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No. 19-70115

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PETITIONERS' EXCERPTS OF RECORD VOLUME II of IX

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¹ Unless otherwise specified, the document identifier numbers refer to their document numbers as listed in the Certified Indices, ECF Nos. 26-3 (Sections A through P), 34-3 (Section Q).

² Respondent United States Environmental Protection Agency (EPA) did not produce, but only provided hyperlinks to, publicly available documents. *See* ECF No. 26-3. For the Court's convenience, Petitioners have produced those hyperlinked documents in their entirety in the Excerpts of Record.

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³ This e-mail contains a hyperlink to an online article that Petitioners have produced in its entirety. For the Court's convenience, Petitioners have produced relevant hyperlinked articles in their entirely in the Excerpts of Record. Throughout the index these documents containing hyperlinks are noted with a double asterisk (*e.g.* ____**).

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THE SCIENTIFIC BASIS FOR UNDERSTANDING THE OFF-TARGET MOVEMENT POTENTIAL OF XTENDIMAX

INTRODUCTION

EPA approved the registration for XtendiMax® With VaporGrip® Technology (XtendiMax; EPA Reg. No. 524-617) on November 9, 2016 for over-the-top of Dicamba-Tolerant soybean and cotton based on a range of scientific submissions provided to the agency over the preceding five years, including dozens of scientific studies and field trials assessing the potential for spray drift and volatility. The XtendiMax label was tailored to address that scientific review, with specific requirements to limit the potential for off-target movement, including an in-field buffer, wind speed restrictions, and spray nozzle requirements. EPA also made explicit in the registration that it would reevaluate the potential for off-target movement prior to approving any registration renewal before November 2018.

Since the November 2016 registration of XtendiMax, Monsanto has performed numerous additional studies and assessments, including five further field studies in locations across the U.S. and Australia, three additional studies modeling the possibility of volatilization, and one additional humidome study. In this effort, Monsanto has worked with EPA and university scientists, regarding the protocols for multiple of these field studies, and has performed other specific analyses requested by EPA. Indeed, field studies have been performed over crops planted in a broad range of geographies, temperatures and soil types with a range of pH levels that are highly representative of farming conditions in all U.S. states where cotton or soybean are grown.

To date, all of the post-registration field studies and modeling data confirms the scientific conclusions EPA reached in the 2016 XtendiMax registration, that under the XtendiMax label requirements: (1) vapor drift occurring due to volatilization should not result in impacts off the treated field; and (2) spray drift will not occur past the label's required buffer distances in amounts that would have an adverse effect on plant height.¹ This submission summarizes that body of hard scientific evidence.

In addition to all of these supplemental scientific analyses, Monsanto also addresses herein inquiries of off-target movement reported to Monsanto during the 2017 and 2018 seasons regarding alleged dicamba drift. Multiple new dicamba herbicides were applied in 2017 (Engenia®, XtendiMax, FeXapanTM) for over-the-top use, while older higher volatility formulations that lack label restrictions intended to limit the potential for off-target movement remained in use in many locations for multiple purposes, including for use over corn (which is

¹ U.S. EPA, M1691 Herbicide, EPA Reg. No. 524-582 (Active Ingredient: Dicamba Diglycolamine Salt) and M1768 herbicide (Xtendimax), EPA Reg. No. 524-617 (AI: Diglycolamine Salt with VaporGripTM) – Review of EFED Actions and Recent Data Submissions Associated with Spray and Vapor Drift of the Proposed Section 3 New Uses on Dicamba-Tolerant Soybean and Cotton, 5; Second Addendum to the Environmental Fate and Ecological Risk Assessment for Dicamba DGA salt and its Degradate, 3,6-dichlorosalicylic acid (DCSA) for the Section 3 New Use on Dicamba-Tolerant Soybean at 6.

naturally tolerant to dicamba) and on pastures. The scientific evidence does not support an assumption that the symptomology alleged in these reports is caused by the use of XtendiMax in accordance with label requirements. As a threshold matter, although 2017 saw an increase in reported complaints of alleged dicamba drift in specific locations and geographies, the frequency of complaints has dropped this year both in actual terms and in a per-million acres sprayed basis (as of July 19, 2018).² And the official 2017 soybean and cotton yield reports in the locations with the highest number of 2017 complaints generally increased or even hit record yield levels. See infra Section VIII or MRID 50639401 for a detailed summary of state and certain county specific reports. While a 2017 late season drought in multiple Northern Plains states impacted, soybean yield in those specific locations, a close evaluation of yield data across all states generally identifies higher yield in locations with more of the alleged complaints-and lower yield in locations with fewer complaints. In other words, there is no scientific basis to conclude that 2017 complaints regarding alleged dicamba off-target movement actually caused any wide-scale negative yield impacts. Indeed, 2017 yields in locations with the most concentrated uses of dicamba herbicides tended to increase. This evidence leads to two common sense conclusions: First, over-the-top use of dicamba provides tremendous value to American soy and cotton growers. Second, to evaluate any report of suspected "off-target movement" of dicamba, it is necessary to carefully verify all the relevant facts in order to support informed conclusions on an inquiry-by-inquiry basis. Throughout the 2018 growing season, Monsanto has taken exactly that approach, and has conducted several hundred field visits to evaluate any such reports it receives. Among other things, Monsanto has learned from these evaluations that grower training has been successful, and that any off-target movement of XtendiMax can be addressed through additional grower training.

In sum, the voluminous scientific evidence discussed herein:

- Confirms the conclusions regarding spray drift and volatility in EPA's 2016 risk assessment (and subsequent addendums) and registration decision.
- Demonstrates that there is no material difference in the volatility characteristics of XtendiMax across a wide range of soil types and pH levels, geographies, and temperatures, rebutting any hypotheses that such variations may cause volatility in quantities that will impact plant height outside of the treated field.
- Rebuts any hypothesis that off-target movement has caused widespread yield impacts by demonstrating that on a yield per acre basis, soybean and cotton yields were higher in 2017 than in any year other than 2016, and yields were higher than any other year in certain key states where complaints were reported to be highest even in the face of complaints regarding alleged off-target movement (whether XtendiMax or not).
- Identifies a decrease in reported off-target movement inquiries in 2018, and identifies a series of conclusions Monsanto has reached from evaluating hundreds of reports of alleged off-target movement, confirming again that applications of

² In any event, the volume of inquiries is not a reliable indicator of whether "off-site incidents are occurring at unacceptable frequencies or levels."

XtendiMax in conformity with the label should not result in adverse effects. This decrease in inquiries reflects the positive impacts of the voluntary label amplifications made in 2017, including grower training.

I. NEW FIELD FLUX DATA IS CONFIRMATORY OF FLUX DATA ANALYZED BY EPA IN 2016 REGISTRATION

Monsanto has conducted of 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 six were previously submitted to EPA (Table 1). Site meteorological and flux monitoring meteorological data were recorded at each test site, and were used to calculate peak flux (volatility) rates using the aerodynamic flux and integrated horizontal flux methods.³ The peak flux rates from studies conducted after the 2016 XtendiMax registration are consistent with and confirmatory of studies submitted prior to the registration. Monsanto then utilized only the *highest* peak flux rates from these calculation methods to model the potential for off-target movement due to volatility. Every modeled offsite dicamba air concentration was lower than both the NOAEC determined prior to the 2016 registration and the refined NOAEC that was later determined at EPA's request as described more fully below. In addition, for each of the field studies, Monsanto determined how much dicamba mass loss occurred relative to the amount of dicamba applied (percent mass loss); percent mass loss results for the studies conducted after the 2016 XtendiMax registration were consistent with those previously considered by EPA.

³ For site meteorological data, seven environmental conditions were measured at, or within close proximity of, the test plots: (1) daily precipitation; (2) hourly soil moisture; (3) hourly air temperature at three different heights; (4) hourly soil temperature at three different depths; (5) hourly solar radiation; (6) minutely wind speed and direction at three different heights; and (7) minutely relative humidity. For flux monitoring meteorological data, a meteorological station near each plot measured three environmental conditions every minute and every hour at four different heights above the crop canopy: (1) air temperature; (2) wind speed; and (3) wind direction.

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Table

emarks	Study Number	Year	State	Spray Area (acres)	Spray Mix	Study Duration (days)	Application Type	Volatility (Flux)	Drift	Plant Effects
reviously	WBE-2015-0221	2015	GA	~4	Xtendimax	3	Pre-Emergent	×		
wiewend hu	WBE-2015-0311	2015	TX	~10	Xtendimax	3	Post-emergent DT-cotton	×		
FPA	WBE-2015-0220	2015	GA	~4	M1691 Herbicide	3	Pre-Emergent	×		
5	WBE-2015-0312	2015	TX	~10	M1691 Herbicide	Э	Post-emergent DT-cotton	×		
	STC-2016-0545	2016	TX	~4	Xtendimax + PowerMax	3	Pre-Emergent	×		
reviously		2016	TX	~10	Xtendimax + PowerMax	3	Post-emergent DT-cotton	×		
ubmitted to EPA	REG-2017-0646	2017	NSW, Australia	~37	Xtendimax + PowerMax + Intact	3	Post-emergent RR-soybean	×		N.
	STC-2018-0088	2018	AZ	~26	Xtendimax + PowerMax + Intact	З	Post-emergent RR-soybean	×	×	×
This bmission	STC-2018-0084	2018	ОМ	~10	Xtendimax + PowerMax + Intact	5	Post-emergent DT-soybean	×		H
	STC-2018-0091	2018	NE	~100	Xtendimax + PowerMax + Intact	3	Post-emergent DT-soybean	×		

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A. Volatility Field Studies Submitted Prior to the 2016 XtendiMax Registration

