

EXHIBIT

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MONSANTO



**SUMMARY OF CONFIRMATORY SPRAY DRIFT AND
VOLATILITY STUDIES FOR XTENDIMAX APPLICATIONS**

TEST GUIDELINE

Not Applicable

STUDY COMPLETION DATE

September 19, 2018

SPONSOR/PERFORMING TESTING FACILITY

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Company: Monsanto Company

Company Agent: Thomas B. Orr

Title: Regulatory Affairs Manager

Signature: 

Date: 9/19/2018

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GLP COMPLIANCE STATEMENT

This report does not meet the requirements of the Good Laboratory Practice (GLP) standards as specified in 40 CFR Part 160 as it is not a study *per se* but an assessment of data from other studies and reports.

A handwritten signature in black ink, appearing to read "Thomas B. Orr". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Thomas B. Orr
Regulatory Affairs Manager
Monsanto Company

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A Multitude of Spray and Volatility Drift Studies Already Confirm Appropriate Buffer Distances for XtendiMax Applications

Before EPA's initial registration in 2016, and repeatedly since that time, specific studies by Monsanto¹ and a range of independent academic researchers have produced generally consistent results, demonstrating that anticipated spray or volatility related drift remains within expected parameters in a wide range of environmental circumstances. To assist EPA in its evaluation of an extension to the current XtendiMax® with VaporGrip® registration (which otherwise expires November 9, 2018), this paper first summarizes the results of fifteen such studies, and then suggests an appropriately rigorous approach to another inconsistent and preliminary data set that appears to be flawed by a number of significant testing issues.

Background

The many consistent studies described herein originate from the following sources:

1. Monsanto: A series of pre- and post- registration Good Laboratory Practice (GLP) or similar² studies, which are summarized in Monsanto's August 3, 2018 submission, "The Scientific Basis for Understanding the Off-Target Movement Potential of XtendiMax" (MRID 50642701; referred to here as the "White Paper").
2. 2017 Academic Studies: Studies by a number of academics from universities in the U.S., which collectively resulted in findings regarding drift within the same general bounds as demonstrated by Monsanto. These 2017 academic researchers included Professors Bryan Young, Lawrence Steckel, and Jason Norsworthy. While academic studies such as those summarized in this submission serve a variety of purposes, Monsanto notes at the outset that such studies differ in material respects to the guidelines and requirements imposed by EPA on pesticide registrants.³
3. A number of ongoing 2018 Academic Studies: Studies by multiple academics from U.S. and Canadian Universities. Only certain results are available at this

¹ Monsanto is an indirect, wholly-owned subsidiary of Bayer.

² The Australia field study summarized in the White Paper was not a GLP study, however as discussed in the White Paper, there were quality control measures in place akin to the GLP standards to ensure the accuracy and validity of the study.

³ Typically, academic studies such as those discussed in this submission do not conform to GLP requirements or follow EPA study guidelines. Data quality standards arise under both FIFRA and the Data Quality Act. For example, the GLP standards codified at 40 C.F.R. Part 160 were promulgated "to assure the quality and integrity of data submitted" to EPA under FIFRA. These and other FIFRA data requirements comply with EPA's information quality obligations under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658).

point, but these are again consistent with prior Monsanto results and results from 2017 academic studies.

4. One Master’s Thesis by a student at the University of Arkansas for other *non-XtendiMax* dicamba herbicides, which was analyzed in Monsanto’s September 14, 2018 submission, “Review of Applicability of Data Considered for Endangered Species Action Area Determination” (MRID 50679201). With the exception of a single extreme outlying data point (which itself is not supported by any actual observed herbicide-related plant symptomology), this thesis also is generally consistent with the results above, recognizing the important differences among dicamba herbicides.

To put these many confirmatory studies in context, we note that each evaluates drift to sensitive soybean crops. Soybeans are known to be the plant *most sensitive* to dicamba (Porch 2009, MRID 4778115102). Thus, impacts to soybean plants overstate anticipated impacts to other plants, including other dicots. But even for soybeans, less than 40% visual symptomology from dicamba exposure does not generally result in any significant yield impact.⁴

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

To Monsanto’s knowledge, none of the studies submitted to EPA, or completed by academics over the past two years, suggest off the field symptomology for XtendiMax anywhere approaching 40% visual symptomology under the current XtendiMax label. To the contrary, both the GLP (and similar) studies submitted by Monsanto, and other available literature, suggest visual symptomology (if any occurs) would be far lower than 40% even within 110 foot downwind buffer distance—indeed in most cases less than 20%, and very small (if even observable) temporary symptomology beyond that distance. As described in the White Paper’s summary of the official 2017 soybean and cotton yield reports, yields in the locations with the

⁴ In this study, Professor Kevin Bradley of the University of Missouri conducted an assessment of dicamba symptomology in a Missouri soybean field at the R1 stage and compared that assessment to yield data provided by the grower. See <https://www.missouriruralist.com/herbicide/does-dicamba-drift-cause-soybean-yield-loss>.

highest number of 2017 dicamba drift complaints generally increased or even hit record yield levels. *See* White Paper Section VIII.

