreasonable.

Second, EPA considered information suggesting dicamba concentration in rainfall as a potential problem. But, as Plaintiffs note, dicamba may occur in rain because of the "accumulation of dicamba in vapor in the air." Pls.' Br. 17. Dicamba in rainfall is thus a

derivative risk of volatility. EPA considered the primary risk of volatility and anticipated that label-based restrictions would reduce vapor loading, and by extension, reduce the risk of dicamba in rainfall. A.9 at 17.

Third, EPA considered risks of wide-area effects, reviewing reports of dicamba injury (including reports of wide-area injury) and concluding that those injuries were likely due to temperature-driven volatility. A.9 at 59; *id.* at 310. The 2020 labels' calendar-based cut-off dates reduced the risk of volatility by shifting application to cooler periods earlier in the growing season, thus reducing the likelihood of wide-area effects. A.9 at 57; A.4 at 20. Plaintiffs' claim that 2020 labels were "only designed to address 'near field' effects," Pls.' Br. 18, misses the mark.

Finally, EPA accounted for the possibility of dicamba injury to trees. In conducting risk assessments, EPA selected non-DT soybean as "a reliably representative species for evaluating potential effects to sensitive non-target plant species." A.9 at 49. That choice was reasonable because dose-response studies under greenhouse conditions confirmed that non-DT soybean "was more sensitive" than other plants. *Id.* Thus, EPA's use of non-DT soybeans to assess risks of dicamba-related injury was protective of less dicamba-sensitive species, including trees. Plaintiffs dispute that conclusion, arguing that a study by Bayer showed that American red oak is more sensitive to dicamba than non-DT soybean. Pls.' Br. 19.[3] While the study's author drew this conclusion from the underlying data, EPA

[3] Plaintiffs insist that the Bayer tree study was "deficient" because it used Clarity which was "not meant for over-the-top use." Pls.' Br. 19 n.14. But they offer no reason why the dicamba in Clarity would be insufficient to establish a dose-response. And the use of Clarity in the tree study was also appropriate for direct comparison with the dose-response study conducted on non-DT soybean. *See* G.31 (dose-response study using Clarity on trees); G.12 (dose-response study using Clarity on other plants including soybean). Plaintiffs also say that EPA viewed the study as "*not scientifically sound*" because it lasted just 90 days. Pls.' Br. 19 n.14. But nothing in EPA's review suggests that the study was deficient because of its duration. And EPA's review also describes the study as "*scientifically sound*," classified it "as *acceptable*," and found that certain deviations from EPA guidelines "*did not* have an impact on the acceptability of this study." G.31 at 3, 15. (emphases in original). Read in context, the cherry-picked statement that "the study *is not scientifically sound*" is clearly a typographical error.

explained that the conclusion rested on assumptions at odds with EPA protocols for measuring impacts to plant growth rates. G.31 at 14. EPA does not rely solely on others to interpret experimental data and instead draws its own conclusions from available data. *Id.* In doing so here, EPA concluded that growth reductions to apple and red oak were less than the 25% reduction in growth found in non-DT soybeans at the same level of dicamba exposure. *Id.* It therefore concluded that a further (Tier II) study was not necessary and that measures protective of non-DT soybean would protect trees as well. The Court should not disturb that reasoned conclusion.

D. The 2020 Registrations met the requirements for unconditional registrations.

Plaintiffs next contend that EPA erred by issuing the 2020 Registrations under FIFRA's "unconditional" standard, arguing: (1) that the 2020 applications did not meet data requirements for unconditional registration; and (2) that label restrictions in the 2020 Registrations prevented OTT dicamba formulations from performing "'intended functions'" and were contrary to "'widespread and commonly recognized practice.'" Pls.' Br. 22 (quoting 7 U.S.C. § 136a(c)(5)(D)). Both arguments fail.