To evaluate the potential volatility of XtendiMax, EPA performed an independent assessment of four field volatility (flux) studies for XtendiMax and M1691 conducted in Georgia and Texas. U.S. EPA, M-1691 Herbicide, EPA Reg. No. 524-582 (Active Ingredient: Dicamba Diglycolamine Salt) and M-1768 herbicide (Xtendimax), EPA Reg. No. 524-617 (AI: Diglycolamine Salt with VaporGrip[™]) – Review of EFED Actions and Recent Data Submissions Associated with Spray and Vapor Drift of the Proposed Section 3 New Uses on Dicamba-Tolerant Soybean and Cotton, 5-12 (Nov. 3, 2016) [hereinafter M-1768 Review of EFED Actions]; Final Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean at 18. The field studies of XtendiMax and M1691 in Georgia and Texas tested real-world volatility potential under different application conditions and soil types. M-1768 Review of EFED Actions, Appx. at 6-7; MRIDs 49888501, 49888503, 49888401, 49888403. The soil type in the four-acre Georgia field study was a Tifton loamy sand with a soil pH of 5.6; the soil type in the 10-acre Texas field study was a Lake Charles clay with a pH of 6.0. The peak surface soil and air temperatures during the Georgia field study were 117°F and 89°F, respectively. The peak surface soil and air temperatures during the Texas field study were 155°F and 95°F, respectively. EPA concluded that the weather conditions in the Texas and Georgia field studies "made for near-idealized conditions for volatilization occurring after applications," thus approaching the worst-case scenario for volatility (flux). M-1768 Review of EFED Actions at 6. The highest peak flux values following XtendiMax and M1691 applications on a pre-emergent soybean field in Georgia were 0.0010 µg/m²/sec and 0.0069 µg/m²/sec, respectively. The highest peak flux values following XtendiMax and M1691 applications on a post-emergent dicamba-tolerant cotton field in Texas were 0.0003 µg/m²/sec and 0.0007 µg/m²/sec, respectively (Table 2).

B. New Volatility Field Studies Submitted Following the 2016 XtendiMax Registration

Since the initial registration in 2016, and for EPA's evaluation for the 2018 reregistration of XtendiMax. 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.⁴ These field studies not only confirm information provided prior to 2016, but also mimic many "real world" commercial applications and capture the full range of potential conditions that might cause volatility. These studies have been conducted in Texas, Australia, Arizona, Missouri and Nebraska. Final reports for the Texas (MRID 50578902) and Australia (MRID 50606801) studies have been previously submitted to EPA.

The field studies were designed to supplement prior scientific evaluations, and in particular to address the following questions:

⁴ A drift reduction agent such as IntactTM is required by the XtendiMax label for application of XtendiMax-glyphosate tank mixes and does not impact the volatility potential of XtendiMax.

- Are the results of studies that EPA previously assessed representative of applications in a variety of other conditions and geographies?
- 2. Does volatility peak dramatically beyond three days after application?
- 3. Are studies conducted on small areas representative of large commercial-scale applications?

Like the field studies submitted in support of the 2016 XtendiMax registration, with the exception of the 2017 Australia study, these field studies were conducted in accordance with FIFRA's Good Laboratory Practice (GLP) Standards (40 C.F.R. § 160).⁵ The study designs adhered to field volatility study guidelines as outlined in EPA's Fate, Transport and Transformation Test Guideline (2008). The measurement of dicamba from pre-application, application, and post-application was analyzed according to analytical method ME-1902.⁶ Conducting these studies required significant man-hours and resources: for example, from field preparation to conclusion, the Arizona study alone required 22 trained personnel spending 696 total man-hours in the field. In designing the Australia and Arizona field studies, Monsanto coordinated testing protocol development with agricultural scientists at Purdue University, the University of Nebraska, and Mississippi State University, and, with regard to the Arizona field study, coordinated with and incorporated many specific recommendations from EPA.

1. Texas Volatility Field Study, MRID 5057892

In October 2016, Monsanto completed a GLP volatility field study using a XtendiMax and PowerMax tank mix in Fort Bend County, Texas, a key cotton-producing region. This study evaluated volatility over three days on two fields—one bare soil, pre-emergent field of approximately 4.6 acres (Bare Ground 1) and one post-emergent dicamba-tolerant cotton field of approximately 9.1 acres (OTT1). After application, samples from polyurethane foam (PUF) collectors were collected from five sampling heights above the soil/crop surface (0.15, 0.33, 0.55, 0.90, and 1.5 m) in the approximate center of each field at intervals of 6, 12, 24, 36, 48, 60, and 72 hours post-application. The highest peak flux rates for Bare Ground 1 and OTT1 were 0.003915 $\mu g/m^2/sec$ and 0.003032 $\mu g/m^2/sec$ respectively, which are consistent with peak flux values from

⁵ The Australia field study discussed infra Section I.B.3 was not a GLP study, however there were quality control measures in place akin to the GLP standards to ensure the accuracy and validity of the study. Such measures included, for example, (1) selection of the location of individual plots within the larger field based on prevailing wind direction, not any specific agronomic characteristics; (2) analysis of data in accordance with accepted statistical methods; (3) confirmation that instruments used to measure meteorological conditions during application were used according to manufacture instructions; (4) monitoring by the study director of data collection and analysis; and (5) review by Monsanto Quality Assurance personnel of study documentation such as field notebooks and data contained therein.

⁶ In addition, field exposed polyurethane foam (PUF) collectors were spiked with a known amount of dicamba for each field study site and weathered for approximately 6 and 12 hours to determine the amount, if any, of dicamba lost during sampling and to confirm the accuracy of on-field measurements.

the Texas and Georgia studies submitted prior to the 2016 XtendiMax registration (Table 2). This additional data demonstrates that the volatility potential of a relevant dicamba tank mix combination is consistent with the data previously assessed by EPA.

2. Arizona Volatility Field Study

In May 2018, Monsanto completed the field phase of a GLP field study on 26 acres of postemergent glyphosate-tolerant soybean near Maricopa, Arizona. In designing the study protocol. Monsanto solicited feedback from EPA and incorporated study design recommendations from the Agency, including moving the location of the flux meteorology station, analyzing the tank mix samples for pH in the field and in the laboratory, placing additional upwind sample collectors, etc. Volatility was determined by analyzing air samples collected from (a) a single in-field air profile monitoring station with collectors at five heights (approximately 0.15, 0.33, 0.55, 0.9, and 1.5 m above crop height) located in the approximate center of the spray area, and (b) eight monitoring stations located around the perimeter of the sprayed application area with air monitoring collectors at 1.5 m above crop height. Samples from PUF collectors were taken approximately 6, 12, 24, 36, 48, 60, and 72 hours following application. The highest peak flux rate was 0.00044 µg/m²/sec. which is consistent with peak flux values from the Texas and Georgia studies submitted prior to the 2016 XtendiMax registration (Table 2). This data demonstrates that the previously assessed studies on smaller acres are in fact representative of commercial applications that would take place on larger acres and that the extreme temperatures observed during the studies do not increase the maximum volatility measured.

3. Australia Volatility Field Study, MRID 50606801

In December 2017, Monsanto completed a spray drift and volatility field study in Walgett Shire, New South Wales, Australia, that mimicked the real-world commercial application of an XtendiMax tank mix over a larger number of acres during high temperatures. While not a traditional GLP study, there were robust data quality measures in place akin to the GLP standards to ensure accuracy, data quality and reconstructability (all of which are critical elements of the GLP standards). The study was conducted on glyphosate-tolerant soybean totaling approximately 37 acres which is representative of a commercial application. Air and soil surface temperatures during application reached 92.2°F and 113.7°F, respectively. Post-application, air temperatures reached approximately 105°F during each day of the study.

Flux was measured using an in-field air profile monitoring station located in the approximate center of each test plot spray area with sample collectors at five heights (0.15, 0.33, 0.55, 0.90, and 1.5 m above the crop surface). Samples were collected from PUFs at the five established sampling heights at intervals of 6, 12, 24, 36, 48, 60, and 72 hours post-application. The highest peak flux rate was 0.00109 μ g/m²/sec, which is consistent with peak flux values from the Texas and Georgia studies submitted prior to the 2016 XtendiMax registration (Table 2). This additional data again demonstrates that the studies previously assessed on smaller scale are representative of larger commercial applications and that extreme temperatures do not significantly increase the volatility potential of XtendiMax.

Missouri Volatility Field Study

In May and June 2018, Monsanto completed a GLP volatility field study in Scott County, Missouri, a key geographic region that reported incidents of alleged dicamba symptomology. This study evaluated volatility over an extended duration of five days on an approximately nine-acre field planted with dicamba-tolerant soybean. Prior to application, air samples were collected to determine the level of background dicamba within the application area and soil samples were collected and tested to determine soil pH and soil composition. Following a single application of the XtendiMax tank mix, volatility was measured for five days by analyzing air samples collected by 13 PUF collectors at approximately 6, 12, 24, 36, 48, 60, 72, 84, 96, 108, and 120 hours following application. Specifically, air samples were analyzed from (a) an in-field monitoring station in the approximate center of the spray area that collected air samples at five different heights, and (b) eight perimeter monitoring stations located approximately five meters from the edge of the sprayed area that collected samples at 1.5 meters above the tops of the plants. The highest peak flux rate was 0.00079 µg/m²/sec, which is consistent with peak flux values from the Texas and Georgia studies submitted prior to the 2016 XtendiMax registration (Table 2). This data demonstrates that confirmatory flux is observed in a location that had a larger number of alleged drift complaints in 2017, that the maximum flux measured over five days is consistent with that measured over three days, and that extreme temperatures do not dramatically impact the volatility potential of XtendiMax.