In contrast with these many generally consistent study results regarding spray drift and volatility, we understand that one researcher in 2018 has decided to submit preliminary data to EPA with extremely outlying results, perhaps with relevant impacts alleged at hundreds of feet from the field. Those results are not yet available to Monsanto (although Monsanto funded the study with an unrestricted grant of \$30,000). While Monsanto will address that study in greater detail once the results and data are made available, we already understand that flaws have been discovered in certain of that study's preliminary data, which render certain data points unusable. From first hand observations of the study, we are also aware of several other significant confounding factors and deviations from the study protocols followed by other academics nationwide. We preliminarily itemize certain of those deviations and confounding factors below for EPA's consideration, and anticipate providing a more fulsome analysis as soon as the preliminary data becomes available to Monsanto.

I. MONSANTO-SUBMITTED GLP (OR SIMILAR) STUDIES

As described in the White Paper, Monsanto has conducted a total of nine XtendiMax, M1691 and XtendiMax tank mix field studies conducted across a wide range of soybean and cotton fields (herbicide-tolerant traits, pre-/post-emergent), geographies, temperatures, humidities and soil types, of which four volatility studies were previously submitted to EPA in support of the 2016 XtendiMax registration. Since the initial registration in 2016, Monsanto has conducted a total of five additional volatility field studies. These particular studies utilized the XtendiMax tank mix that is used on 90% of all dicamba-tolerant soybean and cotton acres: XtendiMax (MON 76980) plus PowerMax (MON 79789, a glyphosate potassium salt) and a drift reduction agent (hereafter the "XtendiMax Tank Mix"). The results of these field studies mimic many "real world" commercial applications and capture the full range of potential conditions that might cause volatility. These post-registration studies were conducted in Texas, Australia, Arizona, Missouri and Nebraska, and the peak flux rates are consistent with and confirmatory of studies submitted prior to the registration. Moreover, as described below, all of Monsanto's GLP (or similar) studies are also consistent with results of numerous academic studies conducted in 2017 and 2018.

Results of Monsanto's field study conducted in Arizona that evaluated volatility, spray drift, and plant effects (MRID 50642801) and corresponding deposition and air concentration modeling (MRID 50642804), are representative of all the results. These studies confirmed that plausible effects of dicamba would be limited to the confines of the treated field, and thus no species off the field would be affected as a result of application. As noted in the White Paper, in designing the Arizona field study protocol, Monsanto solicited feedback from EPA and incorporated study design recommendations from the Agency. Using the flux rates determined from the Arizona field study, Monsanto modeled the dicamba dry and wet deposition and air concentration estimates that could potentially occur downwind of an application of the XtendiMax Tank Mix (MRID 50642804). The results of the air concentration modeling were below both the NOAEC used in the 2016 XtendiMax registration and the refined NOAEC later determined at EPA's request. As discussed in the White Paper, a spray drift field study conducted in conjunction with the Arizona volatility field study was confirmatory of (1) EPA's

2016 determination that no spray drift would occur outside of the 110-ft. buffer area in amounts that could have an effect on plant height, and (2) a Texas field deposition study that showed that dicamba would be present in amounts below the no-effect rate (NOER) at distances less than 110 feet from the edge of the field (MRID 49770301). Thus, the Arizona volatility and spray drift field study confirms EPA's 2016 conclusion that no buffer is necessary to address concerns regarding volatility and that a 110-ft. buffer is sufficient to address concerns about spray drift. Other studies in Texas, Missouri and Nebraska provided data on volatility of XtendiMax that specifically supports the results in Arizona. *See* White Paper Section I.B and Table 2.

II. 2017 ACADEMIC STUDIES

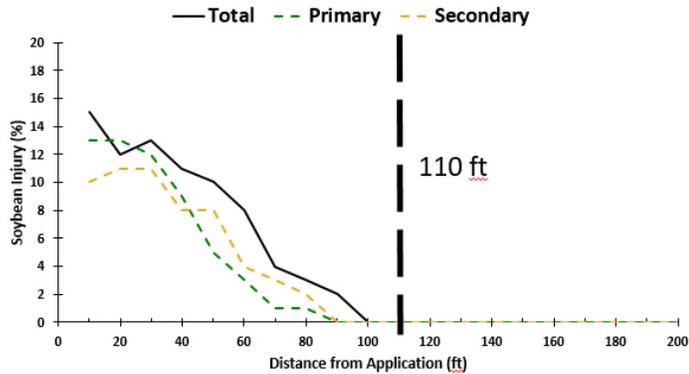
The results of academic studies align with the results of GLP (and similar) studies performed by Monsanto. Monsanto recognizes that these academic studies were not GLP studies (as were multiple of Monsanto's studies). But, taken at face value, these studies confirm that visual symptomology would not occur past 110 feet downwind of the application area at levels that would impact yield. The academic studies discussed below were conducted in various key soybean-producing states that have reported inquiries of potential dicamba symptomology, including Arkansas, Tennessee, and Indiana.

