Summary of Submissions: Support for Registration of XtendiMax®

TEST GUIDELINE

Not Applicable

STUDY COMPLETION DATE

July 24, 2020

SPONSOR/PERFORMING TESTING FACILITY

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Date: 7/24/2020

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Steven T. Callen
Regulatory Affairs Manager
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Summary of Submissions: Support for Registration of XtendiMax®

Introduction

Bayer Crop Science (Bayer) is seeking approval of its XtendiMax®[1] dicamba pesticide for agricultural uses in 2021 and beyond, including for use over-the-top (OTT) on dicamba-tolerant soybeans and cotton crops. XtendiMax and other OTT dicamba formulations have recently been the subject of litigation. On June 3, 2020, a panel of the United States Court of Appeals for the Ninth Circuit issued a judicial order vacating multiple dicamba product registrations; thereafter EPA issued a June 8, 2020 existing-stocks order allowing certain continuing applications during the 2020 season. To address the judicial vacatur, and consistent with EPA's existing-stocks order, this paper summarizes the core scientific predicate for Bayer's request for registration of XtendiMax for 2021 and beyond. Although Bayer disputes the conclusions reached by the Ninth Circuit panel and has filed a petition for rehearing *en banc*, Bayer proposes to make *multiple important changes* to its product label (or "use requirements") for the upcoming seasons to provide further assurance that XtendiMax will not drift or volatilize in the manner alleged in that litigation. Based upon prior scientific submissions and other available information summarized herein, Bayer anticipates that EPA can fully and completely address the issues identified by the Ninth Circuit vacatur.

Over the past decade, both soybean and cotton farmers have struggled to address the onset of glyphosate-resistant weeds in many locations across the U.S. *See infra* pp. 30–32. It is undisputed that those weeds have been challenging to control with prior herbicide options. Indeed, resistant weeds can cause significant yield losses where they are prevalent. *See infra* p. 37. Bayer and other agricultural companies have worked to provide solutions. Specifically, Bayer (previously Monsanto) spent many years developing specialized soybean and cotton seeds with multiple pesticide tolerances, including dicamba tolerance, and other key traits. Bayer competitors have sought to do the same with other tolerance traits. Together, XtendiMax and other products supply multiple modes of pesticidal action; the availability of these multiple pesticidal options continues to be critical to managing weed-resistance risk nationwide. *See infra* pp. 28–33. With the in-crop use of dicamba and other new technologies, applicators and growers have made significant progress in combatting these resistant weeds year by year—and these new technologies have been markedly more effective than other products previously on the market. *Id.* The continued control of resistant weeds is essential. Even one season of ineffective control can materially exacerbate the resistance problem. *See infra* p. 32.

Substantial support for XtendiMax from the soybean and cotton grower communities is a testament to XtendiMax's success in weed control:

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[1] The Bayer Group has acquired Monsanto Company, the former registrant of XtendiMax. XtendiMax is formulated with Bayer's VaporGrip® Technology to reduce volatility.

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- U.S. Department of Agriculture (USDA) Secretary Sonny Perdue recognized in a public statement in June 2020 that efforts to restrict dicamba use would "cripple American farmers and further limit their ability to feed, fuel, and clothe this nation and the world."[2]
- The National Association of State Departments of Agriculture informed EPA in May 2020 that "continued use of the dicamba formulations through this season is essential."[3]
- In 2018, the American Soybean Association explained its support for OTT dicamba to "combat evolving plant pests and weeds" and noted that the glyphosate-resistant Palmer amaranth alone can create yield losses of 79%.[4]
- Similarly, an informal survey of growers by the Cotton Foundation found that 100% of respondents believed that registration for auxin herbicides (such as XtendiMax) should be continued, and that Palmer amaranth, in particular, "could not be controlled without" these products.[5]

Indeed, grower groups, State agricultural officials, and many others reacted immediately and definitively to the Ninth Circuit order vacating the registration of XtendiMax. *See infra* p. 29. For example, as EPA noted in its June 8, 2020 Existing Stocks Order, Secretary Perdue encouraged EPA "to use any available flexibilities to allow the continued use of already purchased dicamba products, which are a critical tool for American farmers to combat weeds resistant to many other herbicides, in fields that are already planted."[6] And the American Farm Bureau Federation warned EPA in a June 5 letter that growers unable to use these dicamba products would be "expos[ed] to potentially billions of dollars in noxious weed damage."[7]

Bayer is heartened by the widespread support of soybean and cotton growers for its dicamba technology and has always taken very seriously the need to minimize the potential for

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[2] Press Release, Secretary Perdue Statement on Dicamba Plaintiffs' Attack on EPA Order (June 12, 2020), https://www.usda.gov/media/press-releases/2020/06/12/secretary-perdue-statement-dicamba-plaintiffs-attack-epa-order.

[3] Letter from Barbara P. Glenn, Chief Executive Officer to Acting Administrator Wheeler (May 8, 2020).

[4] Letter from John Heisdorffer, President of American Soybean Ass'n, to Acting Administrator Wheeler at 1–2 (Sept. 10, 2018).

[5] Letter from Bill M. Norman to Richard Keigwin at 2–3 (Aug. 23, 2018).

[6] EPA, Final Cancellation Order for Three Dicamba Products (XtendiMax with VaporGrip Technology, Engenia, and FeXapan) at 5 (June 8, 2020) ("Existing Stocks Order").

[7] *Id.* at 6.

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drift and volatility. In light of the recent judicial ruling, Bayer is committed to work with EPA to make yet further changes to the label and uses of its products. We note that the Ninth Circuit decision focused on certain grower "complaints" and other record materials alleging off-target dicamba movement to *soybean fields* in 2017 and 2018. We address those concerns in soybean regions herein, but we also stress that these same concerns were *not* identified in all states where XtendiMax was utilized. *See infra* p. 19 (identifying cotton-growing states with few or no drift allegations in recent years). Accordingly, Bayer's proposals for label changes herein differ in certain respects for applications over soybeans and cotton. Specifically, as described in detail herein, Bayer proposes:

(1) ***Mandatory* tank mixing of XtendiMax with additional volatility-reduction agents and drift-reduction adjuvants**: XtendiMax was designed as a lower-volatility dicamba formulation. Over the past several months, Bayer has submitted results from scientific field tests conducted by Bayer and by independent academic experts demonstrating successful trials with a tank mix of XtendiMax and a volatility-reducing tank mix agent (VRA) branded VaporGrip Xtra®.[8] These trials show significant reductions in volatility and ***no evidence of any plant height impact due to volatility.*** Bayer will soon be submitting to EPA humidome testing for tank mixes with VaporGrip Xtra, demonstrating the very significant volatility reductions. *See infra* 15. Bayer proposes that XtendiMax's new label *mandate* the addition of VaporGrip Xtra—or another equivalent VRA—and a drift reduction adjuvant (DRA) as tank mix adjuvants with XtendiMax. XtendiMax is already considerably less volatile than available dicamba products widely utilized over corn and for other agricultural uses. *See infra* p. 19. With the addition of a VRA like VaporGrip Xtra, XtendiMax will be *profoundly* less volatile than all other conventional dicamba herbicide previously registered for any agricultural use. Additionally, the use of DRAs as a tank mix partner is recognized by EPA as a best-practice spray-drift-reduction tool. *See infra* p. 13. As explained in detail below, by mandating use of VaporGrip Xtra or similar VRAs, along with mandatory DRAs, EPA can address many of the principal concerns identified in the Ninth Circuit's judicial vacatur.

(2) ***Expanding XtendiMax's mandatory downwind drift buffers* from 110 to more than double that distance**: Based on field testing and other data available to date, Bayer is also proposing that the mandatory downwind buffer for XtendiMax be expanded significantly from 110 feet (in the prior XtendiMax label) to 250 feet. As explained in detail herein, the large majority of scientific field tests conducted over multiple years in a wide range of geographies supported the 110-foot downwind buffer, but even so, the company is proposing a substantial expansion. Based upon data available to date, a downwind buffer of 250 feet should account for most data points, including substantial outliers, in currently available studies. Bayer anticipates that its annual field testing program will yield certain additional data in the coming weeks and welcomes discussion of those results as they become available. This proposed downwind buffer would be in addition

[8] *See* MRID 51134101 (May 1, 2020).

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to Bayer's recommendation that EPA mandate a DRA for all applications, which will further ensure successful reduction of any prospect of drift.[9]

(3) ***Limited Timeframe* for OTT Soybean Application Windows**: Bayer also proposes an important change to the timing of XtendiMax OTT applications over soybeans, allowing applications only through soybean V4 vegetative stage, instead of, as currently labeled, to the later R1 reproductive stage. As explained below, data collected by Bayer since 2017 suggest that the drift-related incident reports the company received were largely made relatively late in the season. As indicated previously, we believe that the large majority of those reports could be traced to issues not associated with volatility or drift from appropriate label-compliant XtendiMax applications (*see* MRID 50642701 at 31; MRID 51038601 at 43), and that yield impacts associated with such reports were rare, if they occurred. We are nevertheless proposing to restrict the application window for these OTT applications over soybeans. Even assuming that pesticide applications had a role in the reports, a V4 spray limitation should eliminate the vast majority of those incidents. Importantly, the number of reports regarding drift from OTT cotton applications were very limited, and national data from multiple sources has not identified any unusual number of issues with those applications. *See infra* p. 19. Indeed, the Ninth Circuit opinion addresses OTT soybean applications almost exclusively. Thus, this proposal addresses OTT soybean applications only.

(4) ***Alternative Application Options—Shielded or Hooded Sprayers***: Although Bayer is proposing considerable additional limitations on OTT soybean applications, it recognizes that this may result in challenging logistical problems for certain growers who will still face the critical need to maintain weed control: (1) over areas on the downwind perimeter of the field within that buffer distance; and (2) later in the growing season (potentially through R1 reproductive stage). Although very few shielded or hooded spray systems are available now, and relatively few could be made available for 2021, field testing and other data indicate that the use of shielded or hooded sprayers can dramatically reduce any potential for drift. *See infra* pp. 13–14. Thus, for those applicators who can utilize such options in 2021 or thereafter, extensive downwind buffers and limited application windows should be unnecessary. *Id.* Accordingly, Bayer is proposing an exception to the expanded downwind buffer and narrowed application window on OTT soybean application for applicators who can employ appropriate shielded or hooded sprays systems. *See id.*

(5) **Simplification of the product label**: EPA imposed a restriction in 2018 requiring that XtendiMax be applied only by specially trained state-licensed certified applicators. Data and feedback from recent years demonstrates that training programs for this already highly specialized group of professional applicators have been successful in addressing many potential application

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[9] We are also pleased to discuss further potential approaches in the counties where endangered plants are present. Bayer has previously identified specific information identifying the locations of these plants through its Pre-Serve program, which assembles information from the NatureServ database. *See* MRID 478995, 48900400, 49022401, 49022402, 49022403, 49093200, 49093201, 50678800, 50678801, and 50678802. Bayer continues to believe that it is most appropriate to utilize that specific information in EPA's Endangered Species Act assessments.

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errors. *See infra* pp. 16-17, 40. That said, in response to the June 3, 2020 Ninth Circuit decision, Bayer proposes to further simplify the product label to help ensure that those applicators fully comply with the label instructions. We also note that the proposed narrowing of the application window for OTT soybean applications to the V4 vegetative growth stage (instead of the later R1 reproductive stage) will provide a clear, simple, and absolute restriction on growers in those states.

In these and other ways discussed herein, Bayer is proposing a further registration of XtendiMax in a manner that takes account of and is consistent with all underlying scientific data, the concerns identified by the recent judicial decision, and recent experiences in each particular growing region. The discussion below summarizes how EPA can address all concerns identified by the court.

- **Section I: Analysis Of Drift And Volatility Must Begin With The Dozens Of Applicable Scientific Field Studies (p. 6).** Below, we summarize the dozens of scientific field studies of XtendiMax by the registrant and independent academics, confirming that the measures Bayer is proposing will provide an additional and significant margin of safety. Section I also identifies substantial further reductions in volatility that would be achieved by mandating tank mixes with VaporGrip Xtra or another appropriate VRA.

- **Section II: The Number Of Dicamba Drift Inquiries Has Fallen Dramatically Since 2017 In Most States; Investigations Of Such Incidents Identify Causes Other Than XtendiMax (p. 16). Section II** summarizes the decline in off-target inquiries relating to XtendiMax from 2017–2019 in most growing areas, reflecting the successes of prior XtendiMax label changes and improved applicator training. As explained below, use of older dicamba formulations (which lack many of XtendiMax's volatility-reducing characteristics) in certain geographic areas co-located with corn production may have caused a considerable portion of the inquiries related to dicamba off-target movement in those areas. And the majority of the drift inquiries received by Bayer occurred later in the growing season—beyond the V4 vegetative growth stage. This data suggests that the additional restrictions on the timing of OTT soybean applications proposed herein should further reduce the number of drift inquiries allegedly associated with XtendiMax applications.