Nebraska Volatility Field Study

In June and July 2018, Monsanto completed an approximately 100-acre GLP volatility field study in Seward County, Nebraska, a key geographic region that reported incidents of alleged dicamba symptomology. The field study was conducted over three days on an approximately 100 acre field with a 110-foot no-spray buffer around the plot. Following a single application of the XtendiMax tank mix, volatility was measured by analyzing air samples collected by 13 collectors at approximately 6, 12, 24, 36, 48, 60, and 72 hours following application. Specifically, air samples were analyzed from (a) an in-field monitoring station in the approximate center of the spray area that collected air samples at five different heights, and (b) eight perimeter monitoring stations located approximately five meters from the edge of the sprayed area that collected samples at 1.5 meters above the tops of the plants. The highest peak flux rate was 0.00183 µg/m²/sec, which is consistent with peak flux values from the Texas and Georgia studies submitted prior to the 2016 XtendiMax registration (Table 2). Again, this data also confirms that the smaller-scale studies are representative of larger commercial applications, and that extreme temperatures do not dramatically impact the volatility potential of XtendiMax. Furthermore, the volatility results spraying over-the-top of DT-soybean and non-tolerant soybeans are consistent and confirmatory results.

C. Summary and Conclusions of Volatility Studies Submitted Before and After the 2016 Registration

Collectively, the submitted field studies capture a wide range of potential conditions that might arise in commercial applications of XtendiMax, including large application areas, extreme high temperatures, extreme high and low humidity, sandy soils, low or high soil pH levels and nighttime temperature inversions. These field studies targeted key states, geographies or climates

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that experienced reports of alleged dicamba symptomology in 2017, and in certain cases measure volatility for an extended period post-application to capture any possibility of volatility occurring during an extended time period.

Table 2: Summary of Conditions in which Field Studies have been Conducted To-Date

Remarks	Year	State	Treatment	Timing	Flux	Cumulative Mass Loss	Max. Soil Tomo / 501	Max. Air Temp	Off-Site Air Concentration	Off-Site Dry Deposition	Soil Type	H	Average
		1			(µg/m ² -s) ¹	(%) ²	(1) duran	(1)	(ng/m ³) ⁵	(g/m ²) ⁶			Humidity (%)
		GA	XtendiMax with VaporGrip Technology + Induce	Pre-Emergent	0.001	0.047	117	88	5.3	1.43E-06	pues	56	2.44
EPA Reviewed Previously	2015	Ϋ́	XtendiMax with VaporGrip Technology + Induce	Post-Emergent	0.0003	0.063	155	96	2.4	9.93E-07	clav	0.9	0.04
	_	GA	M1601 Harhinda	Pre-Emergent	0,004	0.078	117	89	13.4	3.47E-06	loamv sand	5.4	42.3
		XL		Post-Emergent	0,0007	0.122	155	95	7.7	2.12E-06	clay	5.5	46.4
	2016	ř	XtendiMax with VaporGrip Technology + Roundup	Pre-Emergent	6600.0	0,195	125	100	15.6	4,12E-06	Clay loam	5.5	75.6
Previously			Powermax Herbicide	Post-Emergent	0:0030	0.141	125	66	12.6	3.25E-06	Clav	ag	7.27
	2017	New South Wales, Australia	XtendiMax with VaporGrip Technology + Roundup Powermax Herbicide + Intact	Post-Emergent	0,0011	0.077	133	108	4.35	1.50E-06	clau load		27.0
	2018	ΑZ	XtendiMax with VaporGrip Technology + Roundup Powermax Herbicide + Intact	Post-Emergent	0.00054*	0.094*	129	106	3.6	1.00E-06	clay	8.1	17.5
In This Submission	2018	WO	XtendiMax with VaporGrip Technology + Roundup Powermax Herbicide + Intact	Posl-Emergent	0.0008	0.204	135	95	TBD	TBD	silt loam	6.7	63.6
	2018	NE	XtendiMax with VaporGrip Technology + Roundup Powermax Herbicide + Intact	Post-Emergent	0.0018	0.146	127	91	TBD	TBD	silt loam	4.9	74.2
Peak flux value fron Represents mass lo	n the 72-ho ss over du	our profile us	sing AD and IHF methods, pri idy; all studies were conducte	e- and post- emerc d over 3 days with	gent plots exeption of MC) study that was c	conducted over	r 5 days					

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ourrace soil temperature data from sile meteorological station

"Based on data from flux meteorological station.

35th percentile air concentration at 5 m from edge of field, 24 hr averaging, based on PERFUM modeling and all values are below the NOAEC of 138 ng/m¹ in MRID 50578901, Gavick 2016 30th percentile dry deposition at 5 m from edge of field, 24 hr averaging, based on AERMOD modeling and all values well below the vegetative vigor endpoint NOAEC of 2.91E-05 g/m/

The indirect method produced the peak flux value and the mass loss for this study

The flux rates calculated across all eight field studies is consistent, and is characterized by a peak flux rate that is reached during the first 24 hours following application and low flux rates following the first 24-hour period, with slight diurnal variations (Table 2). The highest peak flux value was for M1691 in Georgia. The flux rates from studies submitted following the 2016 XtendiMax registration are comparable to those previously reviewed by EPA and equal to or below the maximum result for M1691 under a wide range of agronomically-relevant spray application scenarios.

With regard to soil pH levels, the 2017 and 2018 field studies, together with prior field studies for XtendiMax and other dicamba formulations, capture the relevant range of soil pH levels on which soybeans are grown in the United States. In order to determine whether pH levels in the field studies are representative of soybean fields across the United States, Monsanto used the USDA SSURGO database to extract pH values for soil in any field on which soybeans were grown at any point between 2012 and 2016 in six key soybean-growing states—Arkansas, Georgia, Illinois, Missouri, North Dakota and Tennessee. This analysis shows that Monsanto's field studies have captured the pH levels of 99% of soybean fields (Figure 1).

Figure 1: Comparison of soil pH measured during field volatility studies and under soybean growing areas in six major soybean growing states



Critically, a comparison of the soil pH level from each field study and the estimated flux using the aerodynamic method shows no statistically significant correlation between soil pH and flux (p = 0.2326; Figure 2). In other words, even in particularly acidic soils, flux measurements fell within the same range as for applications over less acidic soil (compare flux measurements for soils with pH levels of 5 and 5.5 to soils with a pH level of 6.5).





Thus, volatility field studies conducted in 2016, 2017, 2018 and in prior years rebut any suggestion that the application of XtendiMax over particularly acidic soils (with pH levels between 5 and 6) can cause unanticipated volatility at levels greater than those previously determined in EPA's regulatory analyses. Of course, any contrary hypothesis would also be at odds with basic principles of chemistry, which have been addressed by <u>chemist Dr. William Abraham</u>. Specifically, VaporGrip® Technology in XtendiMax uses an acetic acid-acetate buffering system to scavenge any extraneous protons that could be brought into the system from the tank mixtures, or on the surface of foliage or soil as the spray droplets dry, thus significantly limiting the formation of volatile dicamba acid. XtendiMax is designed with the buffering capacity of VaporGrip® Technology to control potential changes in pH and prevent the formation of volatile dicamba acid. Considering most agricultural soils conducive to plant growth and development have a resulting pH well above any that would influence increased volatility of this technology, the buffering capacity of VaporGrip® Technology is adequate to resist any changes in the pH of the residue from the spray.

II. MASS LOSS DATA FROM RECENT FIELD STUDIES FURTHER CONFIRMS PREVIOUSLY SUBMITTED STUDIES

For each field study, Monsanto calculated the mass of dicamba estimated to be volatilized during the duration of the study to understand the potential amount of dicamba that could be transported off-target. The calculated mass loss was consistent across all field studies described herein, regardless of geography, climate, or other application conditions and confirmed that only a small amount of dicamba is available to move off-target due to volatility, of which even a smaller amount could be in contact with non-target plants due to dispersive forces such as wind. These results further confirm EPA's previous risk assessment conclusions that volatility is a minor

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component of off-target movement and the downwind buffer will be protective of potential effects due to volatility.

A. Mass Loss Data Submitted Prior to the 2016 Registration Shows That Minor Amounts of Dicamba Volatilize Following Application

For the Texas and Georgia field studies using XtendiMax and M1691 submitted prior to the 2016 registration, mass losses were (1) 0.047% for the Georgia XtendiMax application (MRID 49888501), (2) 0.063% for the Texas XtendiMax (MRID 49888503), (3) 0.078% for the Georgia M1691 (MRID 49888401), and (4) 0.122% for the Texas M1691 application (MRID 49888403).

- B. New Mass Loss Data is Consistent with Data Submitted Prior to the 2016 Registration
 - 1. Texas Volatility Field Study, MRID 5057892

For the Texas field study submitted following the 2016 registration, total mass losses for the Bare Ground 1 plot was 0.195%. Total mass losses for the Cropped 1 plot was 0.141%. These mass loss calculations are consistent with mass losses in GLP field studies previously submitted to EPA.

2. Arizona Volatility Study

For the Arizona field study, total mass losses were 0.094%. These mass loss calculations are consistent with mass losses in GLP field studies previously submitted to EPA, thus showing that volatility does not increase over larger application areas and high heat conditions.

3. Australia Volatility Study, MRID 50606801

For the Australia field study, total mass losses were 0.077%. These mass loss calculations are consistent with mass losses in GLP field studies previously submitted to EPA, thus showing that volatility does not increase over larger application areas and high heat conditions. Further, these results show consistency in mass loss across various high heat field studies.

4. Missouri Volatility Study

For the Missouri field study, total mass losses were 0.204%. These mass loss calculations are consistent with mass losses in GLP field studies previously submitted to EPA, and show that mass loss does not increase significantly even over a measurement period of five days instead of three.

5. Nebraska Volatility Study

For the Nebraska field study, total mass losses were 0.146%. These mass loss calculations are consistent with mass losses in GLP field studies previously submitted to EPA, and show that mass loss does not increase significantly even over a larger application area (100 acres).