Plaintiffs' first argument misreads the record. They claim that EPA failed to justify an unconditional, rather than a conditional, registration because, they say, the Agency's sole statement about data sufficiency was that "'EPA received studies and other information necessary to comply with the data requirements for the use of these products.'" Pls.' Br. 20 (quoting A.4 at 19). But EPA also explained that studies available in 2020 "encompass[ed] field trials, under variable environmental conditions and performed in a wide distribution of geographic locations including regions with high numbers of incidents reported," which gave it "high confidence" that the "large pool" of data "provides a fuller understanding" of "what is happening in the field." A.9 at 52. From that statement, EPA's basis for concluding that data supported an unconditional registration "may reasonably be discerned." *Alaska Dep't of Envtl. Conservation v. EPA*, 540 U.S. 461, 497 (2004).

Trying a different tack, Plaintiffs invoke the EPA Inspector General's report on the 2018 Registrations and insist that any "pre-2020 data" were "irreparably *tainted* with

politic [sic.] interference." Pls.' Br. 21. But nothing in the Inspector General's report impugns data from pre-2020 studies. Rather, the report faulted certain officials for preventing EPA scientists from using VSI as a regulatory endpoint. OIG Report at 9. That restricted EPA's review to a subset of field studies that used reduced plant height to measure dicamba impact. In 2020, EPA corrected the error by using VSI as a regulatory endpoint, [redacted: SUBJECT TO PROTECTIVE ORDER].

Plaintiffs' passing swipe at the available data on VRAs is equally unpersuasive. To begin with, EPA did not merely "accept[] registrants' assurances" that VRAs would reduce volatility. Pls.' Br. 21. On the contrary, it met with academic scientists to review Registrants' VRA-related claims. [redacted: SUBJECT TO PROTECTIVE ORDER]. And while Plaintiffs now portray that statement, and another selectively quoted phrase, as admissions that EPA lacked data sufficient to draw any conclusions about VRAs' protective effects, Pls.' Br. 21, context proves otherwise. [redacted: SUBJECT TO PROTECTIVE ORDER]. It then confirmed in its final analysis that available data gave it "high confidence that risks of concern from volatile emissions" would be "addressed" by VRA requirements, "in combination with additional label requirements that address volatility." A.9 at 57. The record thus refutes Plaintiffs' claim that EPA "did *not* have all the data it needed" to approve an unconditional registration. Pls.' Br. 21.

Data sufficiency aside, Plaintiffs argue that unconditional registration was also

improper because restrictions in the 2020 labels prevented OTT dicamba from performing its "intended functions." Pls.' Br. 22 (quoting 7 U.S.C. § 136a(c)(5)(D)). This is simply a recap of Plaintiffs' earlier argument about the supposed "impossibility" of label compliance, and it fails for the reasons set forth above. *See supra* pp. 12-13. Plaintiffs' invocation of the phrase "widespread and commonly recognized practice," 7 U.S.C. § 136a(c)(5)(D), gets them no further. No court has ever held, as Plaintiffs now argue, that FIFRA registrations must conform to an abstract baseline of common practice unrelated to label requirements. In fact, it is widespread and common practice to apply pesticides consistent with their label. And the restrictions on the 2020 OTT dicamba labels would have been reasonably familiar to any grower who used those products in the previous five years, or who used an alternative OTT pesticide product. *See supra* p. 13. Plaintiffs' claim that the 2020 labels were a marked departure from ordinary practice is unfounded.

E. The 2020 Registrations were procedurally proper.

Plaintiffs attack the 2020 Registrations on procedural grounds, arguing that EPA erred because it did not follow notice and comment (or hearing) procedures before approving those registrations. According to Plaintiffs, notice and comment were required because: (1) the 2020 Registrations were for products that were "the subject of a cancellation or order or suspension notice"; (2) OTT dicamba application on DT cotton and soybean was a "new use" at the time of the 2020 Registrations; or (3) in approving the 2020 Registrations, EPA issued a new legislative rule under the APA. Pl. Br. 31-37. These arguments do not withstand scrutiny.