- **Section III: Drift Inquiries Require Investigation Before Any Reliable Conclusion Can Be Drawn About Damage—USDA Data Shows Steady Or Increased Soybean Yields In Many States With The Highest Volume Of Inquiries (p. 25). Section III summarizes** reports that soybean yields, both nationally and region by region, have remained steady or improved since the initial registration of XtendiMax, and that areas with the highest number of drift related reports also saw significant yield gains. This undermines the erroneous assumption that reported drift incidents have caused wide-scale crop "damage" across certain counties or regions. USDA has significant yield and other crop data available and can assist EPA in ensuring that it has performed any required analysis on these issues. Again, it is not appropriate to assume a crop has been injured due to alleged XtendiMax drift without specifically investigating the drift report at issue. *See infra* p. 28 (citing ruling by Judge Limbaugh).

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- **Section IV: Dicamba Is A Critical Element Of Growers' Strategy To Address Glyphosate-Resistant Weeds and Maintain Yields (p. 28). Section IV** describes growers' critical need for XtendiMax as a tool to combat weed resistance. Indeed, national and local grower groups and Federal and State agricultural officials have recently expressed their very strong views supporting the continuing availability of dicamba OTT options.[10] *See infra* pp. 28–30. Experts have also long recognized the need for growers to employ multiple modes of action. Moreover, XtendiMax plays a central role in the dicamba-tolerant seed system, which offers key genetic diversity for maintaining strong yields. Multiple breeding cycles are required to bring highest yield seed to market each year with appropriate pesticide tolerance and disease resistance for each growing region; sufficient seed will not be available in 2021 unless growers continue to benefit from Bayer's Xtend seed and XtendiMax.

- **Section V: EPA's Previous Determination that Dicamba Is Not Likely A Human Carcinogen Remains Supported By The Science (p. 33). Section V** identifies EPA's conclusion, and the conclusion of many other regulatory agencies worldwide, that dicamba is not likely a human carcinogen. There is no new evidence raising serious questions about these long-held findings.

- **Section VI: For All These Reasons, The Economic And Social Benefits of OTT Dicamba Approval Far Outweigh Any Costs (p. 37). Section VI** explains how all of these factors demonstrate that the economic and social benefits of OTT dicamba use far outweigh any costs. This section also addresses certain other elements of the Ninth Circuit's decision, including the Ninth Circuit's concerns about possible "anti-competitive" economic effects and alleged harm to the "social fabric" of farming communities. The panel was incorrect that FIFRA required EPA to consider and address these topics, but we nonetheless discuss how EPA can do so.

- **Section VII: Proposal To Simplify The Label (p. 40).** Finally, **Section VII** proposes simplifications to XtendiMax's label that will further ensure proper application and minimize potential for dicamba movement, responsive to the Ninth Circuit's vacatur decision, and explains more specifically how the label can be made even more effective.

Data and Analysis

I. ANALYSIS OF DRIFT AND VOLATILITY MUST BEGIN WITH THE DOZENS OF APPLICABLE SCIENTIFIC FIELD STUDIES

A substantial body of field studies support EPA's past conclusions that off-target movement of XtendiMax should not occur beyond the label's required buffer distances at levels that would cause unreasonable adverse effects on the environment, or any effects to threatened or endangered species. Non-tolerant soybeans are utilized in these field studies because soybeans are

[10] Existing Stocks Order at 6–7.

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known to be the most sensitive plants to dicamba exposure.[11] Data from XtendiMax field studies conducted in 2019—by independent academic scientists and the registrant—reinforce the results of the prior studies conducted by the registrant and independent academic scientists. Such studies were conducted in a variety of geographic locations and spray conditions. Study data available to date demonstrate that the proposed downwind buffer distance of 250 feet should be protective of potential unreasonable adverse effects to the environment or any effects to threatened and endangered species.

As an initial matter, it is undisputed that mild visual symptomology that might result from pesticide off-target movement (whether from dicamba, 2,4-D, or other causes) does not necessarily result in yield loss or any long term impact on soybean plants. For example, Weidenhamer *et al.* (1989) concluded that, for soybeans, "[m]ost foliar symptoms (i.e., crinkling and cupping of the terminal leaves, leaf margin injury and size reduction, and distorted venation patterns) were not indicative of reductions in yield." Robinson *et al.* (2013) reached a similar conclusion for soybeans: "Although foliar symptoms may appear to be severe, the yield loss may be minimal when only leaves and petioles are malformed." Previous research, including studies by Bradley, suggests that yield losses for soybean crops only tend to result from dicamba exposure when exposure results in observations of 40% or greater visual symptomology.[12]

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[11] Porch et al., BAS 183 09 H (Clarity): A Toxicity Test to Determine the Effects of the Test Substance on Vegetative Vigor of Ten Species of Plants (2009), MRID 4778115102.

[12] In this study, Professor Kevin Bradley of the University of Missouri conducted an assessment of dicamba symptomology in a Missouri soybean field and compared that assessment to yield data provided by the grower. *See* https://www.missouriruralist.com/herbicide/does-dicamba-drift-cause-soybean-yield-loss.

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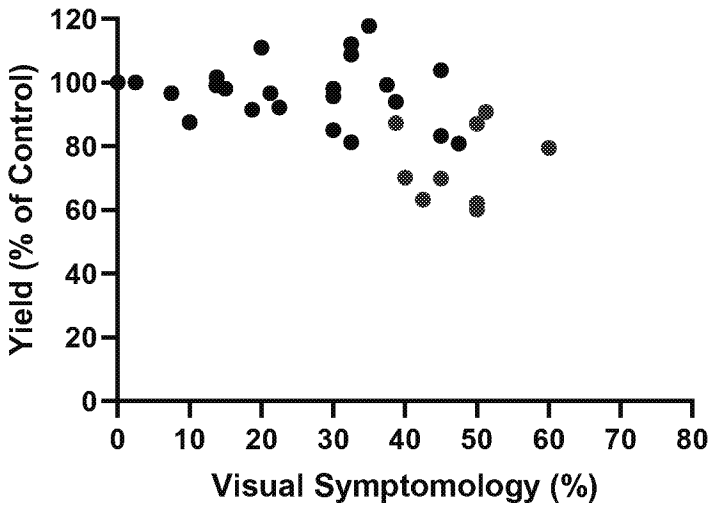
Soybean yield		
% of visual injury	% of historical average	Bushels per acre
0-20%	115%	55
21%-40%	104%	49
41%-60%	68%	32
61%-80%	35%	17
81%-100%	2%	1

Table courtesy of University of Missouri

Registrant data is consistent with this research: The chart below includes both vegetative and reproductive applications, with red dots indicating statistically significant reductions in yield and black dots indicating reductions that are not significant.[13]



[13] Data were compiled from MRIDs 51017504, 51017505, and 51017506.

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Another challenge with visual dicamba-drift symptomology in soybean plants is the subjectivity of the metrics for making observations.[14] The degree of symptomology (or "visual injury") identified can vary depending upon the experience and expertise of the observer; certain studies have shown wide disparities between the reported symptomologies observed and the actual reductions in plant height for the apparently impacted plants. For example, in an Arkansas study in 2017, 20% visual "injury" was reported out to 31 meters from the spray by students recording such observations, but 5% plant height reductions were only found at distances of 3 meters or less.

For both drift and volatility, EPA's 2018 OTT dicamba registration ultimately relied on field studies that evaluated 5% plant height reduction measurements, because of EPA's "confidence in the direct measurements of height effects."[15] As EPA explained, plant height can be objectively measured and is a better indication than subjective estimations of visual symptomology of impacts on the plant's ability to survive, reproduce, and grow.[16] Multiple studies provided data on plant height reduction, demonstrating that XtendiMax applications following the proposed label will not result in off-target movement sufficient to cause unreasonable adverse effects or any impacts to endangered species.

Study Data on Downwind Drift

Multiple studies assessed the average and/or maximum distances downwind at which 5% plant height reduction was observed:

- 3 meters average [10 feet] (Norsworthy 2017, Arkansas),
- 9 meters maximum [30 feet] (Werle 2018, Wisconsin),
- 10 meters maximum [33 feet] (Sprague 2018, Michigan), and
- 10 meters average [33 feet], 12 meters maximum [39 feet] (Kruger 2018, Nebraska).[17]
- Although EPA's 2018 assessment did not include plant height data from the registrant 2018 Arizona study (MRID 50642801), the results of that study indicated no treatment-related effects on plant height due to spray drift.

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[14] Robinson *et al.* (2013).

[15] *See* EPA, Summary of New Information and Analysis of Dicamba Use on Dicamba-Tolerant (DT) Cotton and Soybean Including Updated Effects Determinations for Federally Listed Threatened and Endangered Species at 49 (Nov. 1, 2018), https://beta.regulations.gov/document/EPA-HQ-OPP-2016-0187-0967 ("*2018 EFED Update*").

[16] *Id.* at 49.

[17] *Id.* at 86–87.

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Similar studies are available now from 2019 from Missouri and Wisconsin, also identifying no 5% plant height impacts beyond the following distances:[18]

- 10 meters [33 feet] (Smeda, Missouri), and
- 16 meters [52 feet] (Werle, Wisconsin).[19]

And the registrant's terms and conditions and voluntary studies conducted in 2019 showed distance to no effect on plant height[20] of:

- 10–40 meters [33–131 feet] (Illinois, MRID 51017502),
- 10–24 meters [33–79 feet] (Illinois, MRID 51111901), and
- 10–51 meters, [33–169 feet] (Mississippi, MRID 51017501). This result is highly conservative, as the transects showing the longest no-effect distances were impacted by standing water. Transects less likely impacted by standing water showed no-effect distances out to 27 meters [89 feet].[21]

Before concluding its 2018 analysis and relying upon plant height specifically, EPA had initially (and conservatively) assumed that a 20% estimate of visual symptomology might be predictive of a 5% plant height reduction.[22] This was a particularly conservative metric, given prior published conclusions that no plant height or yield impact normally occurs for soybeans until 40% or greater visual dicamba drift symptomology.[23] Indeed, as noted, a number of field tests contained data where 5% plant height reduction correlated with prior estimates of visual dicamba drift symptomology.[24] Others, however, provided dramatically different data, with estimates of

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[18] Plant height data from the 2019 Nebraska study were too variable to determine this endpoint.

[19] MRID 51134101. In addition, a 2019 study by Li (Alabama) demonstrated a smaller 5% visual symptomology boundary with VaporGrip Xtra and a 2019 Culpepper study (Georgia) found no impact on plant height beyond 50 feet.

[20] These studies used the plateau model which predicts the no-effect distance.

[21] The results of these studies are discussed in Monsanto's February 28, 2020 paper. *See generally 2020 White Paper.* A third study was conducted in southeast Missouri; however, due to the lack of plant growth observed during this study due to the late planting date as a result of persistent wet weather conditions, effects to non-tolerant soybean plants could not be assessed.

[22] *2018 EFED Update* at 79.

[23] *See supra* p. 7 (citing Kevin Bradley, https://www.missouriruralist.com/herbicide/does-dicamba-drift-cause-soybean-yield-loss.).

[24] *See, e.g., 2018 EFED Update* at 87 (Werle 2018 reported maximum distance to 5% plant height reduction at 9 meters and maximum distance to 20% visual symptomology at 10 meters; Sprague 2018 reported maximum distance to 5% plant height reduction at 10 meters and maximum distance

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visual symptomology far more distant from a dicamba spray than any observed plant height impacts.[25]

Bayer is now proposing a considerably more conservative downwind spray buffer to provide further assurance regarding drift. Specifically, based upon the data available to date, Bayer is proposing a downwind buffer of 250 feet, unless growers utilize shielded or hooded sprayers. *See infra* pp. 13–14. As the data before the agency now indicate, such a buffer should be substantially protective. For all but one study through 2019, that downwind buffer would extend further than any observation of 5% plant height reduction or 20% estimated visual symptomology. Average distances to 20% visual symptomology measurements were almost always shorter than 250 feet. Distances to 20% estimates of visual symptomology in independent academic field trials conducted prior to the 2018 registration were generally materially shorter than 250 feet:

- Average 5 meters [16 feet] (Steckel 2017, Tennessee),
- Average 4 meters [13 feet], maximum 6 meters [20 feet] (Young 2018, Indiana),
- Average 10 meters [33 feet] (Young 2017, Indiana),
- Average 9 meters [30 feet], maximum 10 meters [33 feet] (Werle 2018, Wisconsin),
- Average greater than 15 meters [49 feet] (Kruger 2018, Nebraska),[26]
- Average 7 meters [23 feet], maximum 19 meters [62 feet] (Sprague 2018, Michigan),
- Average 19 meters [62 feet] [(Bradley 2017, Missouri),
- Average 31 meters [102 feet] (Norsworthy 2017, Arkansas), and
- Average 43 meters [141 feet] (Kruger 2017, Nebraska).[27]

Consistent with these academic studies, the average and maximum distances to 20% visual symptomology estimates from Monsanto's 2018 Arizona field trial (MRID 50642801) were 4

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to 20% visual symptomology at 19 meters; Kruger 2018 reported maximum distance to 5% plant height reduction at 12 meters and average distance to 20% visual symptomology at greater than 15 meters).