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III. THE REFINED NO OBSERVED ADVERSE EFFECT CONCENTRATION (NOAEC) PROVIDES AN ADDITIONAL MARGIN OF SAFETY

In early 2016, Monsanto submitted a dicamba vapor toxicity response humidome laboratory study that was used to determine a No Observed Adverse Effect Concentration (NOAEC). As described below, to address specific EPA comments, Monsanto has conducted an additional humidome study that determined a refined NOAEC. This refined NOAEC more precisely predicts the point at which exposure to dicamba will impact plant height, thereby providing an additional margin of safety in EPA's analysis of the results of air concentration modeling studies discussed in Section IV.

A. NOAEC Calculated Prior to 2016 Registration (MRID 49925703)

In the first dicamba vapor toxicity response humidome laboratory study used to determine a NOAEC, soybean indicator plants and a dicamba-containing formulation were placed inside a closed dome for 24 hours. MRID 49925703. The closed dome was placed inside a growth chamber and the dicamba that was present inside the dome was measured. The soybean plants were then removed from the closed dome and placed in a greenhouse where they were rated for visual response 14 and 21 days after treatment (DAT) and plant height 21 DAT. In its 2016 risk assessment, EPA concurred with Monsanto's calculation that, based on this study, the maximum dicamba vapor air concentration that would not adversely affect non-target plants—known as the NOAEC—is 17.7 ng/m³. *M-1768 Review of EFED Actions* at 5. EPA noted, however, that the dose spacing in the humidome study resulted in an approximately 30x difference between the NOAEC and the Lowest Observed Adverse Effect Concentration. *Id.* at 5. Thus, the NOAEC was overly conservative and *underestimated* the maximum dicamba vapor air concentration that would not adversely affect non-target plants. As such, EPA recommended an additional humidome study that examined a range of doses between the NOAEC and LOAEC to provide refined, more realistic NOAEC and LOAEC values. *Id.*

B. Calculation of Refined NOAEC (MRID 50578901)

In response to EPA's comments, Monsanto conducted an additional humidome study in late 2016 that determined a refined NOAEC. MRID 50578901. This study used the same procedure as the previous humidome study, but used lower spacing between doses as shown below in Table 3.

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Treatment Number	Spray Solution Composition (w/w)	Dicamba Acid ng/PUF		Dicamba Acid ng/m ³	Plant Height (in)		
		Mean	Standard Deviation	Mean	Mean	Standard Deviation	Significant
1	Deionized water 6 Petri dishes	< 10		< 3.5	28.08	1.18	NA
2	100% M1691 (1.2% ae) 6 Petri dishes	89.9	29.9	31.2	28.75	1.31	
3	95% M1691 (1.2% ae) & 5% Banvel® (1.2% ae) 2 Petri dishes	203	65	70.6	29.42	1.01	
4	95% M1691 (1.2% ae) & 5% Banvel® (1.2% ae) 4 Petri dishes	344	97	120	29.00	2.13	K-
5	95% M1691 (1.2% ae) & 5% Banvel® (1.2% ae) 6 Petri dishes	398	112	138	27.71	1.18	
6	75% M1691 (1.2% ae) & 5% Banvel® (1.2% ae) 2 Petri dishes	684	127	238	24.63	1.11	
7	75% M1691 (1.2% ae) & 5% Banvel® (1.2% ae) 4 Petri dishes	1394	113	484	21.08	2.27	
8	75% M1691 (1.2% ae) & 5% Banvel® (1.2% ae) 6 Petri dishes	1546	638	537	19.88	0.87	

Table 3: Measured	vapor-phase	dicamba	concentrations	in	humidome	and	corresponding I	plant
neight measurement	s							

No plant height effects to soybean plants were observed as a result of vapor-phase exposure to dicamba at concentrations of 138 ng/m³ and below (Treatments 1 through 5). Therefore, the refined NOAEC was 138 ng/m³, which should supplant the previous NOAEC used in EPA's 2016 risk assessment. This refined NOAEC adds an additional margin of safety to EPA's risk assessment, which evaluated air concentration and dicamba deposition as described below.

IV. NEW DICAMBA AIR CONCENTRATION AND DEPOSITION MODELING IS CONFIRMATORY OF MODELING RESULTS ANALYZED BY EPA IN 2016 REGISTRATION

Monsanto has conducted a total of seven modeling studies using peak flux data from field studies to predict "upper-bound peak" or "worst-case" dicamba deposition and air concentration in three locations in key soybean or cotton-growing regions,⁷ These studies used the Probabilistic Exposure and Risk model for FUMigants or PERFUM (air concentration) and the AERMOD (deposition) models, which have been adopted by EPA and are the Agency's preferred models for

⁷ The locations modeled were Peoria, Illinois; Lubbock, Texas; and Raleigh, North Carolina. Multi-year meteorological files for each location were developed using standard EPA preprocessor programs and National Weather Service data sources.

such modeling. For the deposition analyses, AERMOD was used to estimate 24-hour average dicamba deposition for several downwind distances from the edge of the field following an 80acre application of M1691, XtendiMax, or the XtendiMax + PowerMax tank mix. The deposition estimates represent high-end values that may occur in the direction the wind is blowing during meteorological conditions that are least conducive to gas dispersion. For the air concentration studies, PERFUM was used to estimate dicamba air concentration estimates for several downwind distances from the edge of the field following an 80-acre application of M1691, XtendiMax, or the XtendiMax + PowerMax tank mix. Additionally, air concentration estimates were made for four different averaging times, including 1, 4, 8, and 24 hours. As a conservative measure, these estimates represent the 95th percentile of the range of dicamba concentrations at each distance at different directions from the field based on the effects of the wind direction and variations in meteorological conditions. Thus, the air concentration estimates represent high-end values that may occur in the direction the wind is blowing during meteorological conditions that are least conducive to gas dispersion. The dicamba air concentration predicted by each AERMOD study are below both the NOAEC used by EPA in its 2016 risk assessment and the refined NOAEC later determined by Monsanto at EPA's request.

A. Air Concentration and Deposition Modeling Submitted Prior to the 2016 XtendiMax Registration

As recommended by EPA, prior to the 2016 XtendiMax registration Monsanto used the peak flux data from the Texas and Georgia field studies to model upper-bound peak acid deposition and air concentration following XtendiMax applications in three locations. *M-1768 Review of EFED Actions* at 6; MRIDs 49925801 & 49925802. EPA compared these air concentration results to the NOAEC discussed in Section III.A. Based on that analysis, EPA determined that "the predicted upper bound peak air concentration values for the M-1768 formulation are essentially at or below the soybean vapor-phase NOAEC." *M-1768 Review of EFED Actions* at 6. EPA acknowledged certain uncertainties in its analyses, but concluded that "the amount of uncertainty in the exposure estimates is small enough that it is very unlikely that the exposure will exceed the effect threshold (NOAEC)." *Id.* at 7. Thus, EPA concluded, no buffer—other than already applicable for spray drift—was necessary to address any concerns regarding volatility. *M-1768 Review of EFED Actions* at 3.

B. New Air Concentration and Deposition Modeling Submitted Following the 2016 Registration

In 2017 and 2018, Monsanto conducted new PERFUM and AERMOD modeling to supplement the modeling previously performed in 2015. The recent additional studies used the peak flux data from the post-registration Australia, Texas and Arizona XtendiMax tank mix field trials to calculate air concentration and deposition in the same three locations previously modeled (Raleigh, North Carolina; Lubbock, Texas; Peoria, Illinois). The results of the new deposition and air concentration modeling further demonstrate that, in a wide range of weather conditions and geographies, the commercial-scale application of XtendiMax will not result in air concentrations that will impact plant height outside the field.

1. Deposition and Air Concentration Modeling for a Spray Solution Containing MON 76980 Mixed with MON 79789 and Intact – Australia (MRID 50606802)

Using the flux rates determined by the Australia field study (MRID 50606801), Exponent modeled the air concentration and dry and wet deposition estimates of dicamba that could potentially occur downwind following application of the XtendiMax tank mix.

AERMOD deposition estimates: At 5 meters from the edge of the field, the maximum 24hour average dry deposition ranged from 1.5×10^{-6} to 2.8×10^{-6} g/m² and the maximum wet deposition ranged from 1.3×10^{-7} to 2.5×10^{-7} g/m². At the same distance, 5 meters from the edge of the field, the 90th percentile dry deposition ranged from 8.8×10^{-7} to 1.5×10^{-6} g/m², and the 90th percentile wet deposition ranged from 3.4×10^{-9} to 1.4×10^{-8} g/m². The results of the AERMOD modeling showed comparable deposition rates for Raleigh, Peoria and Lubbock, but that were slightly higher for Raleigh. As expected from general principles of air dispersion modeling, deposition declined with distance from the field.

24-hour PERFUM air concentration estimates 5 m downwind from edge of field: The estimated concentrations ranged from 2.9 to 4.4 ng/m³. The Raleigh dataset produced highest air concentrations, and the concentrations declined with distance from the field. The concentrations also declined with higher averaging times because variability in wind directions results in concentrations declining over longer averaging times at a given location.

The results of the air concentration modeling are below both the NOAEC used in the 2016 registration and the refined NOAEC later determined at EPA's request. Thus, these new data further confirm EPA's conclusion in 2016 that no buffer is necessary to address any concerns regarding volatility.

 Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with Formulation MON 79789 – Texas (MRID 50578903)

Using the flux rates determined by the post-registration Texas field study (MRID 50578903), Exponent modeled the dicamba dry and wet deposition and air concentration estimates that could potentially occur downwind of an application of the XtendiMax tank mix.