Plaintiffs first contend that EPA was bound by the notice and hearing requirements of 40 C.F.R. Part 164, Subpart D (40 C.F.R. §§ 164.130-.133). Those requirements apply to applications for "registration of a pesticide" that was "the subject of a previous Agency cancellation or suspension notice under FIFRA sec. 6." 40 C.F.R. § 152.100(a). A "FIFRA sec. 6" cancellation notice is an EPA action that entails detailed procedural requirements, including, at the registrant's request, a formal hearing before an Administrative Law Judge. 7 U.S.C. § 136d(b). The subsequent registration of a pesticide that was subject to a Section

6 cancellation order amounts to a reversal or modification of that cancellation order. And Subpart D's procedural requirements exist so that Section 6 cancellation actions "may not be reversed or modified without . . . *similar notice and hearing opportunities*." 40 C.F.R. § 164.130 (emphasis added). Here, however, EPA's cancellation of the 2018 Registrations was "under FIFRA section 3," not Section 6. Cancellation Order at 4. The cancellation order followed the Ninth Circuit's vacatur, and EPA did not, and indeed could not, delay that action pending a hearing. Thus, Subpart D—which is predicated on procedural symmetry between a hearing-based cancellation and a later registration—is inapposite.

Likewise inapposite are the "new use" notice and comment requirements under 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102. In 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 authorizes 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." 40 C.F.R. § 152.3. Neither condition applies here. Plaintiffs concede that at the time of the 2020 Registrations, Tavium was registered for OTT dicamba application to DT cotton and DT soybean in 34 states. *See* Pls.' Br. 33 n.26 (Tavium "was not at issue" in *NFFC II*). And it is undisputed that the 2020 Registrations involved the same active ingredient, applied in the same manner, to the same crops, in the same states. 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. Nor did EPA approve an additional use pattern when it "*extended* over-the-top Tavium use beyond 2020." Pls.' Br. 34. The 2020 Registration for Tavium maintained the status quo of an existing use pattern; an established use is not a "new use."

Center for Food Safety v. Regan, 56 F.4th 648 (9th Cir. 2022) is not to the contrary. There, the Ninth Circuit held that EPA registered "new uses" when it amended a registration to remove restrictions on already-registered uses and to allow pesticide application on additional crops. 56 F.4th at 655. Here, by contrast, EPA registered OTT

dicamba application on the same crops as the operative 2019 Tavium registration and did so under what Plaintiffs themselves describe as an "even *more* restrictive 2020 label." Pls.' Br. 22. *Center for Food Safety* is thus readily distinguishable, and Plaintiffs' appeal to "new use" notice and comment requirements falls flat.

Plaintiffs' appeal to the APA fares no better. They claim that footnote 19 in EPA's "Decision Memorandum" for the 2020 Registrations was a "rule" and so was subject to the notice and comment procedures applicable to "rule making" under 5 U.S.C. § 553(b) and (c). Pls.' Br. 35-37. But 5 U.S.C. § 553(d)(2) exempts from those procedural requirements statements "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Perez v. Mortg. Bankers Ass'n,* 575 U.S. 92, 96-97 (2015) (internal quotation marks omitted). Those statements are called "interpretive rules," and they differ from "legislative rules," which must go through notice and comment, because they "merely explain, but do not add to, the substantive law that already exists." *Wilson v. Lynch*, 835 F.3d 1083, 1099 (9th Cir. 2016).

A three-sentence footnote in a document supporting an adjudicatory order should not be construed as a "rule." But assuming *arguendo* that it was, footnote 19 would be "textbook interpretive." *Id.* at 1100. In it, EPA explained that FIFRA Section 24(c), which allows states to authorize "additional uses" of registered pesticides, does not authorize states to restrict existing uses of registered pesticides. Plaintiffs do not (and could not) dispute that this conclusion follows from FIFRA's plain text and that the statute authorizes—indeed compels—EPA to deny state attempts to restrict existing uses, rather than add new uses, under Section 24(c). *See Erringer v. Thompson*, 371 F.3d 625, 630 (9th Cir. 2004) (a rule is interpretive "when, in the absence of the rule," there would still be "an adequate legislative basis for enforcement action."). Similarly, Plaintiffs do not (and could not) argue that EPA "explicitly invoked its general legislative authority" by including an advisory footnote in a decision memorandum supporting a license. *Id.* Finally, Plaintiffs do not (and could not) argue that footnote 19 is inconsistent with, and thus "effectively amends," any duly promulgated regulation. *Id.* Plaintiffs' argument thus flunks the Ninth