A. Young Study

A large-scale study of primary and secondary drift conducted in Indiana by Professor Bryan Young of Purdue University (hereafter the "Young Study") aligned with the results of other studies discussed in this submission and the White Paper. First, although the wind changed directions multiple times following the application of XtendiMax to a three-acre spray area, there was no upwind movement of dicamba. Second, the maximum distance to 5% visual symptomology was 110 feet from the application area 14 days after treatment, and 101 feet 24 days after treatment. Along the transects on the field, 5% visual symptomology⁵ ranged from 70 to 92 feet 14 days after treatment, and 24 to 58 feet 28 days after treatment.

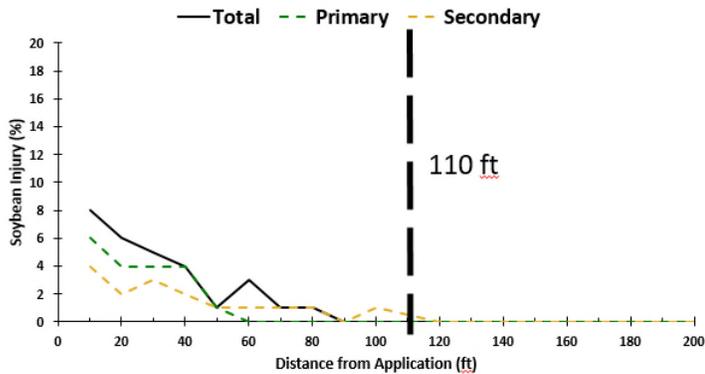
⁵ 5% visual symptomology is used to represent the furthest distances in which dicamba symptomology can be observed. Visual symptomology is not a relevant risk assessment apical endpoint such as survival, growth, or reproduction. Furthermore, visual symptomology at such low levels is not associated with yield reductions. *See* <https://www.missouriruralist.com/herbicide/does-dicamba-drift-cause-soybean-yield-loss>.

Large-Scale Study Xtendimax – 14 DAT



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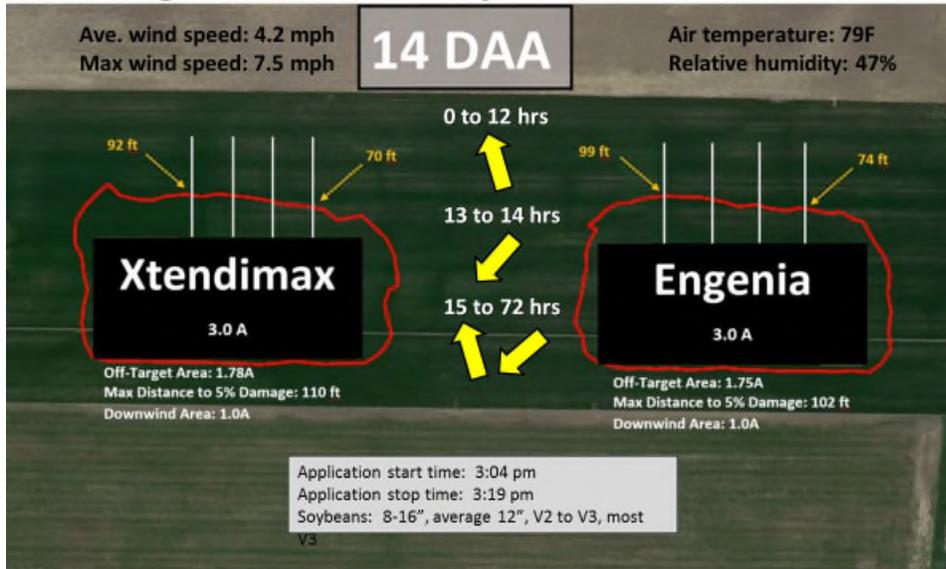
Large-Scale Study Xtendimax – 28 DAT



PURDUE
UNIVERSITY
Weed Science

The results of the Young Study align with other studies discussed in this submission and in the White Paper, and confirm that no impact on yield would occur greater than 110 feet downwind from the application area. Moreover, as you can see, there is no indication of XtendiMax drift upwind.