AERMOD deposition estimates: For the fluxes from the bare ground at 5 meters from the edge of the field, the maximum 24-hour average dry deposition ranged from 4.45×10^{-6} to 7.50×10^{-6} g/m² and the maximum wet deposition ranged from 3.59×10^{-7} to 8.45×10^{-7} g/m². At the same distance, 5 meters from the edge of the field, the 90th percentile dry deposition ranged from 2.39×10^{-6} to 4.12×10^{-6} g/m², and the 90th percentile wet deposition ranged from 6.80×10^{-9} to 3.94×10^{-8} g/m². For the fluxes from the cotton fields, at 5 meters from the edge of the field, the maximum 24-hour average dry deposition ranged from 3.53×10^{-6} to 6.05×10^{-6} g/m² and the maximum wet deposition ranged from 3.48×10^{-7} to 7.28×10^{-7} g/m². At the same distance, 5 meters from the edge of the field, the maximum wet deposition ranged from 3.48×10^{-7} to 7.28×10^{-7} g/m². At the same distance, 5 meters from the edge of the field, the 90th percentile dry deposition ranged from 1.91×10^{-6} to 3.25×10^{-6} g/m², and the 90th percentile dry deposition ranged from 1.91×10^{-6} to 3.25×10^{-6} g/m². For the field, the 90th percentile dry deposition ranged from 1.91×10^{-6} to 3.25×10^{-6} g/m². The field from 3.48×10^{-7} to 7.28×10^{-7} g/m². The same distance form the edge of the field from 3.48×10^{-7} to 7.28×10^{-7} g/m². The same distance form 1.91×10^{-6} to 3.25×10^{-6} g/m².

meteorological sites, the highest concentrations were for Raleigh, North Carolina, and deposition declined with distance from the field.

24-hour PERFUM air concentration estimates 5 m downwind from edge of field: Estimated concentrations ranged from 10.0 to 15.6 ng/m³ for the fluxes from the bare ground, and from 8.1 to 12.6 ng/m³ for the fluxes from the cotton field. The Raleigh and Peoria meteorological datasets produced similar air concentrations, while the concentrations were lower in Lubbock. As expected, the concentrations declined with distance from the field.

The results of the air concentration modeling are below both the NOAEC used in the 2016 registration and the refined NOAEC later determined at EPA's request. Thus, these new data further confirm EPA's conclusion in 2016 that no buffer is necessary to address any concerns regarding volatility.

Deposition and Air Concentration Modeling for Dicamba Formulation MON 76980 Mixed with Formulation MON 79789 – Arizona

Using the flux rates determined from the Arizona field study, Exponent modeled the dicamba dry and wet deposition and air concentration estimates that could potentially occur downwind of an application of the XtendiMax tank mix.

AERMOD deposition estimates: At 5 meters from the edge of the field, the maximum 24-hour average dry deposition ranged from 1.1×10^{-6} to 1.9×10^{-6} g/m² and the maximum wet deposition ranged from 6.5×10^{-8} to 1.5×10^{-7} g/m². At the same distance, 5 meters from the edge of the field, the 90th percentile dry deposition ranged from 5.9×10^{-7} to 1.0×10^{-6} g/m², and the 90th percentile wet deposition ranged from 1.7×10^{-9} to 9.2×10^{-9} g/m². For meteorological sites, the highest deposition levels were comparable for all three sites, with the highest modeled deposition found at Peoria and Raleigh. Deposition declined with distance from the field.

24-hour PERFUM air concentration estimates 5 m downwind from edge of field: Estimated concentrations ranged from 2.3 to 3.6 ng/m³. The meteorological dataset for Raleigh produced the highest air concentrations. As expected, concentrations declined with distance from the field.

The results of the air concentration modeling are below both the NOAEC used in the 2016 registration and the refined NOAEC later determined at EPA's request. Thus, these new data further confirm EPA's conclusion in 2016 that no buffer is necessary to address any concerns regarding volatility.

C. Analysis of All Submitted Air Concentration and Deposition Modeling Results

The results of all deposition and air concentration modeling conducted before and after the 2016 registration are below both the NOAEC used in the 2016 registration and the refined NOAEC determined at EPA's request in 2017 (Figure 3). Thus, volatility due to XtendiMax applications will not result in dicamba air concentrations that would have an adverse effect on plant height.

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MRID 50642701



Figure 3: Comparison of PERFUM air concentration estimates to NOAEC and refined NOAEC

Although not considered an apical endpoint by EPA for use in risk assessment, symptomology of potential dicamba exposure to soybeans can be qualitatively evaluated using a visual rating system (e.g., Frans and Talber (1977), Behrens and Leuschen (1979) and Sciumbato et al. (2004)). In these rating systems, 5% symptomology corresponds to a slight crinkling of leaves and represents the lowest level of potential exposure that can be determined under field conditions. In order to understand the potential for exposure outside of the application areas, maximum off-target air concentrations that were modeled based on measured flux results from field studies were compared to the air concentration that resulted in 5% symptomology (31.2 ng/m³) reported in Gavlick (2016). The dicamba air concentrations will not result in dicamba air concentrations that would cause 5% visual symptomology for any of the locations for which these data are available (Figure 4).

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Figure 4: Comparison of PERFUM modeled air concentration estimates to 5% visual symptomology concentration



. MODEL VALIDATION CONFIRMS AIR DISPERSION MODELS ACCURATELY REPRESENT OFF-TARGET AIR CONCENTRATIONS

Both field studies and mathematical modeling tools have been used to evaluate pesticide losses due to off-target movement post volatilization. Modeling tools have the advantage of being able to be run over a long-time period to represent a wide range of environmental conditions under which applications can be made, thus allowing the assessment of the probability and risk of vapor transport to off-target areas. It is neither feasible nor practical to conduct the quantity of field studies over a range of conditions that can be modeled using established regulatory mathematical models. Furthermore, a risk-based approach for off-target assessment is sensible in a regulatory setting, where conservatism can be built at different levels to provide adequate margin of safety. For example, EPA PERFUM model in regulatory risk assessments.

In order to further confirm the utility of air-dispersion models such as PERFUM and AERMOD for use in regulatory risk assessment, and as part of a GLP field study conducted on 26 acres of post-emergent glyphosate-tolerant soybean near Maricopa, Arizona in May 2018, Monsanto collected additional meteorological information and conducted an expanded the off-field air sampling program to facilitate air dispersion modeling verification. The expanded off-field air sampling program included eight perimeter samplers placed at 5 m (16 ft) from field edge that continuously measured dicamba air concentration over each of the 6 sampling periods (totaling 63.6 hours after application). Dicamba air samples were also collected at the center of the field for the duration of study and was then used to calculate flux using EPA-recommended methods (i.e. aerodynamic and integrated horizontal flux). The aerodynamic flux was then used as input to the AERMOD model along with relevant meteorological data collected during the study. The predicted air concentrations were then compared to measured perimeter air concentrations outside of the field that were collected throughout the duration of the study to confirm suitability of air-
dispersion models for dicamba off-target movement due to volatility⁸. The strong level of agreement between predicted and measured concentrations was determined using percent bias (PBIAS) model evaluation statistics. PBIAS measures the average tendency of predicted data to be larger or smaller that their measured counterparts. The results of the PBIAS evaluation indicated that the predicted concentrations are within 15% of their predicted counterparts (Figure 5). The predicted results show close agreement with measured concentrations, which confirmed that air dispersion models such as PERFUM and AERMOD are representative of potential off-target movement of dicamba following a representative commercial-scale spray application following label directions. Furthermore, the sound underpinnings for the models can be used probabilistically to conservatively estimate risk to provide adequate margin of safety.

Figure 5: Relationship between measured and predicted off-target air concentrations using location-specific flux and meteorological information



VI. SPRAY DRIFT DATA

A. Spray Drift Field Study Results Prior to the 2016 Registration

Drift exposure is "the principal risk issue" associated with the new uses of dicamba. *Final Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean* at 17-18. In reaching its determination that a 110-ft. downwind, in-field buffer was necessary to protect off-target species from the effects of spray drift, EPA analyzed spray drift modeling, a spray drift droplet deposition

⁸ It should be noted that this location-specific modeling was conducted in addition to the PERFUM and AERMOD modeling that was conducted using location-specific flux information and historical regional meteorological information that provides a robust probabilistic assessment of potential off-target movement due to volatility.

study, and multiple field trials each with multiple drift scenarios. EPA summarized those results in multiple record documents, including voluminous addenda. Id.; M-1768 Review of EFED Actions; U.S. EPA, Dicamba DGA: Second Addendum to the Environmental Fate and Ecological Risk Assessment for Dicamba DGA salt and its Degradate, 3,6-dichlorosalicylic acid (DCSA) for the Section 3 New Use on Dicamba-Tolerant Soybean at 2-6 (Mar. 24, 2016) [hereinafter Second Addendum]; U.S. EPA, Addendum to the Environmental Fate and Ecological Risk Assessment for the Section 3 New Use of on Dicamba-Tolerant Soybean, 4-8 (May 20, 2013) [hereinafter First Addendum]. Based on a weight of evidence approach and the results of spray drift modeling using the AgDRIFT model, EPA estimated the 90th percentile for the average distance of extra-course and ultra-course droplets from the field at 107 feet for a 0.5 lbs a.e./A application. Second Addendum at 2-4; First Addendum at 5-7. These results were further supported and confirmed by the result of eight spray field trials that were conducted under varying field conditions to represent a range of application scenarios. Id. at 7-8. In addition, a Texas field deposition study showed that dicamba would be present in amounts below the no-effect rate (NOER) at distances closer than 110 feet from the edge of the field; the corresponding distance in which the deposition was equivalent to the NOER (i.e., no-effect distance) was 77 ft. MRID 49770301. Accordingly, to prevent against the risk of effects from spray drift, EPA conservatively required a 110-foot downwind, in-field buffer when applying XtendiMax at the 0.5 lb a.e./A application rate, and a 220-foot buffer when applying at the 1.0 lb a.e./A application rate. First Addendum at 18.