[25] *Id.* at 86 (Norsworthy 2017 reported average distance to 5% plant height reduction at less than 3 meters and average distance to 20% visual symptomology at 31 meters).

[26] No measurements or observations were available for this study beyond 50 feet, so a maximum distance is not discernable.

[27] *See 2018 EFED Update* at 86–87; MRID 50681101. The Kruger 2017 study was reportedly confounded by a nearby application of dicamba, which likely explains its higher average visual symptomology distances. *See 2018 EFED Update* at 87.

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meters [13 feet] and 15 meters [49 feet].[28] Four additional registrant studies in 2019 identified the following distances to 20% visual symptomology estimates:

- Average 4 meters [13 feet], maximum 10 meters [33 feet] (Illinois, MRID 51111901),
- Average 19 meters [62 feet], maximum 33 meters [108 feet] (Illinois, MRID 51017505),
- Average 21 meters [69 feet], maximum 35 meters [115 feet] (Southeast Missouri, MRID 51017506), and
- Maximum >90 meters, [>295 feet] (Mississippi, MRID 51017504). Again, this is conservative, as the transects showing the longest distances were likely impacted by standing water. Transects less likely impacted by standing water showed 20% symptomology out to 50 meters [164 feet].

For downwind drift study data available today (as well as for volatility data described below), the principal outlier is a 2018 Arkansas study that observed 20% visual symptomology at between 20 and 82 meters [66–269 feet].[29] However, that study was conducted on a soybean field during the R1/R2 growth phase (when EPA's label does not allow spraying)—a problematic study timing because, as EPA noted in the 2018 EFED Update, plant height measurements are unreliable in this reproductive stage. As EPA acknowledged, that study did not follow the testing protocol that the academics had collectively established and reached results that were inconsistent with the other studies' conclusions.[30]

Moreover, the flux and deposition data from that study were consistent with (or even less than) the data noted above from multiple other 2018 academic studies that found far smaller distances to visual symptomology and 5% plant height reduction.[31] However, the Arkansas deposition and flux measurements only became available in 2019, so they were not available to EPA in connection with its 2018 XtendiMax registration decision. One would expect that, as the Arkansas study had similar deposition and flux results to the other studies, it would also have similar visual symptomology observations. The fact that it does not suggests that there are

[28] *See id.* at 86.

[29] *2018 EFED Update* at 86.

[30] *Id.* at 25, 86–87, 133.

[31] *See* Soltani et al., Off-Target Movement Assessment of Dicamba in North America (Jan. 31, 2020), https://doi.org/10.1017/wet.2020.17.

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problems with the Arkansas study's visual symptomology observations, and thus that they cannot confidently be relied upon.[32]

In sum, the extensive body of data on spray drift currently before EPA supports the conclusion that the proposed buffer distances should be protective of potential unreasonable adverse effects on the environment or any effects to threatened or endangered species. Again, Bayer is pleased to discuss this data and anticipates that additional data from annual studies will become available in the coming weeks. Of course, Bayer is proposing that EPA mandate that applicators use a DRA as a tank mix partner, which is a best practice to mitigate potential for spay drift. DRAs create larger droplets that minimize the potential for droplets to be carried away when the pesticide is applied. EPA has recognized the use of a DRA tank mix partner as a spray drift reduction tool.[33]

Use of Shielded or Hooded Sprayers to Further Reduce Drift

As explained, Bayer recommends that EPA provide applicators with an option to utilize shielded or hooded sprayers to further reduce drift in lieu of the expanded buffer or limits on the XtendiMax application window for soybeans. We would be pleased to discuss this option in additional detail. Hooded sprayers are devices used on application booms specifically to prevent drift by enclosing the spray to prevent exposure of the spray pattern to wind.[34] Research demonstrates significant reduction in drift with use of a hooded sprayer—especially with fine and medium droplets, but even with ultra-course droplets.[35] The figure below shows the significantly minimized spray drift with use of a hooded sprayer.

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[32] EPA inquired of the researcher "why his results were different than those in other areas of the country?" The researcher responded that he was not sure. *2018 EFED Update* at 133.

[33] EPA, Drift Reduction Technology Program, https://www.epa.gov/reducing-pesticide-drift/about-drift-reduction-technology-program.

[34] REDBALL, Redball-Hooded Spray Demo & Benefits, https://www.willmarfab.com/hood-demo.php.

[35] *See* Foster et al., The Effect of a Redball Hooded Boom on Off-Target Movement of Various Size Spray Droplets, https://www.willmarfab.com/pdf/2017-MSU-of-Neb%20-Testing_Feb-8_Rev-1-May-15-2020.pdf?nc=476700.

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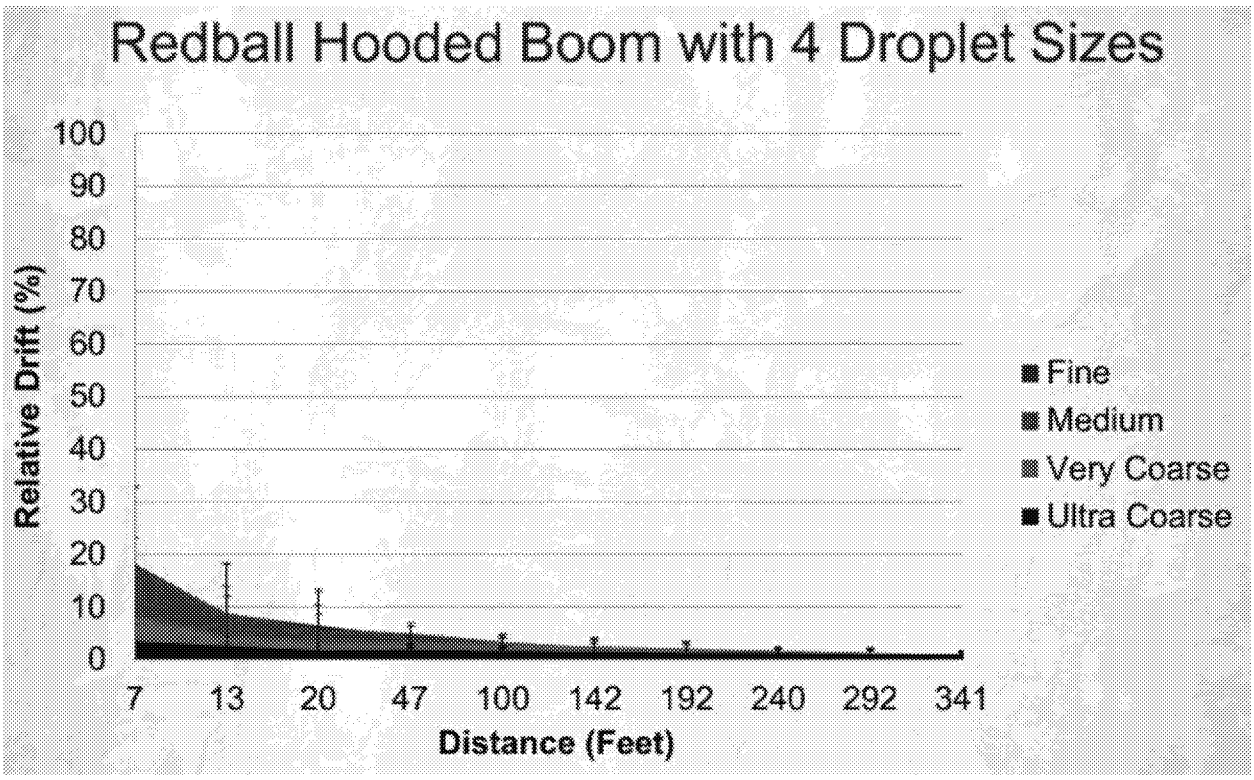

Source: Foster et al., The Effect of a Redball Hooded Boom on Off-Target Movement of Various Size Spray Droplets

Data Related to Volatility

Importantly, in addition to showing minimal downwind drift, the available studies further confirm XtendiMax's low volatility. Multiple studies found no indication of any plant height impact or visual symptomology either in a non-downwind direction or on areas tarped during spray at any significant distance from the spray, for any time period measured. To the extent any such impact was located anywhere upwind (*i.e.* not downwind), it was very close to the sprayed field. Here is as summary of those results:

- no visual symptomology observed in upwind transects (Monsanto Arizona 2018, MRID 50642801),[36]

[36] *2018 EFED Update* at 18, 20. In the Arizona study, there was some slight symptomology observed in one upwind corner of the field outside the measurement transects for this study. But this symptomology was located in the corner of the field where the sprayer exited the field after spraying.

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- no visual symptomology observed in upwind transects (Steckel 2017, Tennessee),[37]
- no visual symptomology observed in upwind transects (Young 2017, Indiana),[38]
- no visual symptomology observed in upwind transects (Young 2018, Indiana),[39]
- 0.8 meters [2.6 feet] to 20% visual symptomology upwind (Sprague 2018, Michigan),[40] and
- no visual symptomology observed in upwind transects, 9 meters [30 feet] to 5% plant height reduction (Werle 2018, Wisconsin).[41]

As explained herein, Bayer proposes that EPA mandate use of VaporGrip Xtra or another VRA as a tank-mix agent to further substantially reduce XtendiMax's already low volatility. Recent humidome testing that is being provided to EPA following this submission further confirms the significant volatility reduction potential of using VaporGrip Xtra in the tank mix VRA. On average, tank mixes with VaporGrip Xtra demonstrated a more-than-80% reduction in relative volatility, and, in many cases, lowered dicamba concentrations to below the limit of detection. Additionally, field studies conducted by the registrant and several independent academics in 2019 also indicate that this tank mix would materially reduce the potential for volatility related movement. Specifically, for every one of these studies ***there was no effect on plant height in any transects that measured volatility***.[42] Additional field testing with VaporGrip Xtra is ongoing this year and Bayer will continue to update its analysis. To address any remaining questions regarding volatility, Bayer proposes that EPA should require registrant volatility testing of VRA tank mix products before adding those products to the approved list of tank mix partners.

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[37] Summary of Confirmatory Spray Drift and Volatility Studies for XtendiMax Applications at 6–7, MRID 50681101 (Sept. 19, 2018) ("*2018 Studies Paper*").

[38] *Id.* at 4–6.

[39] EPA/EFED Analysis of plant height data from five 2018 large scale studies (indexed as Administrative Record document O.153 from administrative record for *National Family Farm Coalition v. EPA*, Case No. 19-70115 (9th Cir.)).

[40] *2018 EFED Update* at 33.

[41] *Id.* at 27–28. Norsworthy (2017, Arkansas), Bradley (2017, Missouri) and Kruger (2017 and 2018, Nebraska) did not record upwind measurements. The 2018 Arkansas study included visual symptomology for an upwind transect; however, for the reasons explained above (*supra* pp. 12–13), the 2018 Arkansas study was an outlier in both downwind drift and volatility data.

[42] Summary of Studies Conducted with MON 51817 in XtendiMax® With VaporGrip® Technology Tank Mixtures, MRID 51134101 (May 1, 2020). The maximum distance to 5% visual symptomology (an extremely low and subjective threshold) in the volatility transects was 10 meters [33 feet].

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In sum, the studies EPA considered in the 2018 registration and numerous new studies that were not in the record before the Ninth Circuit have confirmed that XtendiMax is minimally volatile and will remain within the proposed downwind buffer. The further confirmatory studies conducted since the 2018 registration, along with the reduction in volatility achieved through the use of VaporGrip Xtra as a tank-mix agent and in spray drift achieved through the use of a DRA, the increased protection of a longer downwind buffer, and the other measures proposed by Bayer, all provide support for EPA to conclude that XtendiMax does not present a risk of any unreasonable adverse effects on the environment or any effects to threatened and endangered species.

II. THE NUMBER OF DICAMBA DRIFT INQUIRIES HAS FALLEN DRAMATICALLY SINCE 2017 IN MOST STATES; INVESTIGATIONS OF SUCH INCIDENTS IDENTIFY CAUSES OTHER THAN XTENDIMAX

Drift inquiries related to dicamba are down across almost the entire country. Under the terms of its 2018 registration, Monsanto and the other registrants were required to provide EPA with reports of inquiries regarding "potential damage to non-target vegetation from use of dicamba during the 2019 and 2020 growing seasons regardless of any determination that the incident resulted from misuse . . . [and] regardless of which dicamba product may have been used and/or whether or not the alleged damage resulted from a product being used according to label directions."[43] Registrants were specifically required to "include available information regarding acreage involved, plant species involved, severity of damage, and similar information received."[44] Information from the 2020 season is still pending; many locations seem to be presenting a reduced level of inquiries this year (including, so far, Illinois[45]). But we will not have a comprehensive set of data for at least a few weeks.[46]

Putting 2020 aside, the data as a whole shows that inquiries decreased dramatically from 2017 to 2019. As Monsanto explained in its 2020 White Paper to EPA, the number of inquiries

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[43] Notice of Pesticide Registration, 524-617 at 5 (Nov. 1, 2018).