Large-Scale Study

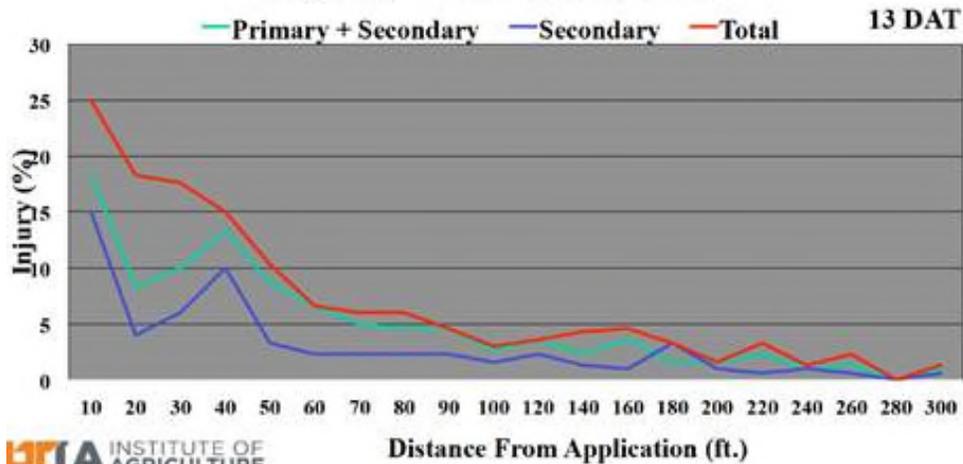


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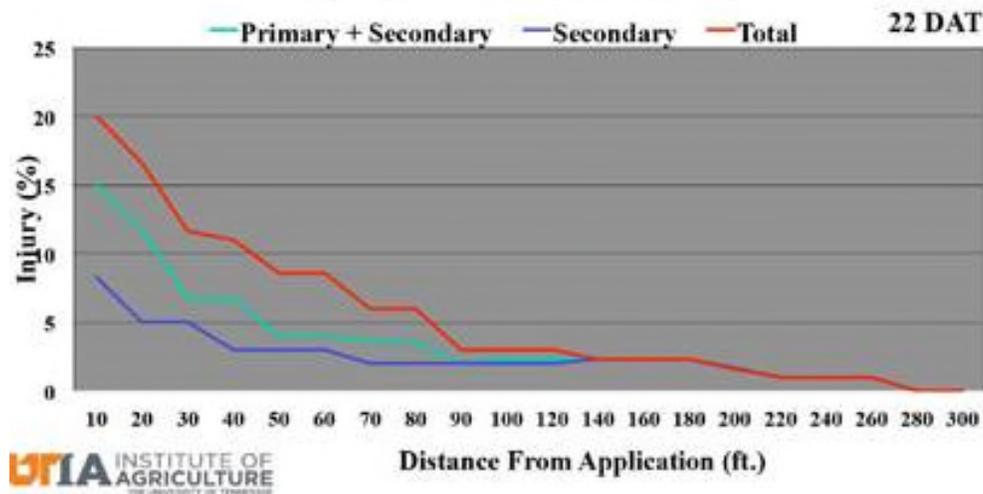
B. Steckel Study

A study by Professor Lawrence Steckel of the University of Tennessee (hereafter the “Steckel Study”) evaluated primary and secondary movement of an XtendiMax +Roundup PowerMax + Intact tank mix (the “study tank mix”) on dicamba-sensitive soybeans grown in Sharon, Tennessee. The results of this study generally align with those of other studies discussed in this submission and in the White Paper. Primary and secondary movement of dicamba from the study tank mix together caused less than 5% visual symptomology at distances greater than 90 feet from the application area both 13 and 22 days after treatment.

22 fl. oz. Xtendimax + 32 fl. oz. Roundup Injury + 0.5 % Intact



22 fl. oz. Xtendimax + 32 fl. oz. Roundup Injury + 0.5 % Intact



Notably, there was no indication of upwind movement of dicamba following application, and all of the symptomology of visual symptomology occurred in the direction of the prevailing winds during and after application. And nothing in these results suggests anything close to downwind impacts exceeding 20% visual symptomology at hundreds of feet. Furthermore, the Steckel Study was conducted in warm conditions with a relative humidity of 84%, thus providing additional confirmation that humid conditions do not lead to increases in off-target movement due to volatility.

The results of the Steckel Study therefore align with other studies discussed in this submission and in the White Paper, and confirm that no impact on yield would occur greater than 110 feet from the application area. The Steckel Study is yet another example of a real-world application of an XtendiMax tank mix resulting in minimal amounts of movement outside of the application area.

C. 2017 Norsworthy Study

A large-scale study of primary and secondary drift conducted by Professor Jason Norsworthy of the University of Arkansas (hereafter the “2017 Norsworthy Study”) in Arkansas produced somewhat further drift distances to Young and Steckel, but nothing close to 20% visual symptomology at hundreds of feet. (And we note that evaluation of visual symptomology is a subjective process that may vary among observers.) In the 2017 Norsworthy Study, a largely label-compliant application of XtendiMax⁶ was made to 3.5 acre field of dicamba-sensitive soybeans. The study measured the plant effects of dicamba movement both inside and outside of the application area.

⁶ Average wind speeds during application were slightly below the 3 mph minimum required by the XtendiMax label.