Circuit's three-part test for defining legislative rules, *see id*., and their invocation of the APA's notice and comment procedures is unavailing.[4]

II. Plaintiffs Lack Standing to Challenge the 2023 and 2023 Amendments, Which Were Reasonable in any Case.

To challenge a final agency action, a plaintiff must demonstrate standing by showing that the action at issue caused it an "injury in fact," which is both "fairly traceable" to the final agency action and "redressable" by a decision from the Court. *Nat'l Family Farm Coal. v. EPA*, 966 F.3d 893, 909 (9th Cir. 2020) ("*Enlist Duo II*"). EPA's approvals of the 2020 Registrations and 2022 and 2023 Amendments are final agency actions and Plaintiffs must demonstrate standing to challenge each action. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 n.5 (2006) (a litigant cannot "by virtue of his standing to challenge one government action, challenge other governmental actions that did not injure him"). They have not done so here.

Plaintiffs say they were injured by the use of OTT dicamba products. Those injuries are fairly traceable only to the 2020 Registrations. The 2022 and 2023 Amendments restricted the alleged injury-causing conduct, reducing the likelihood of injury. In no way did the amendments cause or even threaten an actual injury. And while Plaintiffs contend that the Amendments did not go far enough in restricting dicamba application, that is not a cognizable injury for purposes of standing. *See Lo Shippers Action Comm. v. ICC*, 808 F.2d 64, 65 (D.C. Cir. 1986) (a complaint "that the challenged action did not go far enough in abating a pre-existing injury" "will not suffice to confer standing"). Lacking the required causal connection between action and injury, Plaintiffs lack standing to challenge the 2022

[4] It is immaterial that EPA had, at times in the past, not objected to restrictive state registrations under FIFRA Section 24(c), and that EPA had posted on its website guidance that restrictive Section 24(c) registrations may be permissible under certain limited circumstances. Pls.' Br. 35. Neither EPA's past acquiescence to restrictive state registrations, nor its prior guidance, "went through formal rulemaking procedures," and so neither was a "regulation[] having the force of law" that could only be undone by a rule issued following notice and comment. *Chief Prob. Officers of Cal. v. Shalala*, 118 F.3d 1327, 1334 (9th Cir. 1997) *accord Erringer*, 371 F.3d at 632.

and 2023 Amendments.

Plaintiffs also cannot show that relief from this Court as to the 2022 and 2023 Amendments would redress their injury. If the Court to set aside the 2022 or 2023 Amendments as Plaintiffs request, it would simply restore the 2020 Registrations to their pre-amendment condition. *See Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005) (vacatur of an amended action typically restores the pre-amendment version of that action). This would exacerbate, rather than redress, Plaintiffs' asserted injuries and for that reason as well, Plaintiffs lack standing to challenge the 2022 and 2023 Amendments.

Should the Court reach the merits, it should reject Plaintiffs' challenges to the 2022 and 2023 Amendments. EPA approved those amendments after concluding that they would shift dicamba application earlier in the growing season, when temperatures are generally lower and thus less conducive to volatility. *See supra* pp.7-8. Plaintiffs do not dispute that reasoning. Instead, they contend that the "scope" of the Amendments was too narrow, and that EPA should have imposed further use restrictions through some other action. Pls.' Br. 9. This misconstrues the nature of the challenged actions. As noted above, EPA's legal authority is limited to either granting or denying Registrants' proposed voluntary amendments. *See generally* 7 U.S.C. § 136a(c)(3), (5)-(6). It chose to approve the 2022 and 2023 Amendments. Plaintiffs have not shown that denial would have been a better choice under the circumstances. And if Plaintiffs believe that EPA should now cancel the 2020 Registrations—the apparent crux of their objection to the 2022 and 2023 Amendments—then they could petition the Agency to issue a notice of intent to cancel, and then challenge EPA's denial of, or nonaction on, the petition. *See Ellis*, 252 F. Supp. 3d at 807. They have not done so, however, and the only claims before the Court are challenges to discrete agency actions, not actions that the Agency did not take.