B. Spray Drift Field Study Results Following the 2016 Registration

Following the 2016 registration, Monsanto conducted an additional spray drift field study in Arizona (which was in conjunction with the volatility field study discussed above in Section I.B.2). This field study evaluated spray drift by measuring the amount of dicamba that was deposited onto a total of 18 filter paper pads located along each of three transects, perpendicular to, and downwind of, the spray area at the following approximate distances: 5, 10, 15, 20, 25, 30 meters outside of the application area. Measured deposition rates downwind of the application area declined as distance from the application area increased and ranged from 0.000401 to 0.000132 on fraction of applied basis (Figure 6). No dicamba was detected in the upwind measurements.

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Figure 6: Spray drift deposition was less than the no-effect rate for all downwind sample distances.

These results are consistent with and 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, (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). These results also corroborate the plant effects results that were observed in the same field study and described in the following section.

VII. PLANT EFFECTS DATA SHOWS THAT SPRAY DRIFT IS THE PRIMARY MEANS OF OFFSITE MOVEMENT

The Arizona spray drift and volatility field study also measured the relative contributions of spray drift and volatility on visual symptomology. Plant heights and visual symptomology were measured approximately 14 and 28 days post-application on ten plants at each distance along each transect (5, 10, 15, 20, 25, 30 m). Transect areas of approximately 30 m upwind and downwind of the application area were covered with tarps during application and for 30 minutes after application concluded in order to isolate the effects of volatility versus spray drift. Plants not covered by the tarps were exposed to dicamba caused by spray drift, whereas plants covered by the tarps were exposed to very little spray drift. Thus, by comparing visual symptomology and plant heights from both tarped and un-tarped areas of the field, Monsanto determined the relative contributions of volatility and spray drift to off-target movement. Visual symptomology was assessed on a scale of 0 to 100 with 0 representing no visible plant response and 100 representing complete plant death. This plant response rating scale was consistent with visual response ratings

described in Frans and Talber (1977), Behrens and Leuschen (1979) and Sciumbato et al. (2004). In addition, cross-checks were implemented to ensure consistency across ratings.

Downwind symptomology was observed for un-tarped dicamba-sensitive soybeans located downwind of the application area; this symptomology decreased as distance from the sprayed area increased. No symptomology was observed for plants that were located under the tarps during the spray application at 28 days after treatment (Figure 7).

Figure 7: Downwind symptomology results for drift (untarped) and volatility (tarped) transects



Although the results showed some downwind visual symptomology from spray drift inside the buffer distance, there was no statistically significant difference in plant heights for tarped and un-tarped soybean plants located downwind from the application area (Figure 8). Thus, although visual symptomology occurred within the buffer distance for soybeans exposed to spray drift, this symptomology was not sufficiently significant at any distance to result in reductions in plant height. This shows that spray drift levels were not high enough to reduce plant height, which is fully consistent with, and expected, given that the measurement of deposition were rates less than the NOER for plant height in all downwind locations. Indeed, <u>a recent University of Missouri</u> study indicates that visually identifiable symptomology below 40% does not generally signal a

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reduction in or impact to soybean yield.⁹ Just as importantly, the upwind "volatility" transects showed no impact at all on plant height at any distance from the field.

Figure 8: Downwind plant height results for drift (untarped) and volatility (tarped) transects



These results further confirm that spray drift—not volatility—is the primary route of exposure for the off-target movement of dicamba.

⁹ Moreover, five percent symptomology equates to slight crinkling in terminal leaves, but terminal bud growth is not inhibited and there therefore is no impact on yield. (<u>Purdue</u> University, 2017).

IX. 2017 SOYBEAN AND COTTON YIELDS: NATIONWIDE AND IN PARTICULAR STATES

A. Nationwide Production and Yield

On a nationwide basis, total U.S. production of soybeans and cotton hit record high levels in 2017¹⁰—notwithstanding a "punishing drought" that plagued the Northern Plains from May through the remainder of the year and "erratic rainfall" that depressed other Midwestern soybean yields.¹¹ Although increased soybean and cotton acreage in 2017 was one relevant factor in these record production totals, nationwide per acre soybean and cotton yields were also higher than those of any prior year in U.S. history, except for soybean per acre yields in 2016.¹² (The 2016 growing season saw more favorable Midwestern weather conditions, which contributed to the extraordinary yields that year.¹³) The success of 2017 soybean and cotton crops is reflected in USDA and other

¹¹ United States Department of Agriculture, National Agricultural Statistics Service, Crop Production Summary at 110 (Jan. 2018) http://usda.mannlib.cornell.edu/usda/current/CropProdSu/CropProdSu-01-12-2018.pdf ("2017 Crop Production Summary").

¹² See USDA, National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Location: National; Time: 2018 through 1924; Period Type: Annual) (showing national soybean yield in 2017 as bested only by 2016 national year, which is the highest on record); See USDA, National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Cotton; Category: Yield; Data Item: Cotton, Upland- Yield Measured in Lb/Acre; Domain: Total; Geographic Location: National; Time: 2018 through 1954; Period Type: Annual) (showing national cotton yield in 2017 (895 lb/acre) as highest on record).

¹³ United States Department of Agriculture, National Agricultural Statistics Service, *Crop Production* Summary at 105 (Jan. 2017), http://usda.mannlib.cornell.edu/usda/nass/CropProdSu//2010s/2017/CropProdSu-01-12-2017.pdf ("In the Midwest, showery weather and the absence of extreme heat fueled record-high ... soybean yield and production."). To be sure, comparing 2017 national soybean yields (49.1 bu/acre)

¹⁰ Soybean production in 2017 totaled a record 4.39 billion bushels, and upland cotton production is estimated to be 21.3 million 480-pound bales, the highest totals reached by U.S. cotton growers in the prior decade and a 24 percent increase from the 2016 season. 2017 Crop Production Summary at 122-23; see USDA, National Agricultural Statistics Service. https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Cotton; Category: Production; Data Item: Cotton, Upland-Measured in 480 LB Bales; Domain: Total; Geographic Location: National; Time: 2018 through 2006; Period Type: Annual) (showing 2017 upland cotton production levels as highest in the prior ten years). Notably, two types of cotton are grown in the United States-upland cotton and pima cotton. Of that, 98.1% harvested is upland cotton. 2017 Crop Production Summary at 62.

publicly available production/yield data and in public comments by national grower organizations, who in amicus briefs in pending litigation expressed the following views:

Soybean Growers Association:

- "With the benefit of Xtendimax, soybean growers set record production and crop yield levels during the 2017 growing season."
- "Soybean yields set records in nine states where Xtendimax was used."
- "With Xtendimax, soybean growers have demonstrated the ability to control glyphosate-resistant weeds and weed seed banks and set record production and yield levels on a record number of acres planted. Requiring soybean growers to battle glyphosate-resistant weeds without the critical benefit of Xtendimax is sure to diminish production and yield levels and reduce control over weed seed banks, in turn disrupting growers' contributions to the food supply and agricultural economy and reversing environmental benefits, not only in the immediate future but also for years to come."¹⁴

National Cotton Council:

• "[T]he importance of dicamba—a herbicide that historically has been registered for use on other crops, but which the development of herbicide-resistant cottonseed has rendered safe and cost-effective for use on cotton—cannot be overstated. While previous formulations of dicamba have been registered for many years, the EPA concluded that the new formulations registered for use on the dicamba herbicide-tolerant crops pose less risk than previous formulations."

The EPA, in fact, reached the same conclusion that cotton growers across the country have reached based on their experience: Dicamba herbicides are an extremely effective tool whose potential harms can be safely cabined. Indeed, access to the dicamba chemistry in its improved formulations has

against 2015 national soybean yields (48 bu/acre) is a more reliable comparison, where in 2015, Midwest farmers suffered from a "much more unfavorable rainfall distribution." United States Department of Agriculture, National Agricultural Statistics Service, *Crop Production Summary* at 84 (Jan. 2016), *available at* https://www.usda.gov/nass/PUBS/TODAYRPT/cropan16.pdf (further identifying that "torrential late-spring and early-summer downpours in the lower Midwest led to flooding and planting delays, following by a late-summer turn toward dryness that stressed poorly rooted corn and soybeans.").

¹⁴ See Brief of Amici Curiae American Soybean Association and American Sugarbeet Growers Association, National Fam. Farm Coalition v. EPA, No. 17-70196 (E.C.F. 126-2).

become crucial to a grower's efforts to sustain weed control and effectively rotate MOAs ["modes of action"].¹⁵

B. Specific State and County Yield Data

Although certain litigants have contended that off target movement from multiple dicamba herbicides had widespread yield effects on soybean and cotton crops in specific locations where growers complained about dicamba applications, publicly available yield data demonstrates otherwise. Yields in Arkansas and Missouri provide two good examples. The two states received the highest number of grower dicamba complaints—by far—but also saw extremely positive soybean and cotton yields per acre.¹⁶ Arkansas alone accounts for roughly 36% of all the nationwide complaints of alleged dicamba drift in the 2017 growing season.¹⁷ But Arkansas also reported the highest yields per acre in the state's history in 2017.¹⁸ Even more telling are the yields per acre reported from the specific counties in Arkansas where farmers reported the greatest number of alleged dicamba drift reached double- or triple-digits in ten counties in the state.¹⁹

¹⁶ For the purpose of cataloging the number of alleged complaints, we cite information compiled by Dr. Kevin Bradley of the University of Missouri, as his compilation purportedly collects the unverified reports made to all state agricultural agencies as well as information collected from university extension weed scientists. Bradley's "Final Report on Dicamba-Injured Soybean Acres" accessed (October 2017) may be 30, https://ipm.missouri.edu/IPCM/2017/10/final_report_dicamba_injured_soybean/ (last visited July 25, 2018) ("Bradley Report"). Bradley indicates that in 2017, Arkansas growers made 986 complaints and Missouri growers made 310 complaints relating to alleged damage to soy acreage. To our knowledge, there are no estimates available from any source relating to alleged dicamba damage to cotton. We note, however, Dr. Bradley's acknowledgement that his "complaint" totals are unofficial "estimates" that do not reflect any conclusions of investigations by the state regarding whether the application of XtendiMax or of any other dicamba product was responsible for the purported damage nor the degree of any symptomology or potential yield impacts.