[44] *Id.*

[45] *See* Margy Eckelkamp, *Illinois Sows Dramatic Decline in Dicamba Reports*, AGWEB (July 21, 2020), https://www.agweb.com/article/illinois-shows-dramatic-decline-dicamba-reports.

[46] We note that the circumstances of this 2020 season are somewhat unique; the Ninth Circuit's decision, and in particular petitioners' attempt to persuade the court remove XtendiMax from the market, seems to have caused significant uncertainty for growers resulting in an effort by many growers to apply XtendiMax on a schedule anticipating that the court might soon make it unavailable. It is unclear how this will impact the data this year, and we anticipate a dialog on that topic in the coming weeks.

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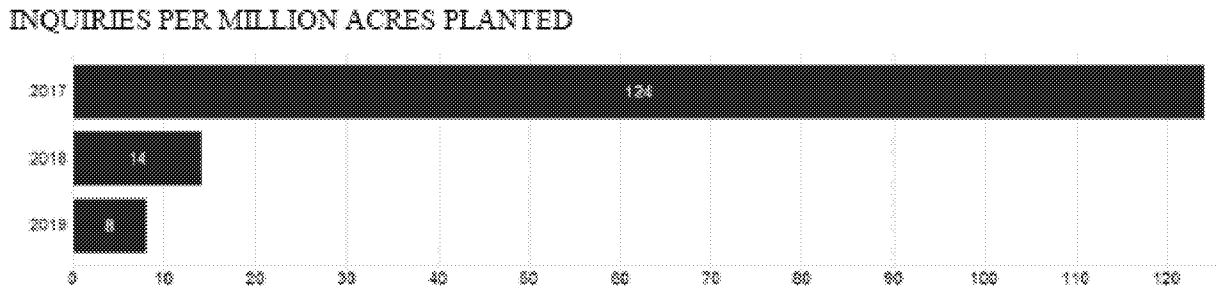
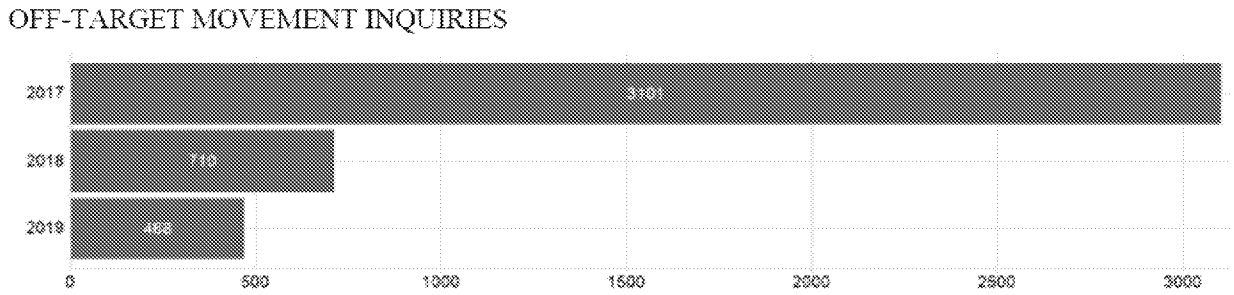
received by Monsanto regarding possible off-target movement decreased in 2019 compared to 2018 and 2017, even as Xtend soybean and cotton acreage continued to increase.[47]





This trend of decreased inquiries was consistent across the vast majority of states for which EPA approved OTT dicamba uses. The registrant received fewer off-target movement inquiries in 2019 relative to 2018 in Illinois, Indiana, Minnesota, Tennessee, and Missouri.[48] Many states for which Monsanto received inquiries in 2018, including North Dakota, South Dakota, Wisconsin, Texas, Georgia, South Carolina, Virginia, Maryland, Kentucky, and New York had zero inquiries in 2019.[49] Colorado, New Mexico, Alabama, Florida, West Virginia, Delaware, and New Jersey had no inquiries in either 2018 or 2019.[50] The only states for which Monsanto received increased inquiries in 2019 over 2018 levels were Pennsylvania, Iowa, Arizona, and Mississippi—and those numbers were *de minimis*.[51]

Publicly available data tells a similar story. Registrants have long been skeptical about the accuracy of third-party "complaint" data, both because it does not necessarily distinguish between different types of alleged pesticide drift and because it in many cases does not involve any

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[47] *2020 White Paper* at 44.

[48] *Id.*

[49] *Id.* at 44–45.

[50] *Id.* at 45.

[51] *Id.*

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meaningful examination of field conditions. But even that data shows a remarkable decrease in reports across the country. For 2017 and 2018, for example, EPA consulted data from Professor Kevin Bradley and the Association of American Pesticide Control Officials (AAPCO), respectively, to estimate drift incidents.[52] There is now AAPCO data on the 2019 growing season that shows incidents have consistently decreased in the many areas of the country. The table below demonstrates illustrative comparisons in key states, ranging from 68% to 92% reduction in 2019 over 2017 incident data for the state.

	Bradley 2017[53]	**AAPCO 2019**[54]	**Percent Reduction**
Missouri	310	98	68%
Kentucky	18	2	89%
Minnesota	250	21	92%
Tennessee	132	22	83%
South Dakota	114	14	88%
Mississippi	78	8	90%

Importantly, although AAPCO reports this incident information, AAPCO has clarified that "the organization has not advocated for the use of OTT dicamba to be cancelled or disapproved" by EPA. AAPCO has also "recognize[d] that there are states that have successfully implemented this technology, particularly in cotton."[55]

The *vast* majority of reports in recent years seem to be occurring in soybean states that also have substantial corn production. Illinois and Iowa, for example, lead the country in both soybean

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[52] EAP/BEAD Summary of 2017 & 2018 Incidents by State (reprinted at ER0529 in Case No. 19-70115 (9th Cir.)).

[53] *See* Kevin Bradley, *A Final Report on Dicamba-injured Soybean Acres* (Oct. 30, 2017), https://ipm.missouri.edu/IPCM/2017/10/final_report_dicamba_injured_soybean/ (2017 Bradley Report).

[54] *See* AAPCO 2020 Dicamba States Survey Results at 9 rows 3, 5, 12, 14, 17, 26, https://aapco.files.wordpress.com/2020/04/pdf-all-data-dicamba-april-2020.pdf (2020 AAPCO Survey).

[55] Statement of Leo A. Reed, AAPCO President (June 5, 2020), https://aapco.files.wordpress.com/2020/06/aapco-6-4-20-dicamba-statement-1.pdf.

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and corn production.[56] And in 2019 Illinois and Iowa combined for approximately 60% of AAPCO's recorded dicamba drift incidents for the entire nation.[57] By contrast, drift incidents have been almost non-existent in cotton growing states. The country's two biggest cotton-growing states are Texas (the largest by far) and Georgia.[58] But these states have registered only single-digit incidents per year.[59]

These findings are consistent with new evidence from Bayer's (and previously Monsanto's) investigations and the publicly available literature suggesting that many of the reported incidents of off-target movement are the result of using *older* dicamba formulations—particularly over corn crops—that are *not* designed to minimize volatility and that may lawfully be applied without the label restrictions mandated for XtendiMax. We also note this: an inquiry alone does not indicate that a field has suffered actual damage or sustained actual yield loss or that any damage was caused by dicamba. As the court handling almost all products-liability litigation relating to alleged dicamba drift has recently found, incident reporting data that is not verified with an on-site investigation is inherently unreliable. Rather, "individual investigation of a given field is required to determine" the cause of an alleged incident.[60] The court's finding is logical because a complaint does not necessarily equate to actual damage from XtendiMax drift.[61] Thus, an actual investigation is necessary to determine what occurred at the particular field, with specific follow-up review to determine (1) what, if any, symptomology was related to dicamba (as opposed to 2,4-

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[56] *See, e.g.*, USDA, 2019 Agricultural Statistics Annual, Chapter 1 – Grain & Feed – at Tbl. 1-36, https://www.nass.usda.gov/Publications/Ag_Statistics/2019/chapter01.pdf; USDA, 2019 Agricultural Statistics Annual, Chapter 3 – Oilseeds, Fats, & Oils – at Tbl. 3-32, https://www.nass.usda.gov/Publications/Ag_Statistics/2019/chapter03.pdf.

[57] AAPCO Survey at 9 rows 1, 6.

[58] *See, e.g.*, USDA, 2019 Agricultural Statistics Annual, Chapter 2 – Cotton, Tobacco, Sugar Crops & Honey – at Tbl. 2-3, https://www.nass.usda.gov/Publications/Ag_Statistics/2019/Chapter02.pdf.

[59] *See* 2017 Bradley Report (0 complaints in Georgia); 2020 AAPCO Report at 9 row 2 (6 complaints in Texas in 2019).

[60] *See In re Dicamba Herbicides Litig.*, 2019 WL 6340260, at *7 (E.D. Mo. Nov. 27, 2019).

[61] The Ninth Circuit's opinion cited and quoted the conclusions of Dr. Ford Baldwin, but Dr. Baldwin's expert testimony assuming dicamba injury from un-investigated alleged drift incidents was deemed too speculative and thus inadmissible under the *Daubert* standard in the products-liability litigation. *See In re Dicamba Herbicides*, 2017 WL 6340260, at *9 (concluding that Baldwin's testimony was inadmissible because "there [wa]s simply too great an analytical gap between the data and the opinion [Baldwin] proffered" about off-target movement). Dr. Baldwin conceded that individual investigations may be necessary to determine whether particular symptomology was caused by dicamba. Baldwin Deposition at 91, 322–23.

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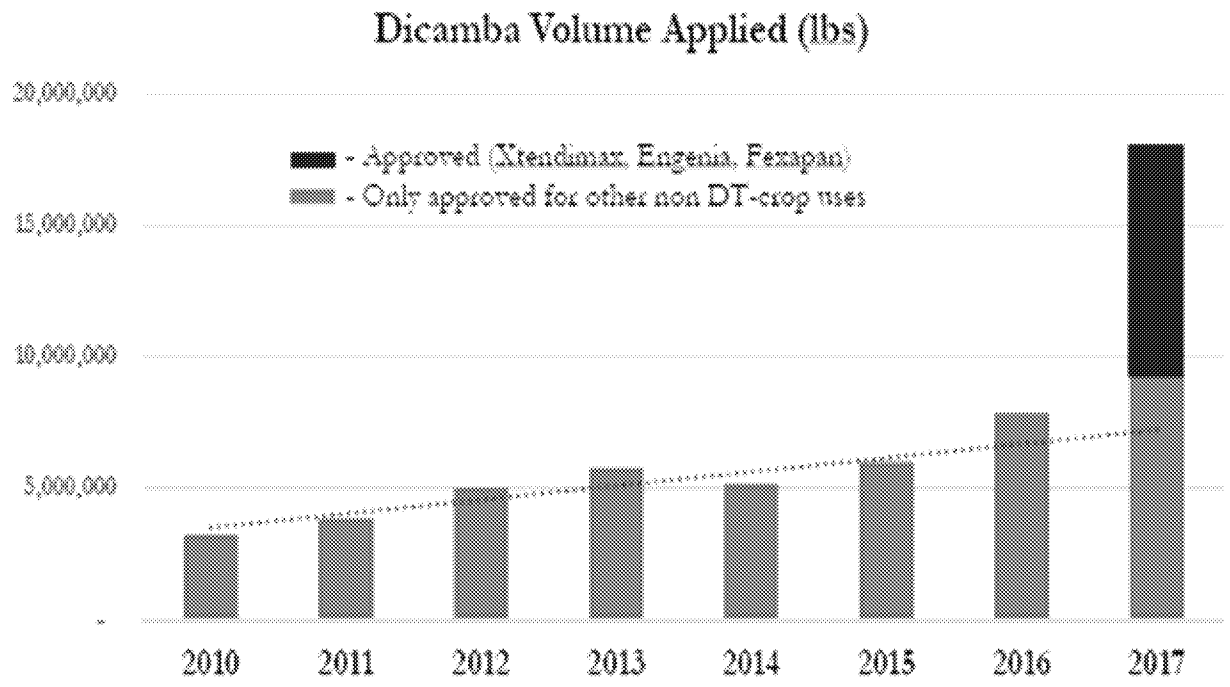
d or another cause); (2) the source of pesticide drift if any occurred; and (3) whether any yield impacts resulted (keeping in mind that levels of dicamba symptomology at 40% or lower generally do not result in any yield impact for non-tolerant soybean crops). *See infra* p. 28 (quoting a judicial ruling by Judge Limbaugh and explaining that no expert can properly generalize about the actual causes of crop damage without specifically taking these investigative actions for a given incident at a given field).

To put this critical issue in context, it is important to understand more fully the growing use of dicamba applications to address multiple herbicide-resistant weeds, including glyphosate-resistant weeds, in ***other*** crops and other agricultural and non-agricultural land—principally on corn, but also on small grains and pastureland. Unlike the dicamba formulations approved for use OTT of dicamba-tolerant crops, the conventional dicamba formulations applied for these other uses are generally not specially formulated for low volatility (as XtendiMax is) and are not subject to the highly restrictive and specialized off-target movement-reduction measures that were mandated by the XtendiMax label.