III. EPA Fully Complied with the ESA.

A. EPA reasonably relied on the LOC/risk quotient method.

EPA reasonably used an LOC/risk quotient method in its analysis of the potential effects of the 2020 Registrations to listed species and their designated critical habitats.

Plaintiffs' arguments ignore important aspects of how EPA applied this method to make effects determinations for the 2020 Registrations and misunderstand the holdings of *Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006 (9th Cir. 2012) ("*Karuk Tribe*") and *Enlist Duo II*, as well as the contents of a 2013 report from the National Academy of Sciences ("NAS Report").

While EPA also used a LOC/risk quotient method to assess risks to nontarget, non-listed species under FIFRA, there is a key difference in how EPA applied this method to make effects determinations under the ESA. Plaintiffs' statement that EPA used the same LOC for listed and non-listed plants is correct. Pls.' Br. 26. However, EPA's approaches for defining the applicable *risk quotient*—the other side of the ledger—for calculating potential effects to non-listed and listed plants differ. For non-listed species, the calculation compares estimated exposures to what is known as the "IC25" endpoint, which is the point at which the species' survival, growth or reproduction is expected to experience a 25% decrease. For listed plant species, EPA compares estimated exposures to the endpoint at which no effects on survival, growth or reproduction will occur (known as "NOAEC"). Overview at 47 and 50; *see also id*. at 42. In the case of dicamba, this difference results in an approximate two-fold difference when comparing the risk quotient for non-listed and listed plant species (non-listed species IC25 of 0.000513 lbs. active ingredient/acre compared to listed species NOAEC endpoint of 0.000261 lbs. active ingredient/acre). *Cf.* Overview at 47 (for "endangered plants, RQs are derived using lower toxicity endpoints than non-endangered plants"); *id.* at 50.

Plaintiffs also insinuate that, because EPA is required to consider both the risks and foreseeable benefits of the use of a pesticide when determining whether the pesticide meets the standard for registration under FIFRA, the LOC/risk quotient method itself accounts for benefits. Pls.' Br. 24. This is inaccurate—the LOC/risk quotient method is a method for assessing effects alone. *See* A.9 at 33 (describing the use of the LOC/risk quotient method to characterize effects). In making a determination under FIFRA, EPA weighs risks identified through this method against benefits. In making an ESA effects determination,

EPA does not consider benefits. *Compare* A.4 at 19 (describing the standard for registration under FIFRA) *with id.* at 26-28 (describing EPA's effects determinations). EPA's use of the LOC/risk quotient method to make effects determinations was reasonable, and the Court should decline Plaintiffs' invitation to "second guess the agenc[y]'s decisions using [its] own judgment." *Alliance for the Wild Rockies v. U.S. Forest Serv.,* 504 F. Supp. 3d 1162, 1189-90 (E.D. Wash. 2020).

Plaintiffs next suggest that EPA's "no effect" determinations made using this method are inconsistent with *Karuk Tribe*'s instruction to agencies to consult on actions that have "any chance of affecting listed species or critical habitat." Pls.' Br. 6, 24. Federal Defendants do not dispute that under *Karuk Tribe*, EPA would have had a duty to consult if its assessment had resulted in "may affect" findings. But it did not make any such determinations except for one species not at issue. Therefore, reliance on *Karuk Tribe* is misplaced. Further, Plaintiffs ignore the numerous cases holding that EPA has the latitude to assess the potential effects of dicamba using the LOC/risk quotient method. For example, considering claims similar to those presented here, the Ninth Circuit upheld EPA's LOC/risk quotient method, which it used to make hundreds of no effect determinations. *Enlist Duo II*, 966 F.3d at 924 (LOC/risk quotient methodology "applies the correct legal standard" under *Karuk Tribe* and "recognition of exposure is not a recognition that" a pesticide "'may affect' protected species and critical habitats").[5]