Effects inside of the application area: The photograph below shows the effects from secondary dicamba drift on dicamba-sensitive soybean plants that were moved inside of the application area field at least 30 minutes following application. The dicamba-sensitive soybean plants were located in the center of the application area—where volatility would be at its highest. Thus, the <20% visual symptomology shown by the minor cupping and crinkling below reflect the *highest level of exposure* due to volatility and likely overestimates any potential exposure to non-target plants located outside the spray application area.⁷

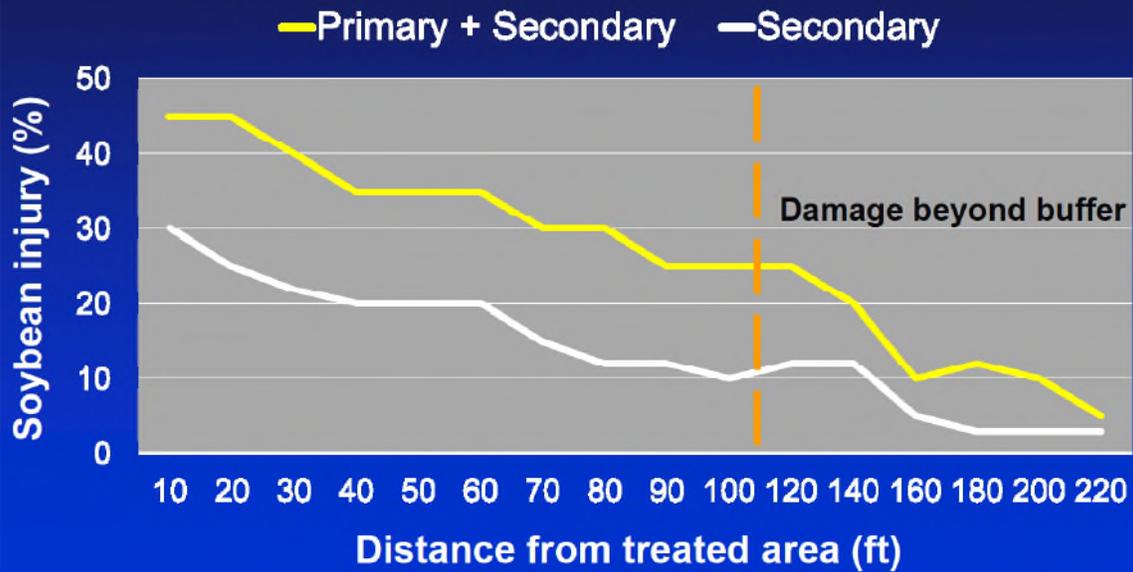


Effects outside of the application area: The 2017 Norsworthy Study also measured visual symptomology due to both primary and secondary movement to soybean plants located outside of the application area. To isolate the effects of primary and secondary movement, the 2017 Norsworthy Study covered certain soybean plants outside of the treated field with buckets prior to and during the application period. Because the buckets can cause stress to soybean plants due to excessive heat buildup, the measurements of secondary movement in the 2017 Norsworthy Study are likely exaggerated. Furthermore, this type of study design increases probability of cross-contamination during bucket placement and removal. The chart from Professor Norsworthy's 2017 results below identifies his measurements at various distances from the field. As you can see, visual symptomology drops significantly after 110-120 feet, and after that point falls well below 20%. There is no indication at all of visual symptomology approaching 20% at hundreds of feet downwind from the field, or at any distance off the field upwind.

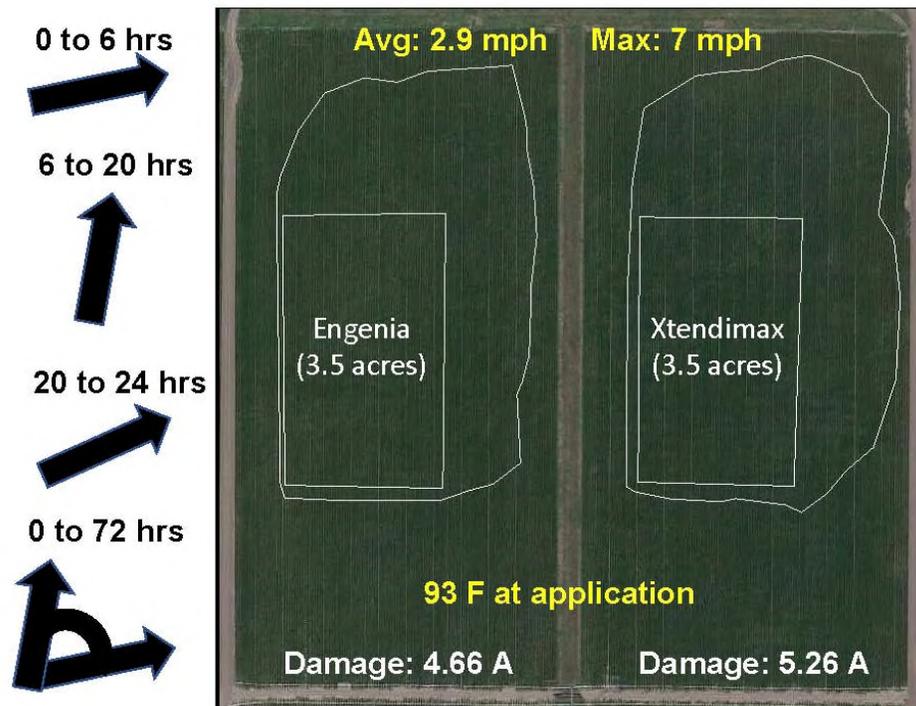
⁷ Changes in plant color are due to causes other than dicamba, including plant stress due to being moved from a greenhouse to a field.