As Monsanto has previously explained,[62] sales of conventional dicamba increased significantly between 2010 and 2017, roughly doubling by 2017 (see figure below). As illustrated, conventional dicamba accounted for nearly half the total dicamba volume applied in 2017.[63]



[62] *See The Scientific Basis for Understanding the Off-Target Movement Potential of XtendiMax*, 35 (MRID 50642701) (Aug. 3, 2018) ("*2018 White Paper*").

[63] *Id.*

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The same trends of increased conventional dicamba use continued in 2018 and 2019. Data obtained from AgroTrak® (and licensed via Kynetec) demonstrate that the volume of dicamba approved for only non-DT-crop uses increased to approximately 9.9 million pounds in 2018 and 11.6 million pounds in 2019.[64]

Dicamba use on corn has increased consistent with conventional usage overall. The data from AgroTrak (licensed via Kynetec),[65] produced in graphical format in the confidential appendix, shows a substantial increase in total pounds of dicamba used on corn over relevant time periods.

In addition to the *more frequent* application over corn than in the past, this use is now *more likely* to coincide with critical growth stages of non-DT soybean crops. Although corn has historically been planted significantly earlier than soybean crops, in recent years, soybeans have been "plant[ed] earlier than ever before."[66] According to Purdue Extension, for example, "67% of Indiana growers plant soybeans one to three weeks earlier than they did 10 years ago."[67] And it is now accepted practice in Iowa, for example, that the best time to plant soybeans in the state is either the last week of April or the first week of May.[68] But that is also *the exact same time* that corn is being planted in Iowa.[69] The same trends are evident in Illinois, as demonstrated from the USDA planting progress data below.

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[64] AgroTrak (licensed via Kynetec) (included in confidential attachment). Dicamba has been used to manage weeds in corn for decades; however, with the rapid adoption of the Roundup Ready technology in corn beginning in the 1990's, growers increasingly relied on glyphosate (the active ingredient in Roundup) to control both broadleaf and grass weeds in corn. Thus, dicamba use on corn gradually decreased. As the spread of resistant weeds, including glyphosate-resistant weeds, began to increase in recent years, corn growers again returned to dicamba to manage hard-to-control broadleaf weeds. Therefore, the data demonstrate increased dicamba use in corn, both in terms of the number of corn acres sprayed with dicamba and the amount of dicamba used.

[65] AgroTrak (licensed via Kynetec) (included in confidential attachment).

[66] Terri Queck-Matzie, *Farming 101: How to Plant Soybeans* (May 5, 2019), https://www.agriculture.com/crops/soybeans/farming-101-how-to-plant-soybeans.

[67] *Id.*

[68] Palle Pederson, *Soybean Planting Date*, IOWA STATE UNIVERSITY, https://crops.extension.iastate.edu/files/article/PlantingDate_000.pdf.

[69] *See, e.g.*, The Old Farmer's Almanac, https://www.almanac.com/gardening/planting-calendar/zipcode/46077 (showing ideal planting time in Des Moines, IA to be between April 26 and May 10).

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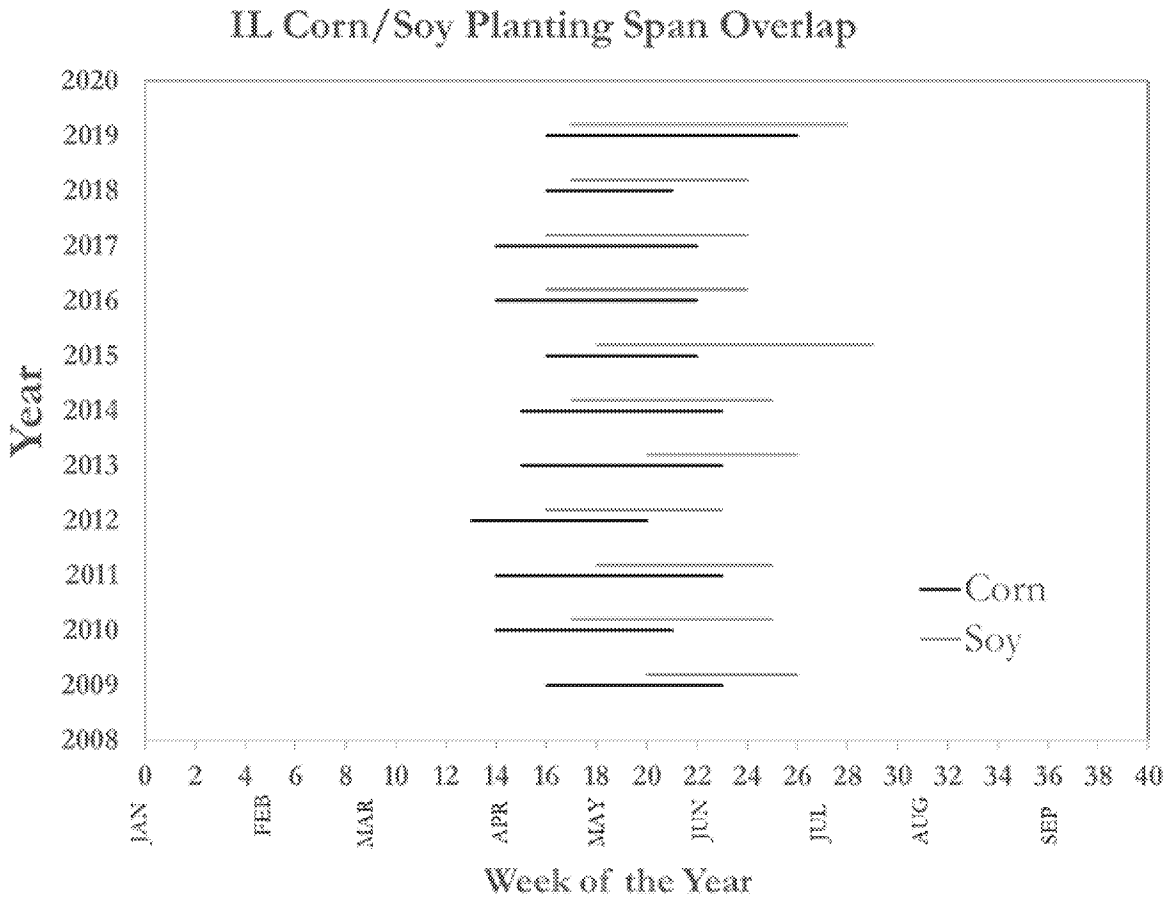

So now, with significant overlap in corn and soy planting, it appears far more likely that an application over corn could result in dicamba symptomology for neighboring non-DT soybean crops than in previous years. The current record before EPA includes significant new information from on-site investigations, demonstrating that many drift inquiries appear attributable to conventional dicamba use rather than XtendiMax, Engenia, or FeXapan. For example, in 2019 many of the inquiries Monsanto received in Illinois involved non-dicamba tolerant soybean fields that were surrounded by adjacent *corn* fields—not adjacent dicamba-tolerant soybean fields.[70] Similarly, in 86% of all inquiry fields exhibiting uniform symptomology, there was at least one corn field within 150 feet of the inquiry field.[71] In contrast, there are comparatively few verified incidents attributable to XtendiMax, Engenia, or FeXapan.

Even setting aside the cause of drift inquiries, it is highly likely that the vast majority of incidents result in minimal damage. As required under the terms of the 2018 registration, when Monsanto visited the fields of incident reports it evaluated the severity of observed symptomology.

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[70] *2020 White Paper* at 49.

[71] *Id.*

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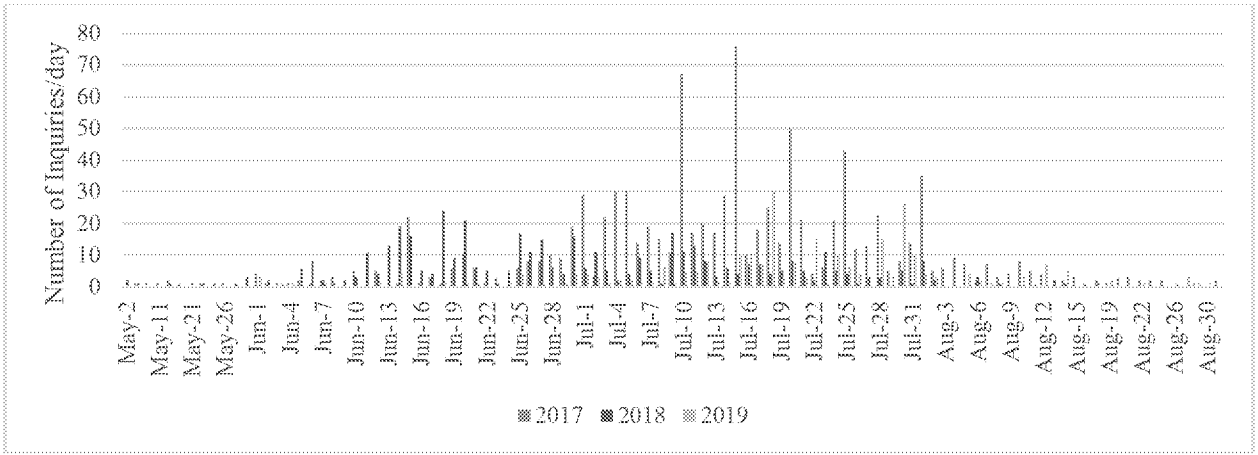
In more than 25% of fields there was *no* symptomology at all. Fewer than 20% of fields showed moderate symptomology and only 1% of fields showed severe symptomology.[72]

Importantly, as reflected in the timing of inquiries received by the registrant over the past few years, the vast majority of the inquiries tend to occur later in the soybean growing season—well after the V4 vegetative growth stage. The proposed narrowed application window would likely result in no OTT soybean applications after early- or mid-June in most instances, meaning that any impacts reported in the end of June or July would not likely relate to XtendiMax applications over soybeans. Assuming, for the sake of argument, that all of the above inquiries actually related to XtendiMax (which was not the case, as investigations demonstrated), the narrowed application window would significantly reduce those incidents. We are prepared to discuss this data in greater detail.



The Ninth Circuit's vacatur of the 2018 registrations was premised, in large measure, on reports from third-party sources that assumed off-target damage from apparent visual symptomology. The court noted, for example, that Professor Kevin Bradley reported that over three million acres of soybean acreage was "damaged" by off-field dicamba movement in 2017, and that other public reports showed what they considered a large increase in dicamba drift reports in 2017 and 2018 over prior years.[73] The record before the Court was limited at the time to information from those specific prior years. But now there is ample evidence before EPA demonstrating that even under an extremely conservative approach (*i.e.*, assuming that most or all reports related to XtendiMax drift instead of conventional dicamba), the number of such drift-related reports or inquiries peaked in 2017 and has dramatically decreased since that time. The Ninth Circuit also faulted EPA for "understat[ing] the DT seed acreage that had been planted in 2018, and therefore the amount of dicamba herbicide" that would be sprayed.[74] But, again, the incident reports show that even using an extremely conservative approach, any possible damage

[72] *Id.* at 46–47.

[73] *Nat'l Family Farm Coalition v.* EPA, 960 F.3d 1120, 1127, 1137 (9th Cir. 2020) ("*NFFC*").

[74] *Id.* at 1136.

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from OTT dicamba has *decreased*—regardless of an increase in DT seed acreage or use of dicamba herbicide. In short, there has been no correlation in increased use of OTT dicamba and incidents; if anything, the opposite has occurred as growers and applicators have become increasingly familiar with the technology and as specialized training required now for certified applicators (who, since 2018, are the only people who can apply the product) has had its intended impact in many areas. *See infra* p. 40.

Relatedly, the Ninth Circuit concluded that complaints from the field may have "understated the amount of dicamba damage" because, for example, many incidents go unreported.[75] But the Ninth Circuit's conclusion was based on the flawed premise that no complaints were attributable to dicamba use over corn. EPA can expressly address whether complaints are being under-reported, but it should likewise correct the court's misperception about conventional dicamba use over corn (and other crops and fields) in order to illustrate that incident reports might in fact *overstate* the frequency of off-target movement from OTT dicamba when label directions are followed. The data clearly shows that conventional dicamba is being applied more frequently to corn now than it was in the past, contrary to the court's suspicions.[76] Even opponents of this technology acknowledge that the impact of conventional dicamba applications over corn has been a relevant part of any analysis of drift in states where corn is grown. In addition, data available through enhanced terms and conditions reporting, which was not part of the record the Ninth Circuit reviewed, supports the conclusion that the increase in conventional dicamba use over corn is responsible for increased injury to non-DT soybeans. This evidence casts significant doubt on the Ninth Circuit's concerns over the lack of "supporting evidence" that "herbicide use on corn fields was at fault" for the increased number of drift incidents in 2017 and 2018.[77]

III. DRIFT INQUIRIES REQUIRE INVESTIGATION BEFORE ANY RELIABLE CONCLUSION CAN BE DRAWN ABOUT DAMAGE—USDA DATA SHOWS STEADY OR INCREASED SOYBEAN YIELDS IN MANY STATES WITH THE HIGHEST VOLUME OF INQUIRIES

Separate from what is actually *causing* incident reports, there is no way to know whether a report correlates with *damage* without actually visiting the affected field—and it is frequently the case that even visible symptomology does not result in any actual loss (*i.e.*, yield reduction or other economic harm).[78] In the context of products-liability litigation relating to alleged dicamba drift, a court recently noted that incident reporting data that is not verified with an on-site investigation is inherently unreliable. This individual review is necessary to determine whether

[75] *Id.* at 1137.