¹⁷ See Bradley Report (Arkansas growers made 986 complaints, alleging 900,000 acres of damaged soybean from dicamba drift).

¹⁸ See USDA, National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Location: State; State: Arkansas; Time: 2018 through 1924; Period Type: Annual) (showing Arkansas' soybean yield in 2017 (51 bu/acre) as highest on record).

¹⁹ Arkansas Dicamba Task Force Report at 26. During the 2017 growing season and for a few weeks thereafter, the Arkansas Plant Board posted online a map tracking complaints posted in various counties. The Plant Board has since taken down this map, but a screenshot of the map as of August 23, 2017 is available at the following website that indicates the same complaint numbers shown in the Arkansas Dicamba Task Force Report: Evan Allgood, ClassAction.com, "Dicamba

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¹⁵ See Brief of Amici Curiae National Cotton Council of America, National Fam. Farm Coalition v. EPA, No. 17-70196 (E.C.F. 118-2).

But in *every single one* of these ten counties, 2017 soybean yields increased from 2016 levels. Mississippi County—which alone accounted for 240 complaints of alleged dicamba drift—saw a 15.9% increase in soybean yields per acre from 2016 levels. Crittenden County (with 184 complaints) reported a 20.6% increase in yield per acre. Craighead County (92 complaints) experienced 8.9% increase. Poinsett County (89 complaints) saw a similar 8.2% increase. Soybean yields per acre increased by 11.7% in Saint Francis County (88 complaints) and Lee County (67 complaints) saw a similar increase at 11.5%. Phillips County (48 complaints) experienced an 8.2% increase; Cross County (45 complaints) a 7.1% increase; Monroe County (22 complaints) a 9.2% increase; and Clay County (15 complaints) a 17.1% increase.²⁰ These data show that there is no negative correlation between complaints reported and purported or actual decreases in yield per acre, as *every one* of the counties with the highest amounts of complaints within the *state* with the highest amounts of complaints experienced significant improvements in yield per acre.²¹

Missouri's 2017 soybean yield data is similar. Missouri's soybean production is concentrated in the southeastern portion of the state in an area known as the "boot heel." According to the Missouri Department of Agriculture, complaints of alleged dicamba damage in the 2017 growing season were concentrated in that region of the state, where there were at least 179 complaints.²² But every one of the "boot heel" counties experienced marked increases in

²² See University of Missouri, Division of Plant Scientists, Off-target Movement of Dicamba in Missouri. Where Do We Go From Here? (August 21, 2017), available at

Complaints in Arkansas Approach 1,000 Mark", https://www.classaction.com/news/dicambacomplaints-arkansas/ (last visited July 25, 2018).

²⁰ Compare Arkansas Dicamba Task Force Report at 26 (indicating numbers of reports of purportedly dicamba-injured acreage in counties in Arkansas) against data available for yields in Arkansas counties from USDA. National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Level: County; State: Arkansas; Counties: Mississippi, Crittenden, Craighead, Poinsett, Saint Francis, Lee, Cross, Monroe, Phillips, Clay; Select Time: 2016 and 2017; Period Type: Annual) (showing soybean yields grew between 2016 and 2017 for Mississippi, Crittenden, Craighead, Poinsett, Saint Francis, Lee, Cross, Monroe, Phillips, and Clay counties).

²¹ For example, Mississippi County yields increased from 48.9 bu/acre (2016) to 56.7 bu/acre (2017); Crittenden County increased from 43.7 bu/acre (2016) to 52.7 bu/acre (2017); Cross County increased from 47.7 bu/acre (2016) to 51.1 bu/acre (2017); Lee County increased from 43.5 bu/acre (2016) to 48.5 bu/acre (2017); Monroe County increased from 43.2 bu/acre (2016) to 47.2 bu/acre (2017); and Phillips County increased from 48.9 bu/acre (2016) to 52.9 bu/acre (2017). *See* USDA, National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Level: County; State: Arkansas; Counties: Mississippi, Crittenden, Cross, Lee, Monroe, Phillips; Select Time: 2016 and 2017; Period Type: Annual).

soybean yield per acre. Butler County (14 complaints) experienced a 23.8% increase in soybean yield per acre in 2017 as compared against 2016 yields. Dunklin County (21 complaints) experienced a 23.7% increase, and New Madrid County (25 complaints) saw a similar 24.9% improvement. Mississippi County (with the greatest among of complaints—50) experienced a 9.8% increase in soybean yield per acre. Pemiscot County (11 complaints) saw a 17.8% increase; Scott County (16 complaints) experienced an 8% increase, and Stoddard County (32 complaints) saw a 5.5% increase. The final county, Cape Girardeau (10 complaints), saw a 2.9% increase in yield per acre over 2016.²³ Arkansas and Missouri reported increases in state-wide cotton yield per acre as well.²⁴

Tennessee provides another helpful example. Although reliable county-level information regarding complaints about purported dicamba drift has not been made publically available, USDA yield data confirms that Tennessee saw record yield per acre for soybean in 2017, despite 132 grower complaints about alleged dicamba off target movement.²⁵ Illinois is another interesting case. Despite the negative impacts of "erratic" weather in the 2017 growing season, the state's 2017 soybean yield data (59 bu/acre) is only negligibly smaller than the state's yields recorded in record year 2016 (59 bu/acre).²⁶ Illinois 2017 yields were greater than those of 2015, 2014, 2013—and all other prior years—despite numerous complaints of alleged dicamba drift in 2017.²⁷

Of course, it was not just Arkansas, Missouri, Tennessee and Illinois that experienced successes in soybean and cotton yields in 2017 despite alleged dicamba drift complaints. Although

https://ipm.missouri.edu/IPCM/2017/8/Off-target_movement/ (last visited July 25, 2017) (indicating numbers of reports of purportedly dicamba-injured soybeans in Missouri boot heel).

²³ Compare, e.g., *id.* (indicating numbers of reports of purportedly dicamba-injured soybeans in Missouri boot heel) *against* data available at USDA, National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Level: County; State: Missouri; Counties: Butler, Cape Girardeau, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard; Select Time: 2016 and 2017; Period Type: Annual) (showing each of the eight boot heel counties in Missouri experienced between a 2.8-24% increase in soybean yields over 2016). Technically, Bollinger County is part of the "boot heel" region as well. That county reported one alleged dicamba drift complaint, but we do not include it in this analysis because USDA does not have yield data available for this county.

²⁴ 2017 Crop Production Summary at 63.

²⁵ 2017 Crop Production Summary at 53.

²⁶ 2017 Crop Production Summary at 53, 100.

²⁷ See Bradley Report (Illinois growers purportedly making 245 complaints); USDA, National Agricultural Statistics Service, https://quickstats.nass.usda.gov/ (last visited July 25, 2018) (select Program: Survey; Sector: Crops; Group: Field Crops; Commodity: Soybeans; Category: Yield; Data Item: Yield Measured in Bu/Acre; Domain: Total; Geographic Location: State; State: Illinois; Time: 2018 through 1924; Period Type: Annual) (showing national soybean yield in 2017 as bested only by 2016 national year, which is the highest on record).

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county level information is not publicly available, USDA state-level yield data further demonstrates the trend: farmers in Alabama, Mississippi, North Carolina and South Carolina all set new state records for soybean on a yield per acre basis in 2017.²⁸

As noted, drought conditions suppressed yields in Northern plains states while other Midwestern states experienced other negative weather conditions.²⁹ Indeed, a large number of those states had relatively few complaints (compared to Arkansas, Missouri and Tennessee, for example), but felt significant impacts from weather and saw negative yield impacts.³⁰ For example, growers in Wisconsin reported only four alleged drift complaints but saw a nearly 15% drop in soybean yields, and Michigan farmers reported two complaints and suffered a 16% drop in yields.³¹

The appropriate conclusions from this data are plain: Complaints alleging dicamba offtarget movement cannot be associated with any widespread yield losses on either soybeans or cotton. In fact, the available data suggests that the most profound yield gains occurred in several of the locations from which the highest numbers of complaints arose.

X. ANALYSIS OF 2018 INQUIRIES

As EPA is aware, Monsanto voluntarily amplified the XtendiMax label following the 2017 growing season to further minimize the risk of applications that might move off-target in the 2018 growing season. Monsanto also voluntarily requested that EPA change the pesticide classification for XtendiMax, making it a restricted use pesticide for 2018. As a result of these changes:

- Xtendimax can be applied only by a certified applicator;
- XtendiMax applicators are subject to recordkeeping requirements that allow EPA and state regulators to better track when and where dicamba products were sprayed and under what conditions;
- XtendiMax applicators must complete dicamba-specific applicator training;
- XtendiMax can be applied only if maximum wind speed is between 3 and 10 miles per hour, reduced from a maximum of 15 miles per hour;

³¹ Bradley Report; Crop Production Summary at 53. Growers in Wisconsin and Michigan do not produce cotton of any type, either. *Id.* at 63.

²⁸ 2017 Crop Production Summary at 122-23.