Plaintiffs' contention that EPA erred because the NAS Report criticized the LOC/risk quotient approach similarly misses the mark. Pls.' Br. 24-25. It is EPA and the Services, not NAS, that decide how to harmonize FIFRA and the ESA and conduct pesticides consultations. In any event, the NAS Report did not discount the usefulness of

[5] An additional problem for Plaintiffs is that such a reading would be inconsistent with the ESA's implementing regulations, stripping action agencies of the ability to make "no effect" / "may affect" determinations under 50 C.F.R. § 402.14(a). That regulation creates a division of labor between action and consulting agencies and requiring consultation only where an agency action actually "may affect listed species or critical habitat." *Id.* (emphasis added). *Karuk Tribe* did not negate 50 C.F.R. § 402.14. Plaintiffs' theory would improperly obliterate the distinction between no effect and may affect.

analysis of exposures, species responses to such exposures, estimated environmental concentration levels, or toxicity thresholds. NAS Report at 8, 12, 33, 93.[6]

Further, in a November 2014 report to Congress, EPA and the Services made clear that EPA would complete endangered species assessments in accordance with its 2004 Overview Document for all new herbicide tolerant crop uses, and that the Overview Document is the basis for EPA's ecological assessments for all chemicals other than chlorpyrifos, diazinon, malathion, carbaryl, and methomyl. Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs, https://www.epa.gov/sites/default/files/2015-07/documents/esareporttocongress.pdf ("Interim Report") at 21-22.[7] Thus, the Services, which Plaintiffs acknowledge are the "expert" agencies, espoused the use of the LOC/risk quotient method for dicamba, and EPA reasonably used this method. Pls.' Br. 1, 6-7, 23-24, 27, n.21; *cf.* Interim Report at 20 (LOC/risk quotient approach incorporated "highly conservative and protective assumptions to evaluate ecological risks").

B. The methodology that EPA used in other biological evaluations is irrelevant.

In their attempt to undermine the LOC/risk quotient method, Plaintiffs also cite seven extra-record biological evaluations ("BEs") assessing potential effects of several other pesticides, such as chlorpyrifos and malathion, reasoning that because EPA made a number of "may affect" or "likely to adversely affect" determinations in those evaluations, it should have made more here. This argument fails for several reasons. As a threshold matter, the argument is based on extra-record material. The Court's review of Plaintiffs'

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[6] EPA has refined its methodology since the version analyzed in the NAS Report (available at https://nap.nationalacademies.org/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides); its assessment here included Step 1 of the Revised Method, discussed *infra* p. 27.

[7] EPA reiterated this position regarding herbicide tolerant crop uses in its December 20, 2019 Interim Report to Congress on Improving the Consultation Process Required Under Section 7 of the Endangered Species Act for Pesticide Registration and Registration Review. *See* https://www.epa.gov/sites/default/files/2020-01/documents/esa-report-12.20.19.pdf.

ESA claims is limited to the Administrative Record before the agency at the time of its decision. *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). While Plaintiffs have requested to add documents to the Administrative Record, they have not done so as to many of the documents cited in their brief, and have therefore waived any argument that they should be considered now. The Court should decline to rely on those documents, which were not considered by (or relevant to) the decision made by EPA. Dkt. 131 at 16-17; *Friends of the Clearwater v. Higgins,* 523 F. Supp. 3d 1213, 1221 (D. Idaho 2021).