[76] *Id.* at 1135 (relying upon the inaccurate assumption that "use of the older formulations of dicamba on corn had been falling in recent years").

[77] *Id.*

[78] *See supra* pp. 7–8.

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any actually occurring symptomology is significant enough to cause damage and effect yields, because "[s]ymptomology may or may not [] result in yield loss."[79] Indeed, recent data shows strong soybean yields even in areas which had significant numbers of drift inquiries. In particular, data published by the USDA[80] shows no decrease in average soybean yields per acre in the three years following registration approval compared to the three years preceding it.[81] In fact, several states, including Alabama, Arkansas, Illinois, Mississippi, New York, North Carolina, Ohio, and South Carolina, all set new state records for soybean yield per acre following EPA approval of OTT dicamba use.[82]

Yields were strong even in states where growers reported high numbers of off-target movement inquiries. For example, according to Professor Bradley's 2017 data, Arkansas and Missouri received the highest number of reports about off-target dicamba incidents. But each state also saw extremely positive soybean and cotton yields per acre that year. As Monsanto's 2018 White Paper indicated, USDA data shows that Arkansas experienced record soybean yields in 2017, although Arkansas accounted for roughly 36% of nationwide inquiries that year.[83] And at a more granular level, *every one* of the ten Arkansas counties that experienced the most off-target drift likewise experienced soybean yield increases over 2016 levels.[84] Missouri was similar. Missouri's soybean production is concentrated in the southeastern portion of the state in an area known as the "boot heel," and Professor Bradley's data shows that 2017 incident reports were also concentrated in that area.[85] But every single boot heel county experienced a soybean yield per

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[79] Baldwin Deposition at 297. Bayer recently announced that it has agreed in principle to resolve the dicamba Multi-District Litigation. Pursuant to the settlement, claimants seeking settlement payments will not be eligible to recover unless they produce contemporaneous documents showing that they sustained a yield loss on particular fields (compared to an appropriate benchmark for yield in the relevant location) as a result of dicamba applied over dicamba-tolerant crops.

[80] National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited June 28, 2020) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Level: National; State: US Total; Select Time: 2014 to 2019; Period Type: Annual; Period: Year) (averaging 49.1 bu/acre for each three-year span).

[81] The 2017–2019 average was poised to be *substantially* greater than the preceding three-year average, but unusually challenging weather conditions in 2019 significantly impeded national soybean production, including in states that have experienced literally no dicamba off-target complaints. *See 2020 White Paper* at 43.

[82] *See id.* at 41–42.

[83] *See 2018 White Paper* at 28.

[84] *Id.* at 29.

[85] *Id.*

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acre increase over 2016.[86] Cotton and soybean yields also increased in Arkansas and Missouri on a per-acre basis. Illinois, which accounted for approximately 26% of all the nationwide inquiries to Monsanto related to alleged dicamba off-target movement in the 2018 growing season, experienced the highest soybean yields per acre in the state's history that same year.[87] The two Illinois counties which produced the greatest number of off-target movement inquiries in 2018 reported dramatic yield-per-acre increases of 11% and 35.5%.[88] EPA should consider the strong yields in these states and across the country as evidence that number of inquiries is not a reliable indicator of negative impacts on off-target crops.[89]

The Ninth Circuit's decision to focus on alleged dicamba-related reports (*i.e.*, symptomology), rather than looking to actual yield data, led it to overestimate the risks of dicamba usage.[90] As discussed above, research from Professor Kevin Bradley, the registrant, and others has shown that anything less than 40% visual symptomology from dicamba exposure in soybean plants does not generally result in any significant yield impact. *See supra* p. 7.

Judge Limbaugh in the dicamba drift litigation was thus correct to exclude plaintiffs' yield loss expert in the dicamba multi-district litigation in part due to data from his own analysis that showed no statistical correlation between dicamba exposure and reduced yields.[91] And although the Ninth Circuit's decision credited the views of Dr. Ford Baldwin, Judge Limbaugh granted a motion preventing Dr. Baldwin's testimony in the dicamba drift litigation because his "opinions related to dicamba injuries to fields he has not visited" and it appeared to the court "there is simply

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[86] *Id.* at 29–30.

[87] National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited June 28, 2020) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Level: State; State: Illinois; Select Time: 2011 to 2018; Period Type: Annual) (showing soybean yields increasing to 63.5 bu/acre in 2018).

[88] *See 2020 White Paper* at 41–42.

[89] Even at the finest level of granularity, the argument that off-target drift causes economic harm is speculative. For example, the bellwether plaintiff in the nationwide dicamba drift litigation alleged that dicamba drift injured his peach orchards. But, even though he won a jury verdict, as a purely factual matter there is substantial uncertainty whether his orchard field experienced *any* damage. He admitted he did not lose profits from 2015 through 2018, the period when drift allegedly occurred. *See* Case No. 1:16-cv-00299-SNLJ, Dkt No. 580 at 38 (E.D. Mo.). And in 2019 his peach production increased by over ***400%*** from the previous year. *Id.* at 35–36.

[90] *See NFFC*, 960 F.3d at 1137–38.

[91] *In re: Dicamba Herbicides Litig.*, No. 1:18-md-2820 (E.D. Mo. filed Feb. 1, 2018), ECF #519 at 10.

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too great an analytical gap between the data and the opinion proffered."[92] Overall, the strong soybean yield data from the past three growing seasons should give EPA confidence to conclude that OTT dicamba does not present a threat to non-DT soybeans.

IV. DICAMBA IS A CRITICAL ELEMENT OF GROWERS' STRATEGY TO ADDRESS GLYPHOSATE-RESISTANT WEEDS AND MAINTAIN YIELDS

It is critical that farmers continue to have *multiple* modes of action to address glyphosate-resistant weeds and other resistant weeds. According to EPA, "[h]erbicide resistance has become a significant financial, production and pest management issue for many cotton and soybean growers, and agriculture as an industry."[93] And there is a "need in the agricultural community for additional tools to manage resistant weeds."[94]

For these reasons, the grower community has shown significant support for continued access to XtendiMax as an additional mode of action to combat herbicide-resistant weeds. Cotton growers, for example, have explained that Palmer amaranth is common in their fields and has "developed resistance to multiple herbicides, including pyrthiobac-sodium [Group 2 – ALS inhibiting herbicides] and glyphosate."[95] It is important to note that a published population of 2,4-D-resistant Palmer amaranth species was identified in 2015.[96] Dicamba is highly effective at treating Palmer amaranth, and new modes of action are not expected to enter the market anytime soon. "[T]he importance of dicamba" to growers therefore "cannot be overstated."[97] Likewise, when the Ninth Circuit vacated the previous registration, multiple stakeholders submitted letters explaining the substantial consequences that would follow if this product were taken off the market. The National Cotton Council emphasized that [t]he few herbicide [MOAs] viable for today's weed management are at risk due to resistance development. [And] [t]he loss of dicamba will result in a loss of herbicide control due to the lack of a MOA that forces overuse of the remaining MOAs."[98] The American Farm Bureau Federation explained that farmers literally do

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[92] *Id.* at 20 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

[93] Registration Decision for the Continuation of Uses of Dicamba on Dicamba Tolerant Cotton and Soybean at 13 (Oct. 31, 2018) ("*2018 Dicamba Registration*").

[94] *Id.*

[95] *See* Nat'l Cotton Council Amicus Br. at 3, ECF No. 118-2, Case No. 17-70196 (9th Cir.) (NCC Amicus).

[96] *See* http://weedscience.org/Pages/filter.aspx (under "Herbicides" select "2,4-D" and enter "Search").

[97] NCC Amicus at 4.

[98] Existing Stocks Order at 7.

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"not know how they will protect their crops."[99] And the American Soybean Association explained that farmers would be subject to "potentially billions of dollars in exposure to damaging weeds [] that have few or no other treatment options."[100]

Relatedly, "[w]ithout this crucial technology, growers would likely be forced to revert to older, costlier, and less-effective methods of weed control, including tillage"[101]—practices that generally have not been needed since glyphosate-resistant crops were first introduced. "Tillage reduction benefits growers and increases farm efficiency by reducing fuel and labor costs, soil erosion, and water consumption."[102] But "[n]o-till farming depends on effective herbicide-based weed control, so many growers facing glyphosate-resistant weeds are increasing their reliance on conventional tillage and employing increasingly aggressive tillage practices."[103] Without dicamba, farmers may be forced to return to conventional tilling. This would be damaging not only for their yields, but also for the environment.[104] As the USDA has recognized, tilling results in "reduced soil quality from increased erosion; reduced air quality from increased air particulates and increased exhaust emissions from farm equipment; reduced water quality from the release and mobilization of sediments, nutrients, and other chemicals into surface and groundwater; increased greenhouse gases from burning additional fossil fuels and releases of sequestered carbon from disrupted soil; and reduced biodiversity from habitat loss."[105]

Many other agricultural entities and even individual growers have submitted substantially similar comments to EPA repeatedly throughout both of the previous registration approval proceedings. For example, the Tennessee Soybean Association has explained that its members have "been in a tremendous struggle with resistant weeds, especially *Palmer Amaranth*," and that

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[99] *Id.*

[100] *Id.* at 9.

[101] *See* NCC Amicus at 6.

[102] American Soybean Association and American Sugarbeet Growers Association Amicus Br. at 14, ECF No. 126-2, Case No. 17-70196 (9th Cir.).

[103] *Id.* at 19.

[104] *See, e.g.*, Mahdi Al-Kaisi, Frequent Tillage and Its Impact on Soil Quality, IOWA STATE UNIV. INTEGRATED CROP MGM'T, https://crops.extension.iastate.edu/encyclopedia/frequent-tillage-and-its-impact-soil-quality; Jonathan P. Scoll, *The Soil Microbes In Your Future*, 29-SUM NAT. RESOURCES & ENV'T 53, 54 (2014) ("Tillage practices—particularly plowing—expose topsoil and makes it vulnerable to erosion by wind or rain at a rate tens to hundreds of times faster than by nature alone. Dust bowls and deserts are the end result.").

[105] USDA, Monsanto Petitions for Determinations of Nonregulated Status for Dicamba-Resistant Soybean and Cotton Varieties, Final Environmental Impact Statement at ix (2014), https://www.aphis.usda.gov/brs/aphisdocs/dicamba_feis.pdf.

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without this technology its members' "crop losses would be catastrophic."[106] And the Texas Farm Bureau explained that with this technology on the market it had "heard nothing but good things from producers regarding weed control and off-target movement."[107] For ease of reference, Bayer will assemble and resubmit to EPA the dozens of key grower and grower-organization comments to the agency since 2016. Those comments, in combination with the text of EPA's recent Existing Stocks Order, demonstrate beyond question the importance of this technology to growers across the states where it is registered. And in addition to that material, we also urge EPA to analyze the other publicly available statements by independent academics and state agricultural leaders that demonstrate the wide level of support for this technology.[108] In sum, and as the available record amply reflects, almost all voices in the community understand the importance of these dicamba herbicides as an additional mode of action critical for effective weed control.

The facts overwhelmingly support the sentiment expressed by key stakeholders. Over time, herbicide resistance in certain weed species has developed. Growers have needed to continue to adapt and implement evolving weed-management strategies. These types of adaptations in resistance management strategies are not new, as weed resistance has occurred for decades—beginning well before the introduction of herbicide-tolerant crops. In addition, and more recently, there has been an increase in the detection of weed populations with resistance to multiple herbicidal sites of action (multiple resistance) in certain weed species: for example, Amaranthus spp.[109]

The emergence of biotypes with multiple resistance demonstrates that there is a critical need for additional herbicidal sites of action that are effective in major crops. And several of the

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[106] Undated Letter from James H, Dodson, Tennessee Soybean Association, to Acting Administrator Wheeler.

[107] Letter from Brant Wilbourn, Associate Director of Texas Farm Bureau, to Rick P. Keigwin (Aug. 6, 2018).

[108] *See, e.g.*, Clint Thompson, *EPA Decision Helpful for Farmers with Dicamba in Stock*, SOUTHEAST AGNET (June 9, 2020), http://southeastagnet.com/2020/06/09/epa-decision-farmers-dicamba/ (University of Georgia weed scientist Stanley Culpepper recognizing a lack of OTT dicamba would be "catastrophic" and its availability is important "to control the most problematic weed or pest in the state of Georgia, palmer amaranth"); Staff Report, *Officials: Herbicide restrictions could harm S.C. cotton and soybean harvest*, GSA BUSINESS REPORT (June 10, 2020), https://gsabusiness.com/news/agriculture/78675/ (multiple "[o]fficials with Clemson University's Department of Pesticide Regulation warn that [lack of OTT dicamba] could devastate South Carolina's cotton and soybean harvest").