Xtendimax Movement – North Transect

Soybean Injury 12 Days After Application



Keiser 2017



D. Additional 2017 Large Scale Studies

Monsanto also sponsored three additional large scale studies in 2017 conducted by Dr. Greg Kruger in Nebraska, Dr. Dan Reynolds in Mississippi, and Dr. Kevin Bradley in Missouri. The results from the Nebraska study were confounded due to drift from a neighboring field and are not presented in herein because it is not possible to discern treatment-related effects from any potential effects due to other herbicide sources. Results from the Mississippi and Missouri study were not provided to Monsanto and are therefore not included in this summary. These studies were sponsored by Monsanto and are only mentioned for the sake of completeness and full transparency.

E. Reynolds Study

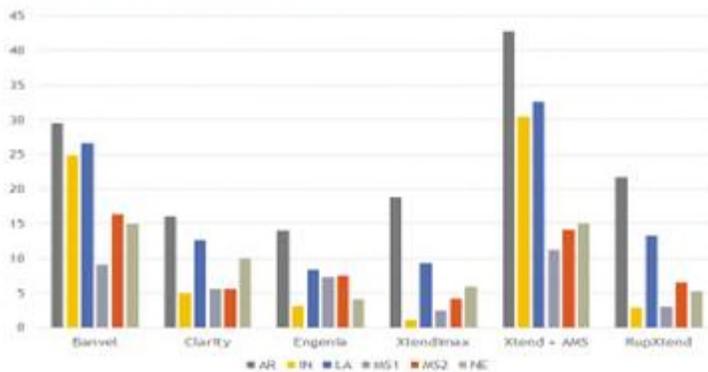
A study conducted by Professor Dan Reynolds of Mississippi State University et al.⁸ (hereafter the “Reynolds Study”) evaluated the volatility of XtendiMax using low tunnels at field sites located in Arkansas, Georgia, Indiana, Louisiana, Mississippi and Nebraska. The 20-foot low tunnels consisted of dome plastic sheeting and treated flats, which were removed 48 hours after application.



Although the Reynolds Study is only suitable to provide relative comparisons and not suitable for risk assessment, it nonetheless is consistent with other studies. Visual symptomology due to the application of XtendiMax + Roundup PowerMax across all locations reached approximately 6-7% 14 days after treatment and 6% 28 days after treatment (with the exception of the results in Arkansas, which were not consistent with other locations), thus aligning with the studies discussed in the White Paper and in this submission that show that volatility is a minor component of offsite movement across a range of different application conditions and locations despite the conservative aspects of the study design, notably an exaggerated (4x) dicamba application rate and artificially high exposure levels under a semi-enclosed low tunnel.

⁸ The full list of authors of this study was T. Barber, S. Culpepper, G. Kruger, J. Norsworthy, G. Oakley, D. Reynolds, R. Rector, R. Scott, D. Stephenson and B. Young.

**VISUAL INJURY 14 DAT
ALL LOCATIONS**



III. 2018 ACADEMIC STUDIES

Multiple studies funded by unrestricted Monsanto grants are underway now. So far, limited data are available, but those data are entirely consistent with prior Monsanto and academic studies. We urge EPA to discuss results with each of the following academics involved in this process:

- Greg Kruger – University of Nebraska – Lincoln
- Dan Reynolds – Mississippi State University
- Bryan Young – Purdue University
- Christy Sprague – Michigan State University
- Rodrigo Werle – University of Wisconsin
- Peter Sikema – University of Guelph (Canada)
- Jason Norsworthy – University of Arkansas⁹