And in any event, EPA's use of the 2020 Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides (March 2020) ("Revised Method") for the 2018 and 2021 BEs that Plaintiffs cite was appropriate because this three-step method was designed for *nationwide* BEs (*i.e.*, those concerning pesticides in registration review with nationwide uses). Revised Method at 6 n.1, https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf. That methodology was not designed for OTT dicamba. As stated earlier, the Services and EPA made clear in Reports to Congress that EPA could continue to employ the Overview Document-compliant LOC/risk quotient approach for ESA assessments of OTT uses like dicamba. Interim Report at 21-22. Plaintiffs provide no basis for requiring EPA to follow the same approach for OTT use of dicamba as it followed with respect to chlorpyrifos, diazinon, malathion, carbaryl, methomyl, atrazine and glyphosate.

C. EPA rationally defined the action area.

EPA reasonably concluded that the appropriate action area is limited to the treated fields, especially considering the additional protective measures, such as the ESA Buffers, that EPA required for the 2020 Registrations. A.9 at 81-106. Plaintiffs' action area and critical habitat arguments largely seek to have the Court review EPA's actions based on post-decisional, extra-record evidence, and should be rejected. Pls.' Br. 26-31.

Plaintiffs' theory—that EPA should have used 5% in lieu of 10% VSI when determining the size of the ESA buffers—lacks merit and would invert the relationship between visual signs of injury and height reduction. Pls.' Br. 28. EPA's point of departure is the

apical endpoint of 5% *height reduction* in soybean plants. It does not start with any particular VSI level, as Plaintiffs contend. *Id.*; *see also* A.9 at 50-52, 133-89 (App. C) and 189-205 (App. D). Working from the 5% height reduction endpoint, EPA determines what percentage VSI would reliably encompass that endpoint. A.9 at 50, 133-89, 189-205. EPA reasonably followed that path here. Plaintiffs have it exactly backwards.

Moreover, Plaintiffs' claim that EPA "switched" from 5% to 10% VSI is unsupported. Pls.' Br. 26-29. Plaintiffs quote snippets of certain discussion notes in their brief. *Id.* at 28 (quoting E.13, E.15, E.16). But nothing that Plaintiffs cite suggests that EPA even contemplated using a 5% VSI metric. The quote on which they rely, that for VSI, "a significant effect is anything greater than 5%," was not made by an EPA official. Pls.' Br. 28 (citing E.16 at 3). Its meaning is, moreover, ambiguous, and could refer to a 5% *height reduction*, 5% visual signs of injury, or 5% of something else. E.16 at 3. In any event, this single, cherry-picked statement is not binding on EPA. The Court should credit instead EPA's robust and careful explanation of its approach to determining what level of VSI it would use. A.9 at 50-52, 133-189 (App. C) and 189-205 (App. D).[8]

Plaintiffs' argument about the size of the ESA Buffers also is plainly wrong. Pls.' Br. 27. It is based on the incorrect assumption that EPA knew in October 2020 that the 2020 mitigation measures would not prevent what Plaintiffs allege was "off-field damage." *Id.* at 27. Plaintiffs' position is improperly based on extra-record, post-decisional documents. The 2020 Registration Decision must stand or fall based on the documents before the agency in 2020.[9]

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[8] The 10% visual signs of injury and 5% height reduction metrics were "considered very conservative." A.9 at 135. In comparison, for non-listed plant species, "the typical effect levels of concern are established at a higher 25% effect level." A.9 at 134.

[9] Moreover, to the extent Plaintiffs are now suggesting EPA should have, but did not take some *other* action in 2021 based on post-decisional information to comply with any consultation obligations, Plaintiffs have waived any such claim. Plaintiffs have never in their notice of intent to sue, complaints, or opening brief suggested that EPA has unreasonably delayed taking any mandatory action pursuant to ESA Section 7 based on information post-dating the 2020 Registration Decisions. Dkt. 149 at 124-139; Dkt. 155 at 23-31; Pls.' Br. 27; 16 U.S.C. § 1536; 5 U.S.C. § 706(1); 50 C.F.R. pt. 402.