[109] Tranel, P.J., C.W. Riggins, M.S. Bell and A.G. Hager. 2010. Herbicide resistances in Amaranthus tuberculatus: A call for new options. Journal of Agricultural and Food Chemistry 59:5808-5812.

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well-established practices for combatting weed resistance confirm that dicamba is a critical and necessary tool for farmers. The Weed Science Society of America (WSSA) has compiled peer-reviewed best management practices to reduce the risk of weeds developing herbicide resistance.[110] The authors advise growers to "(u)se a diversified approach toward weed management focused on preventing weed seed production and reducing the number of weed seeds in the soil seedbank" and "(u)se multiple herbicide MOAs that are effective against the most troublesome weeds or those most prone to herbicide resistance."[111] And other experts have similarly observed that simultaneously using two herbicides with different mechanisms of action significantly reduces the probability of weeds developing resistance to either or both herbicides.[112]

Dicamba-tolerant weed-management systems are used in combination with other herbicides including glyphosate, glufosinate, and other soil residual and post-emergence active herbicides currently labeled for use in either soybeans or cotton. Dicamba is an excellent option to mitigate the potential for resistance to other herbicides because of its broad spectrum activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean and cotton acres. Dicamba is a synthetic auxin herbicide that kills plants by mimicking naturally-occurring plant growth hormones called auxins, thereby destroying tissue through uncontrolled cell division and growth.[113] Dicamba's mechanism of action is different from glyphosate, provides efficacious control of broadleaf weeds, and is complementary to glyphosate on hard to control weeds such as common lambsquarters, hemp sesbania, morning glory species, nightshade, Pennsylvania smartweed, prickly sida, velvetleaf, waterhemp, and wild buckwheat.[114] Additionally, dicamba provides effective control of herbicide-resistant broadleaf weeds, including glyphosate-resistant weeds such as marestail, common ragweed, giant ragweed, waterhemp, and, in particular, Palmer amaranth.[115] As of June 2020, 514 herbicide-resistant weed biotypes have been reported to be resistant to 23 different herbicide mechanisms-of-action

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[110] Weed Science Society of America, "Herbicide Resistance," http://wssa.net/wssa/weed/resistance/.

[111] *Id.*

[112] Powles, S.B., C. Preston, I.B. Bryan and A.R. Jutsum. 1996. Herbicide resistance: Impact and management. Pages 57–93 in Advances in Agronomy. Volume 58. D.L. Sparks (ed.). Academic Press, San Diego, California; Beckie, H.J. and X. Reboud. 2009. Selecting for weed resistance: Herbicide rotation and mixture Weed Technology 23:363–370.

[113] Ahrens, W.H. 1994. Dicamba. 3,6-dichloro-2-methoxybenzoic acid. Pages 91–94 in Herbicide Handbook. Seventh Edition. Weed Science Society of America, Champaign, Illinois.

[114] Johnson et al., Weed control in dicamba-resistant soybeans (Sept. 20, 2020), https://acsess.onlinelibrary.wiley.com/doi/abs/10.1094/CM-2010-0920-01-RS.

[115] *Id.*

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worldwide.[116] But dicamba-resistant weeds account for only 1% of resistant biotypes.[117] Growers and applicators have communicated their significant need to use dicamba herbicides in many recent letters and comments. *See supra* pp. 28–30.

In addition, removing this critical tool would create significant problems throughout the grower supply chain and the broader agricultural market for soybean and cotton.

As background, over the past decade, breeding of dicamba-tolerant seed lines has produced critical yield gains. This is attributed not just to effective weed control, but also to the advanced breeding of high yielding genetics (germplasm) over multiple years, along with specialized crosses with genetics for appropriate disease resistance for each region. For example, Roundup Ready Xtend Soybeans are currently planted on over 40M acres in the United States. Bayer currently supplies a diverse set of germplasm (over 400 products) that are planted on nearly half those acres. And over 150 independent seed companies rely on Bayer for a supply of traits and diverse germplasm. As a result of this specialized breeding program, growers can realize substantial year-over-year yield gains.

Seed breeding is a time-consuming process. Every year seed breeders make predictions both about what disease-resistance traits are needed and how specifically to breed them to maximize yield. This necessarily requires a multi-year planning cycle. Bayer's next-generation dicamba-tolerant seed that will be available nationwide for 2021, for example (XtendFlex Soybeans), was bred over multiple seasons based on the assumption that the subject dicamba herbicides would be on the market and available. We anticipate that XtendFlex Soybeans will be available in sufficient quantities to be planted on nearly ~20M acres in 2021, and a significant number of independent seed companies are currently building supply of XtendFlex products to enable this launch.

If the dicamba herbicides at issue here is not available to growers to combat weed resistance in 2021, growers may instead seek other available seed varieties. However, it is important that growers use seed with the appropriate germplasm to both maximize yield and address disease resistance threats in 2021 and beyond.[118] Other companies (such as Corteva) could theoretically supply a sufficient volume of soybean seeds resistant to 2,4-D by 2022 in a limited number of products. However, reliance on a single mode of pesticidal action could pose resistance risks.[119]

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[116] *See* http://www.weedscience.org/Home.aspx.

[117] *Id.*

[118] As you may know, many cases were filed in 2017 alleging that dicamba-tolerant traits in then-available seed—before low-volatility herbicides were approved by EPA—induced many growers to use higher volatility conventional dicamba products on those crops. *See In re Dicamba Herbicides*, MDL No. 2820 (including 11 cases filed in 2017 or before).

[119] *See supra* pp. 30–32.

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Nor is it likely that Corteva or any competitor could breed the mix of regional varieties of high yield disease resistant seed required for 2021, much less for 2022 or 2023. Lack of diversity itself could put the national soybean supply at substantial risk.[120]

V. EPA'S PREVIOUS DETERMINATION THAT DICAMBA IS NOT LIKELY A HUMAN CARCINOGEN REMAINS SUPPORTED BY THE SCIENCE

EPA has a long record of assessing the human safety of herbicides including dicamba. It has conducted robust and thorough reviews of the available toxicity data for dicamba as part of its registration and re-registration requirements over many years. An important aspect of these reviews is a weight-of-evidence assessment and classification of carcinogenic potential, using available data from studies in experimental animals, mechanistic data (e.g., genotoxicity studies), and consideration of epidemiologic evidence published in the peer-reviewed biomedical literature. EPA, in its record of such reviews, has consistently found dicamba to be not carcinogenic in experimental animals and has repeatedly, including in its most recent review,[121] classified dicamba as "**not likely to be carcinogenic to humans**":

> *In accordance with the EPA Final Guidelines for Carcinogen Risk Assessment (March 29, 2005), dicamba is classified as "not likely to be carcinogenic to humans." This decision was based on the lack of findings in the cancer studies in rats and mice which were tested at adequate dose levels to assess the carcinogenicity of dicamba (TXR No. 0053647). Mutagenicity studies generally did not demonstrate evidence of mutagenic potential for dicamba although some positive results were reported in vitro. Dicamba acid and the dicamba BAPMA salt both induced chromosomal aberrations in human lymphocytes in vitro, however, genotoxicity was negative in vivo in the mouse micronucleus assay, thus the concern for genotoxicity for dicamba or its salts is low. The BAPMA base was negative for genotoxicity in bacteria, but positive for genotoxicity based on in vitro mammalian cell culture. Additionally, the DCSA metabolite also had a lack of findings in a chronic/carcinogenicity study in rats.*

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120 https://www.ars.usda.gov/ARSUserFiles/60663500/Publications/Bruns/2017/Bruns_2017_Corn%20Leaf%20Blight.pdf

https://www.apsnet.org/edcenter/disimpactmngmnt/labexercises/PlantBiotechnology/Pages/History.aspx#:~:text=Southern%20corn%20leaf%20blight%2C%20caused,one%20genotype%20of%20a%20crop.&text=The%20losses%20of%20corn%20were,some%20areas%20of%20the%20U.S.

121 Dicamba and Dicamba BAPMA Salt: Human-Health Risk Assessment for Proposed Section 3 New Uses on Dicamba-tolerant Cotton and Soybean, March 26, 2016.

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EPA's determinations on human health risks, specifically with regard to the lack of carcinogenic risk to humans, are consistent with those of science-based reviews by regulatory authorities around the world, including the European Food Safety Authority,[122] the Canadian Pest Management Regulatory Authority,[123] Japan's Food Safety Commission,[124] and the World Health Organization's Joint Meeting on Pesticide Residues.[125]

The 2016 EPA assessment cited the conclusions of a peer-reviewed publication of an analysis of the Agricultural Health Study (AHS):[126]

> *The authors concluded that 'Exposure (to dicamba) was not associated with overall cancer incidence nor were there strong associations with any specific type of cancer.' More specifically, no statistically significant associations were seen using intensity-weighted lifetime exposure days and the "No exposure" group as a referent category. While a trend was apparent (p = 0.02), none of the individual point estimates was significantly elevated and the authors state that this result is due largely due to elevated risk at the highest exposure level.*

Started in 1993, the AHS is a prospective cohort study of 57,310 licensed private and commercial pesticide applicators and their spouses in North Carolina and Iowa. At enrollment, participants completed a questionnaire about pesticide usage, protective equipment, mixing/loading practices, and area treated. For participants who were also involved in agriculture, questionnaires included information about crops and livestock. This round of questionnaires ran from 1993 to 1997. Participants filled out a second questionnaire from 1999 to 2005. At the time of the second questionnaire, there was a 63% completion rate. The investigators used a standard multiple imputation methodology, which they independently validated for the AHS, to obtain updated information for the remaining members of the cohort.

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[122] European Food Safety Authority. (2011). Conclusion on the peer review of the pesticide risk assessment of the active substance dicamba.

[123] Health Canada Pest Management Regulatory Authority. (2008). Re-evaluation Decision Dicamba RVD2008-28.

[124] Pesticides Expert Committee, Food Safety Commission of Japan, Dicamba Assessment Report (Oct. 2012).

[125] Joint FAO/WHO Meeting on Pesticide Residues. (2010). Pesticide residues in food — 2010 Toxicological evaluations.

[126] Samanic, C., Rusiecki, J., Dosemeci, M., Hou, L., Hoppin, J., Sandler, D., Lubin, J., Blair, A., and Alavanja, M. 2006. Cancer Incidence among Pesticide Applicators Exposed to Dicamba in the Agricultural Health Study. *Environmental Health Perspectives.* 114:1521–15.

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An important component of environmental epidemiology studies is assessment and quantification of exposure. In studies of the AHS, authors estimate exposure to pesticides using "lifetime intensity-weighted days of use," combining information regarding frequency of equipment repair and cleaning, application methods, whether the applicator mixed pesticides, and personal protective equipment use with assumptions regarding days of exposure depending on crops treated. These calculated measures of exposure are then stratified in various ways to examine potential dose-response relationships in outcomes.

An analysis of the available epidemiology studies with dicamba from the AHS has yielded no consistent associations between exposure and cancer risk. As indicated below, the findings are varied among studies, likely due to the small number of cases identified in most of the studies.

For example, Alavanja et al. (2004),[127] in investigating pesticides and lung cancer risk, reported lower lung cancer risk in the lowest exposure category for dicamba, compared with those never exposed. A significant trend in lung cancer was observed with increasing lifetime days of use only when the lowest-exposure group was used as the reference, but not when the no-exposure group was the reference.

In a later analysis of AHS cohort data specific to dicamba use, Samanic et al. (2006)[128] found exposure to dicamba was not associated with overall cancer incidence nor were there strong associations with any specific type of cancer. However, like Alavanja et al. (2004), dicamba appeared to be protective against lung cancer when the referent group was unexposed. When the reference group was the lowest-exposed applicators, a positive trend in risk between lifetime exposure days and lung cancer was observed. Samanic et al. (2006) also reported significant trends of increasing risk for colon cancer for both lifetime exposure days and intensity-weighted lifetime days although there was no dose-response relationship, indicating an absence of any dicamba-related increase in cancer risk.

The findings for lung cancer from Alavanja et al. and Samanic et al. were early analyses of the AHS data based solely on responses to the first questionnaire and with shorter follow-up for cancer outcomes. Samanic et al. noted in their conclusions, "We did not detect much evidence for an association between dicamba exposure and any of the cancer sites investigated, but the patterns of associations observed for lung and colon cancers warrant further attention."

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[127] Alavanja, M.C.R., Dosemeci, M., Samanic, C., Lubin, J., Lynch, C.F., Knott, C., Barker, J., Hoppin, J.A., Sandler, D.P., Coble, J., Thomas, K., and Blair, A. 2004. Pesticides and lung cancer risk in the Agricultural Health Study cohort. *American Journal of Epidemiology.* 160:876-885.

[128] Samanic, C., Rusiecki, J., Dosemeci, M., Hou, L., Hoppin, J.A., Sandler, D.P., Lubin, J., Blair, A., and Alavanja, M.C.R. 2006. Cancer Incidence among Pesticide Applicators Exposed to Dicamba in the Agricultural Health Study. *Environmental Health Perspectives.*114:1521–15.