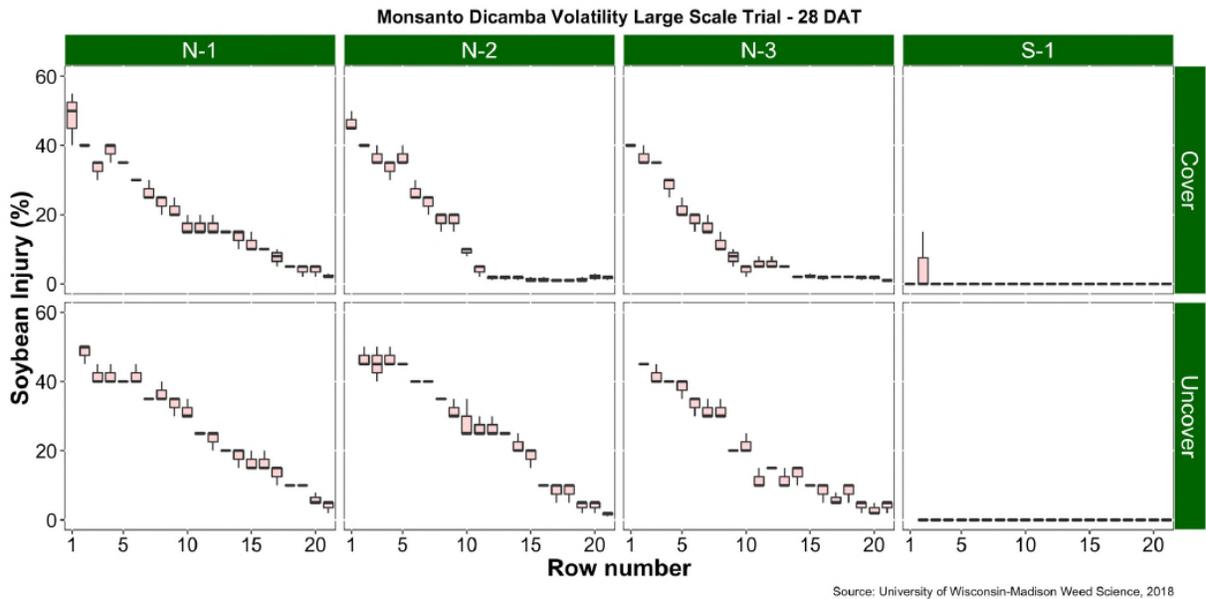
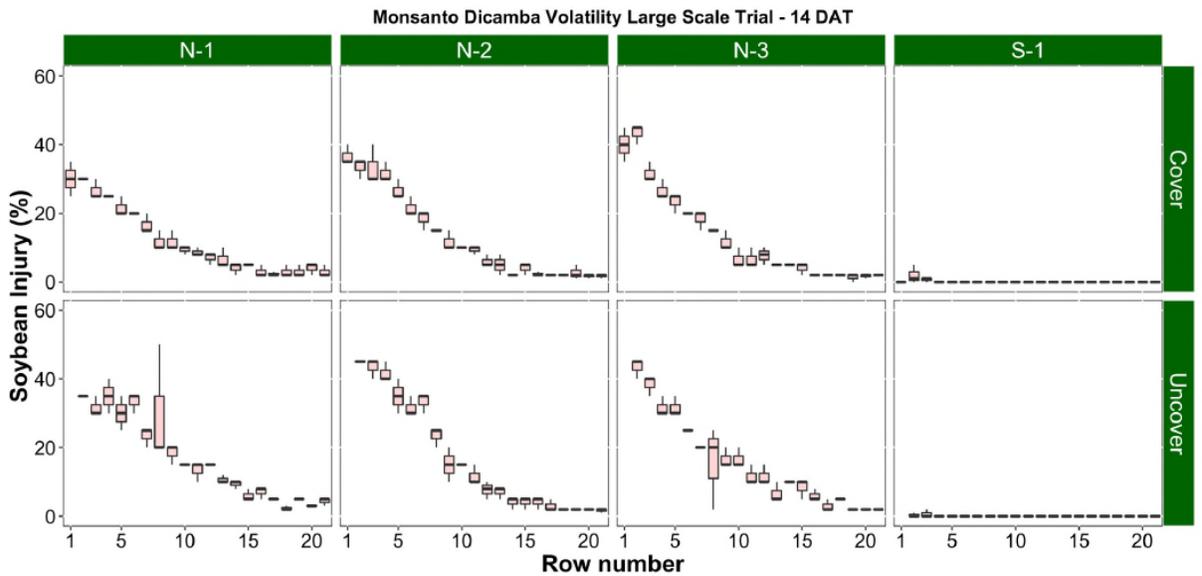
A. Werle Study

A large-scale study of primary and secondary drift conducted in Wisconsin by Professor Rodrigo Werle¹⁰ of the University of Wisconsin-Madison (hereafter the “Werle Study”) also aligned with the results of other academic studies discussed in this submission and the White Paper. In order to distinguish between primary and secondary movement of the XtendiMax Tank Mix, certain soybean plants were covered by a tarp during and shortly after application.

⁹ We understand that EPA is already in touch with Jason Norsworthy regarding his 2018 study, as discussed in Section V below. Monsanto has not yet received any data from this trial.

¹⁰ The full list of authors of this study was Rodrigo Werle, Maxwel Coura Oliveira, Ryan DeWerff, Nikola Arsenijevic, Sarah Striegel, Victor Hugo Vidal Ribeiro and Rachel Benz.

Little to no symptomology was observed upwind of the treated field following application. In addition, minimal symptomology was observed past 55 feet at 14 and 28 days after treatment.



Thus, the Werle Study aligns with other studies discussed in this submission and in the White Paper, and further confirms that dicamba will not occur outside of the 110-foot buffer in levels that would result in reductions in yield.