Plaintiffs' third action area argument is that EPA should have extended the action area to cover additional counties where two butterfly species' critical habitat is located. Pls.' Br. 28-29. But the action area is defined by the extent of any impacts, not the range of a species. *Oceana v. Evans*, 384 F. Supp. 2d 203, 228-29 (D.D.C. 2005). Moreover, EPA *did* include one of the 19 counties that Plaintiffs' extra-record declaration by Mr. Donley cites: Deuel, South Dakota. *Compare* A.9 at 68 *with* 50 C.F.R. 17.95-i-insects *and* Donley Decl. ¶ 15. And EPA reasonably excluded the remaining 18 counties because in those counties, there existed less than a 1% overlap between the action area and listed species' critical habitat. A.9 at 72-73. Plaintiffs do not mention, much less grapple, with EPA's analysis. Pls.' Br. 28-29; *cf.* P.641 (EPA listing counties in which ESA Buffers apply, and associating counties in which particular species or critical habitats exist). The Court should "accord deference to [EPA] in the way it chose to define the action area," and should affirm EPA's choices here. *Enlist Duo II*, 966 F.3d at 927. EPA's assessment of potential effects to critical habitat complied with the ESA.

D. EPA's assessment of potential effects to critical habitat complied with the ESA.

Plaintiffs' argument about adverse modification of critical habitat due to the 2020 Registrations also misses the mark. Plaintiffs' critical habitat assertions rehash ground they have unsuccessfully presented in *Enlist Duo II* and elsewhere. Pls.' Br. at 29-31; *compare Nat'l Family Farm Coalition v. EPA*, No. 17-70810 (9th Cir.) (Dkt. 10833581) (opening brief) at 49-56, *with Enlist Duo II*, 966 F.3d at 928-29 (rejecting Plaintiffs' critical habitat argument that EPA erred by "only considering species [that] use . . . soybean fields"). They fare no better this time. Plaintiffs maintain that EPA should have assessed effects to species' critical habitat and not solely effects to individual members of those species. Pls.' Br. 30. Plaintiffs' critique is based on the unsupported theory that the 2020 Registrations administrative record showed dicamba would "drift[] and volatiliz[e] miles from the fields," exposing critical habitats. *Id.* Yet their brief does not cite any document from the 2020 Administrative Record (or indeed, any document) to support this position. *Id.* The

Court should accordingly affirm EPA's comprehensive "no effect" determinations. *Enlist Duo II*, 966 F.3d at 928 (citing *Arrington v. Daniels*, 516 F.3d 1106, 1112 (9th Cir. 2008)).

IV. If the Court Finds for Plaintiffs, It Should Remand Without Vacatur.

For the foregoing reasons, EPA is entitled to summary judgment. But if the Court holds for Plaintiffs in any respect, it should remand without deadline to EPA and should not vacate the 2020 Registrations, or the 2022 and 2023 Amendments.[10] The decision whether to vacate depends on: (1) the seriousness of the order's deficiencies; and (2) the "disruptive consequences of an interim change that may itself be changed." *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012). When equity demands, an action "can be left in place while the agency follows the necessary procedures" to correct it. *Id.*

As more fully explained in Intervenors' brief, the disruptive consequences of vacatur on growers using the OTT dicamba products warrant remand only. Vacatur could force growers who have already invested in DT crops to expend additional money on alternative seeds and pesticides. It could also increase the risk that growers using DT seed would apply older, more volatile dicamba formulations, which are not at issue here and which remain on the market for other uses. *See* A.4 at 7. Remand without vacatur is also appropriate because Plaintiffs claims rest on alleged defects in EPA's record and, on remand, EPA could correct any perceived flaws by bolstering or clarifying its rationale for the Registrations.

CONCLUSION

For these reasons, the Court should enter summary judgment for EPA on all claims. Alternatively, if the Court finds for Plaintiffs, it should remand without vacatur.

[10] As discussed, the final agency actions challenged here are the orders granting the 2020 Registrations and the 2022 and 2023 Amendments. There is not, as Plaintiffs suggest, a single "Decision" constituting "EPA's continued approval of over-the-top dicamba use." Pls.' Br. 4 n.2.

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