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Bonner et al. (2018)[129] followed up on the lung cancer findings from Alavanja et al. and Samanic et al. with additional exposure information from the second survey and with longer follow-up. Bonner et al. did not report a positive association between dicamba use and lung cancer. Given the findings in Bonner et al., the earlier findings from the same cohort in Alavanja et al. and Samanic et al. are no longer relevant.

The recent Lerro et al. (2020)[130] publication is an additional follow up analysis that provides the most up to date analysis of dicamba use and cancer incidence for the AHS cohort. These authors confirmed the finding of no association between dicamba use and lung cancer from Bonner et al. and further found no association between dicamba use and colon cancer. The statistically significant findings that Lerro et al. report are a mix of positive and negative associations between dicamba use and various cancers with low incidences. Each of these trends used the low exposure group rather than unexposed as a reference group.

All cancers with either positive or negative trends had fewer than 200 total cases out of 49,992 participants except for kidney cancer (261 total cases), for which a trend was found only in the 20-year lagged analysis. Although the study noted positive trends for combined liver and intrahepatic bile duct cancer and/or intrahepatic bile duct cancer, further analysis of that data showed that this finding was driven solely by the intrahepatic bile duct cancer data, for which there were only 16 total cases.

For six of the ten tumors with statistically significant positive trends, there was a decrease in risk ratios among low use groups compared to nonusers. This was the case for liver and intrahepatic bile duct cancers (0.32) and chronic lymphocytic leukemia (0.74) by quartile of use, liver and intrahepatic bile duct cancers after 10- and 20-year lags (0.45 and 0.65, respectively), kidney tumors after a 20 year lag (0.99), and mantle cell lymphoma after a 20 year lag (0.94). Based upon the reported data, it appears that there may have been an overall lower incidence of chronic lymphocytic leukemia among members of the cohort exposed to dicamba as compared to those unexposed.

In their discussion, Lerro et al. note the need to take sample size into account when interpreting results, particularly those with fewer than 20 exposed cases. Intrahepatic bile duct cancer, acute lymphocytic leukemia, mantle cell lymphoma, and tonsil cancer all had fewer than 20 exposed cases.

Comparing results for lung and colon cancer from Lerro et al. (2020) with those from Samanic et al. (2006) indicates that an increased number of participants with lung or colon cancer

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[129] Bonner, M.R., Beane Freeman, L.E., Hoppin, J.A., Koutros, S., Sandler, D.P., Lynch, C.F., Hines, C.J., Thomas, K., Blair, A., and Alavanja, M.C.R. 2018. Occupational exposure to pesticides and the incidence of lung cancer in the Agricultural Health Study. *Environmental Health Perspectives*. 125:544-551.

[130] Lerro, C.C., Hofmann, J.N., Andreotti, G., Koutros, S., Parks, C.G., Blair, A., Albert, P.S., Lubin, J.H., Sandler, D.P., Beane Freeman, L.E. 2020 Dicamba use and cancer incidence in the Agricultural Health Study: An updated analysis. *International Journal of Epidemiology*. 1-12.

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allowed for a more robust analysis and resulted in the previously identified associations decreasing towards the null. Samanic et al. (2006) reported statistically significant positive trends for lung cancer and colon cancer with 147 and 135 cases, respectively. Lerro et al. (2020) reported no association for these cancers with 689 cases of lung cancer and 513 cases of colon cancer.

Given the small numbers of cancers and the changes in results for lung and colon cancers compared to the earlier publication from Samanic et al. as the number of cases increased, it is unlikely that the negative and positive associations between dicamba use and certain cancer types that Lerro et al. report are an indication that dicamba can prevent or cause these cancers. It is more likely that small sample sizes of rare cancer types produced false associations that are unlikely to be reproduced as the cohort ages and the numbers of those cancers increase, just as Lerro et al. did not reproduce the early associations that Samanic et al. reported.

As discussed, after a thorough review of the best available science, as required under FIFRA, EPA has concluded there are no risks of concern to human health when dicamba is used according to label directions, and that it is not likely to be carcinogenic in humans. For the reasons described above, the results of the recent Lerro et al. (2020) publication, while not available to the EPA during its 2018 review of dicamba, do not warrant any change in the conclusions of the current dicamba human health risk assessment that dicamba is "not likely to be carcinogenic in humans" and poses no risks of concern to human health when used according to label directions.

VI. FOR ALL THESE REASONS, THE ECONOMIC AND SOCIAL BENEFITS OF OTT DICAMBA APPROVAL FAR OUTWEIGH ANY COSTS

As all of this data shows, the benefits of OTT dicamba approval far outweigh any costs. And the most recent statements from key stakeholders show that this is more true now than ever. After the *NFFC* court vacated the 2018 registration, growers and other key stakeholders explained to EPA in concrete, economic terms how critical these products are. The National Cotton Council explained that the elimination of the products would result in at least $400 million in losses in one growing season, and that, without OTT dicamba, Palmer amaranth might cause up to 50% yield loss in cotton fields.[131] And the American Soybean Association explained that *billions* were at stake in a single season if the products were lost.[132] Elimination of the product would likely require soybean and cotton growers to use manual labor to control weeds.[133] But manual labor costs up to $60 per acre (if the labor is even available),[134] whereas EPA has already recognized that the cost to apply dicamba is approximately only $12–13 per acre.[135] Growers have also explained that the

[131] Existing Stocks Order at 8.

[132] *Id.* at 9.

[133] *Id.* at 6.

[134] *Id.*

[135] EPA, Over-the-Top Dicamba Products for Genetically Modified Cotton and Soybeans – Benefits and Impacts at 15 (Nov. 1, 2018).

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OTT dicamba registrations have substantial positive downstream economic effects. Cotton, for example, is a critical component in a number of important industries that employ over 125,000 workers and generate over $21 billion in revenue.[136] And even USDA Secretary Perdue recognized that OTT dicamba is a necessary tool to help downstream entities "feed, fuel, and clothe this nation."[137]

The Ninth Circuit nevertheless identified several additional costs that it concluded had been overlooked and should be considered going forward. As an initial matter, the panel was incorrect that FIFRA required EPA to consider these matters in the way the panel identified them. In any event, none cut against granting a new registration.

First, the Ninth Circuit concluded that EPA "failed to acknowledge a social cost that had already been experienced and was likely to increase" conflict between growers who do and do not use dicamba-tolerant soybean and cotton seeds.[138] Although it is a strained reading of FIFRA to suggest the statute compels this assessment, EPA can acknowledge this potential cost, but conclude that the evidence demonstrates that the benefit to the farming community strongly outweighs the cost of such conflict (if any) between growers. The American Soybean Association and National Cotton Council both represent growers who do *and do not* use dicamba-tolerant seeds. And both organizations support the continued availability of OTT dicamba. In addition, recent evidence shows that grower friction is decreasing, in part because of the specialized training provided to certified applicators who apply XtendiMax. Of course, the label change proposals identified herein should also help alleviate any conflicts among growers. And, as USDA has long recognized, important technical innovations in farming have required growers to rise to the challenge and adopt common-sense strategies to co-exist with their neighbors for the past few decades.[139] USDA and other stakeholders have developed a robust set of resources and guidance to help growers succeed with coexistence while utilizing the crops, weed and insect control chemistries, and agronomic practices that are best for their farm.[140] EPA can take into account these successful tools and practices that minimize or avoid friction between growers. EPA can also permissibly recognize

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[136] Existing Stocks Order at 9.

[137] Press Release, Secretary Perdue Statement on Dicamba Plainitffs' Attack on EPA Order (June 12, 2020), https://www.usda.gov/media/press-releases/2020/06/12/secretary-perdue-statement-dicamba-plaintiffs-attack-epa-order.

[138] 960 F.3d at 1143.

[139] USDA, Agricultural Coexistence, https://www.usda.gov/topics/farming/coexistence.

[140] *See, e.g.* USDA, Coexistence Resources and Statistical Data, https://www.usda.gov/topics/farming/coexistence/coexistence-resources-and-statistical-data; American Seed Trade Association, "Existing U.S. Seed Industry Production Practices that Address Coexistence," (Jun. 2011), *available at* http://www.amseed.org/pdfs/issues/biotech/asta-coexistence-production-practices.pdf.

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that although a potential social cost may exist in certain circumstances, it is not possible to quantify precisely on a nationwide level—and as a qualitative matter it does not undercut the many benefits from OTT dicamba use, particularly with the new proposed restrictive measures in place.[141] EPA should therefore re-affirm its consistent position expressed multiple times over the last several years that this technology is necessary and important, and that proposed measures (described *supra* pp. 11–15) to limit off-target movement in the future registration will likely substantially reduce if not entirely eliminate the causes of the anecdotal disagreements.

Second, the Ninth Circuit concluded that "EPA refused to quantify or estimate the amount of damage caused by OTT application of dicamba herbicides, or even to admit that there was any damage at all."[142] As the foregoing data shows, on a national scale there *has been no large scale* measureable evidence of damage and certainly no such evidence tied to label-compliant usage. EPA should acknowledge that this is supported by ample data reflecting stronger yields across the country in 2017–2019 than in the three prior years. And again, the new proposed application restrictions are intended to address and minimize even those granular individual instances.

Third, the Ninth Circuit concluded that "EPA entirely failed to acknowledge the substantial risk that the registrations would have anti-competitive effects in the soybean and cotton industries."[143] A couple points are key here: First, anti-competitive effects that may exist in these industries are not part of EPA's responsibilities under FIFRA. To the extent there is any concern related to the herbicide-tolerant seed market, this is manifestly *not* part of EPA's regulatory charter. Instead, USDA has regulatory authority over genetically modified organisms. Moreover, EPA can and should recognize that the Department of Justice—not the EPA—is the proper regulatory body to address any anti-competitive concerns in either the herbicide or herbicide-tolerant-seed markets.[144] DOJ's Antitrust Division has an entire section dedicated to agriculture (along with transportation and energy).[145] And DOJ has shown that it is attentive to these competitive issues. Second, these industries are competitive: As far as herbicides go, there are presently *four* OTT dicamba products and other herbicides for which resistant seed has been developed. This level of

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[141] *See, e.g.*, *Ass'n of Pac. Fisheries v. EPA*615 F.2d 794, 809 (9th Cir. 1980) (finding no "precise quantification" requirement in statutory cost-benefit analysis); *Mozilla v. FCC*, 940 F.3d 1, 70–71 (D.C. Cir. 2019) (upholding agency's determination to conduct "qualitative" assessment of certain costs and benefits where the record did not provide a basis "to quantify the magnitudes of many of the costs and benefits").

[142] 960 F.3d at 1138.

[143] *Id.* at 1124.

[144] *Cf. Mozilla*, 940 F.3d at 58–59 (deferring to the FCC's decision to let FTC and DOJ police anti-competitive conduct in arena where the FCC had jurisdiction).

[145] *See* DOJ, *Transportation, Energy, and Agriculture Section*, https://www.justice.gov/atr/about-division/transportation-energy-and-agriculture-section.

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competition neutralizes any potential for anti-competitive effects and enabling additional tools for growers does not reduce competition.[146]

VII. PROPOSAL TO SIMPLIFY THE LABEL

The Ninth Circuit concluded that EPA failed adequately to address evidence that the 2018 XtendiMax label was too complex for applicators to follow, leading to misuse of the product. As noted above, the number of dicamba inquiries have declined significantly in most states since 2017, suggesting that applicators were, indeed, able to follow the 2018 label. In fact, EPA's 2018 registration took specific steps to facilitate label compliance. EPA revised the XtendiMax label to "add greater clarity and structure" and also clarified training requirements.[147] EPA further restricted use of the product "to only certified applicators," who are "the most highly trained individuals" with the greatest incentive to follow the label—because their license would otherwise be at risk.[148]

Nonetheless, Bayer proposes to further simplify the product label in multiple ways to help ensure that the highly-trained applicators are fully able to comply with the label instructions. Bayer will provide a specific proposal in the near future, which will include the proposed substantive changes identified herein, as well as the following simplifications:

- Improve the logical flow and layout of label sections based on typical grower/application label use and standardize with other Bayer Crop Science labels.
- Refine label text (*e.g.*, buffer requirement information and removal of unnecessary and redundant language) to provide increased consistency and clarity to the label.
- Update verbiage to align with recent EPA PR notices and guidance.
- Consolidate lengthy paragraphs into concise bullet points; unify overview of general uses and restrictions into a singular section.
- Reduce complexity of tank mixing section to emphasize that only tank mix products on the XtendiMax website are approved for use with XtendiMax.
- Utilize tables for specific crop use directions, which allows for improved readability, consistency, and ease of use for the label.

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[146] *Cf. Citizens Telecommunications Co. of MN v. FCC*, 901 F.3d 991, 1010 (8th Cir. 2018) (upholding agency determination that "markets with only two competitors" were competitive).

[147] *2018 Dicamba Registration* at 18, 22.

[148] *Id.* at 2.

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Ex. 4 CBI

CONFIDENTIAL BUSINESS INFORMATION

Ex. 4 CBI

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