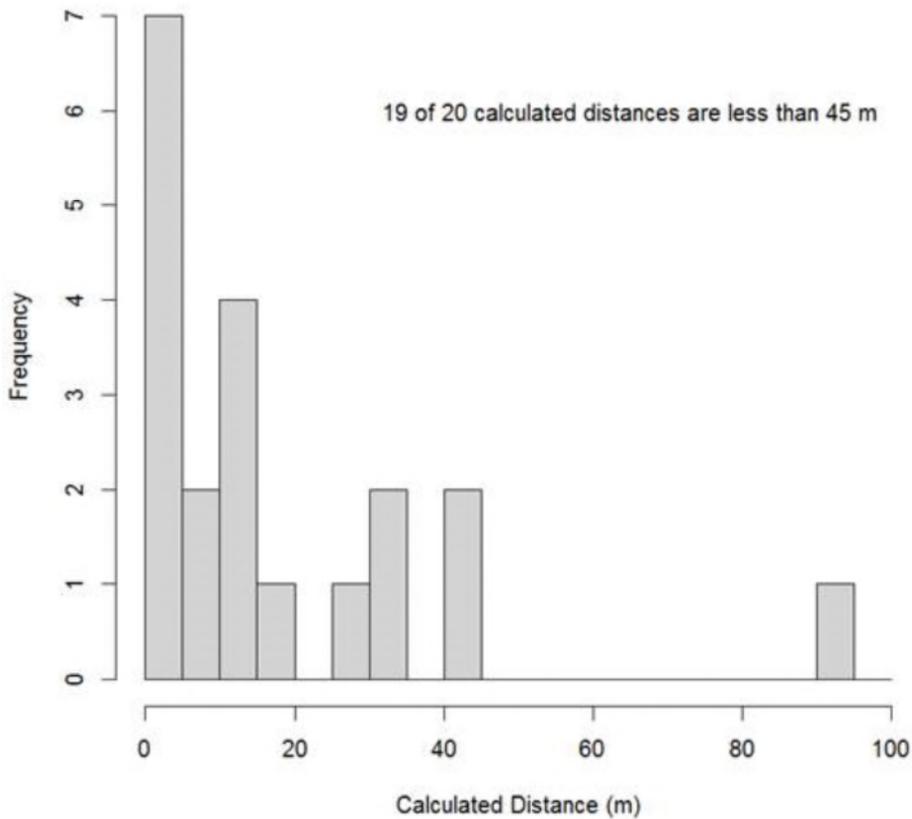
IV. 2018 MASTER'S THESIS

As Monsanto explained in its September 14, 2018 submission to EPA (MRID 50679201), the Master's Thesis of University of Arkansas student, presenting an "Evaluation of Dicamba Off-Target Movement and Subsequent Effects on Soybean Offspring" ("Master's Thesis"), which reports a calculation of yield reduction to soybean at a distance of 90 meters from application that must be disregarded because of fundamental flaws in the assessment. Nonetheless, with the exception of this single extreme outlying data point (which itself is not supported by any actual observed herbicide-related plant injury), this thesis also is generally consistent with the results above, recognizing the important differences among dicamba herbicides.

As an initial matter, and as explained in more detail in Monsanto's September 14 submission, the Master's Thesis did not use XtendiMax, but another dicamba formulation without VaporGrip® Technology it used an unapproved nozzle that increases spray drift, and it evaluated soybean growth stages that are less likely to be exposed when XtendiMax is applied according to label instructions. The 90-meter result (Trial 11) is spurious because the Master's Thesis itself showed <5% visual symptomology and <5% pod malformation at 90 meters. Moreover, the calculated distance of 90 meters for 5% yield reduction in Trial 11 is fundamentally inconsistent with all other endpoints in Trial 11, each of which is known to be more sensitive than yield; however, Trial 11 results reflected the opposite trend in which yield was the most sensitive endpoint. For example, 5% visual symptomology was reached at 60.6 meters, 5% height reduction at 28 DAA was reached at 0 meters (i.e., no impact on height), 5% height reduction at harvest was reached at 15.4 meters, and 5% pod malformation was reached at 60.6 meters. Close inspection of the yield data for Trial 11 (Appendix Figure 22) illustrates that the calculated 90 meters is the result of spatial confounding, and therefore spurious - note the presence of two spatially-segregated clusters, each of which is flat.

When one removes the spurious measurement at 90 meters, all other (19 out of 20) calculated distances to 5% yield reduction are less than 45 meters (as illustrated in the figure below), which is in alignment with the papers described above.

Histogram of Calculated Distances to 5% Yield Reduction



V. OUTLIER REPORT

As demonstrated above, the Monsanto GLP (or similar) studies in support of the 2018 XtendiMax registration and the academic studies conducted in 2017 and 2018 are all aligned in demonstrating the effectiveness of the 110-foot downwind buffer. Any distinct reports that suggest movement beyond this buffer or that suggest upwind movement are demonstrably outliers.

EPA has informed Monsanto of new data provided by Jason Norsworthy relating to 2018 drift and volatility trials. None of this data has yet been provided to Monsanto. We are aware that Professor Norsworthy deviated from the protocols adopted by many other researchers this year and that raises a number of significant questions in our minds, including:

- did irrigation water interfere with the study accuracy?
- were there shortcomings with the application and coverage of tarps over the soybean plants?
- was the spray solution compromised?

- was there a confounding factor with the manner in which a group 15 pesticide was used?
- were there issues with wind variability?

We will address those questions and any other issues when we are given access to the relevant data.

Conclusion

EPA has a robust set of data before it, including GLP or similar studies and data Monsanto provided to EPA as well as a range of studies conducted by independent academic researchers in 2017 and 2018 that have produced generally consistent results. The weight of all of this evidence supports the effectiveness and sufficiently protective nature of the 110-foot downwind buffer requirement for XtendiMax.