²⁹ Id. at 110.

³⁰ 2017 Crop Production Summary at 110. *See also* Bradley Report (indicating complaints made in Illinois, Iowa, Kansas, Missouri, North and South Dakota, and Nebraska along with Wisconsin, Michigan, Ohio, Indiana and Minnesota)

- XtendiMax cannot be applied between sunset and sunrise, preventing applications
 when temperature inversions that exacerbate off-site movement are more likely to
 occur;
- XtendiMax applicators receive additional guidance about proper tank hygiene to prevent contamination; and
- XtendiMax applicators must identify and record the presence of sensitive crops near the application site to increase awareness of the risk to these crops.

As described, our efforts to evaluate hundreds of telephone calls regarding alleged off target movement demonstrated a range of specific circumstances, including neighboring dicamba applications over corn in many locations, issues with crops impacted by other non-dicamba herbicides, crops impacted by other phenomena such as disease or weather, applications that did not comply with required label conditions, and many circumstances where the crops at issue were not actually impacted, much less impacted by any herbicide application. As has become evident, *the number of complaints received does not necessarily correspond with any actual "injured" acreage associated with dicamba*. Indeed, we urge extreme caution in assuming any level of acreage injured simply based on the number of complaints identified. Without specific evaluations, any assumptions of what actually occurred on the field are not possible, and it is certainly not possible to equate the number of calls received with any allegedly harmed acreage totals. Any such assumptions would be unscientific.

Indeed, although we have completed 450 unique evaluations as of July 19, 2018, the number of acres allegedly associated with off-target dicamba movement—caused by a range of issues not implicating proper applications of XtendiMax—were only 14,345 acres

The available evidence shows that applicators have had greater success in avoiding applications that move off-target in 2018—likely due in part to the training by Monsanto of approximately 96,000 growers who apply XtendiMax. Indeed, as shown in the following charts, the number of inquiries made to Monsanto regarding possible off-target movement decreased dramatically in 2018 as compared to the same date in 2017 (468 as of July 19, 2018 as compared to 1002 on the same date in 2017), even as the total acreage of Xtend soybean and cotton nearly doubled:

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This is in sharp contrast to the circumstances reported in the State of Arkansas, where XtendiMax was not approved for use in 2017 or 2018, where, according to the Arkansas Plant Board, the overall number of inquiries did not see as significant of a decrease. Because XtendiMax was not approved for use in the state of Arkansas, growers in that state did not have access to the same training as growers in other states. Moreover, growers in Arkansas who sprayed dicamba in 2018 would have done so unlawfully, and in most instances, likely would have utilized older, more volatile formulations of dicamba, which were offered for sale in the state and would not have had the benefit of lower volatility formulations, or the more protective XtendiMax labeling designed to minimize off-target movement.³²

Importantly, as the analysis discussed below shows, the number of inquiries should not be construed as a valid measure of whether "offsite incidents are ... occurring at unacceptable frequencies or levels." That said, because Monsanto has conducted a detailed and robust evaluation of each inquiry it has received, we have organized this analysis around those inquiries. Similarly, it is important to recognize that even where a field exhibits symptomology consistent with dicamba exposure, that symptomology by itself does not mean that there will be an impact on plant height or yield. In other words, symptomology by itself is not necessarily relevant to EPA's risk assessment, unless it is sufficient to impact plant height and yield.

Moreover, the overall number of acres allegedly impacted by off-site movement of dicamba has decreased dramatically in 2018 as compared to 2017. As shown in the table below, the number of inquiries have decreased from approximately 37 per million acres in 2017 to 8 inquiries per million acres in 2018. (Nor is there any evidence that the acreage allegedly affected per inquiry in 2018 is higher than in 2017.)

³² Although Xtendimax was not sold in Arkansas in 2017 as well, in that year growers were able to apply BASF's Engenia product to Xtend crops. However, according to BASF, in 2017, BASF sold enough Engenia to spray only about half of the acres reportedly sprayed in the state, suggesting that rampant use of unregistered pesticides was a significant factor in 2017 as well.



Figure 10: Comparison off-target movement inquiries – by acres (2018 versus 2017)

At the same time, generic dicamba remains widely available – and widely used on corn, small grains and pasture land³³– and lacks any of the significant formulation advances or label restrictions that are designed to minimize off-target movement. While it is not approved for incrop applications to soybeans or cotton, the following are true for generic dicamba:

- Is not a restricted use pesticide and can be applied by anyone;
- Has no requirement for training to teach applicators how to minimize off-target movement before they can use the product;
- Is dramatically higher in volatility and in drift potential;
- Can be tank mixed with any product including AMS that may further increase drift and volatility potential;
- Need not be used with a drift reduction agent;
- Can be applied without any buffer to minimize downwind off-target movement;
- Can be applied using many nozzle-types rather than being restricted only to ultracoarse nozzle types that minimize drift potential;

³³ Monocots such as corn are not affected by dicamba.

- Can be applied between sunset and sunrise, preventing when temperature inversions that exacerbate off-site movement are more likely to occur
- Can be applied aerially be applied during high wind events; and
- Are subject to absolutely no reporting and recordkeeping requirements.

Because generic dicamba is cheaper than Xtendimax, and approved for use in corn, many corn and small grain growers may prefer to use generic dicamba rather than Xtendimax (or any of the other new formulations). Because generic dicamba sales have increased significantly in recent years, applications of generic dicamba may be responsible for a portion of the reported incidents of off-target movement. There is increased usage of dicamba and dicamba containing pre-mix herbicides, for use in corn, small grains, and pastures, due to the effectiveness of the molecule in controlling resistant broadleaf biotypes (i.e. ALS, PPO, HPPD, PSII, glyphosate, and 2,4-D).





Building off of the lessons learned in the 2017 growing season, in 2018 Monsanto implemented an even more robust and rapid process for evaluating inquiries into off target movement, whether reported by herbicide applicators or by non-applicators. Monsanto's Field Engagement Specialists objectively evaluated every inquiry reported to us. Every inquiry call is answered within two business days, and every field or site allegedly affected is visited as soon as possible, with the goal three business days after return call is obtained. For incidents reported by non-applicators, the Field Engagement Specialists assess the allegedly-injured field to identify symptomology and impacted crops. All relevant facts are documented, including a precise measure of potentially impacted fields; expert panels, independent from the Field Engagement Specialists, review and evaluate all of the facts collected through this process. The data collected through this process is inputted and mapped in a database with a summary of conclusions obtained from the field inquiry.

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As of July 19, 2018, Monsanto had received a total of 468 individual inquiries regarding off-target movement potentially related to dicamba. Of those, 172 were reported by applicators and 296 were reported by non-applicators. Review of 450 of those inquiries have been completed to date.

Nature Of Inquiry	No of Inquiries	Contacted	Completed
OTM - Applicator	172	170	163
OTM - Non Applicator	296	295	287
Grand Total	468	465	450

Table 4: Total inquiries evaluated by Monsanto (through July 19, 2018)

Table 5: Total inquiries evaluated by Monsanto - by state (through July 19, 2018)

Field State	Applicator	Non- Applicator	Grand Total
GA		5	5
IA	41	20	61
IL	52	99	151
IN	16	13	29
KS	6	3	9
KY		7	7
LA	1	8	9
MI	6	3	9
MN	4	10	14
мо	18	15	33
NC		4	4
ND	1	39	40
NE	7	16	23
OH	4	10	14
ОК	64102	2	2
SD	6	11	17
TN		18	18
TX	S	3	3
VA		1	1
WI	1	-	1
Total	163	287	450

ER 0320

This in-depth review resulted in several notable conclusions. *First*, of the 146 inquiries reported to have uniform symptomology, 60% were in Illinois. And virtually *all* of the impacted fields in Illinois had a higher density of corn, small grains, pasture and other fields surrounding the impacted soybeans than Xtend fields. Given the higher propensity of older dicamba formulations to drift and volatilize, coupled with the higher density of fields on which these dicamba formulations would have been used, the most likely conclusion is that the symptomology was the result of application of older dicamba formulations on those corn or small grain fields that bordered soybean fields. The remaining fields showing uniform symptomology were in a range of different states, but our analysis to date suggests that the same situation occurred in those other states as well. An example of such an inquiry evaluated by Monsanto is shown below (Map 1). The yellow shading shows where corn fields are located; blue represents Xtend soybeans, where Xtendimax may have been sprayed; red is the conventional soybeans that alleged an impact; and pink is LibertyLink soybeans.³⁴



Map 1: Example Inquiry Investigated by Monsanto showing surrounding crop fields

As this illustration shows, it is far more likely that old dicamba sprayed on one of the adjacent corn fields was responsible for any alleged symptomology than Xtendimax sprayed on the Xtend field—particularly in light of the many label requirements on the Xtendimax label that are

³⁴ The red flag was Monsanto's point of entry and does not necessarily represent the location of any dicamba symptomology.

designed to prevent off-target movement, requirements which are not present on old dicamba and Group 4 labels used in corn, small grains, or other non-crop uses. This is one of multiple aerial images we can supply showing these circumstances.

The following table illustrates that corn was adjacent or near to potentially impacted fields far more often than were Xtend crops. And including other crops where old dicamba may be used (small grains, pasture, etc.), the numbers are even more disproportionate.

Table 6: Number of reported incidents where Group 4 herbicides may have been used in proximity to susceptible soybean fields (through July 19, 2018)

	Proximity to (Field	UTM - Non-Applicator Inquiry
Landscape/Field*	50 Feel	100 Feet
CORN	611	819
CORN STALKS	2	2
COTTON, XTENDFLEX	1.20	3
SOYBEAN, XTEND**	102	140
SOYBEANS	1	2
PEANUTS	1	2
CRP	10	14
FALLOW	2	2
GOLF COURSE	1	1
HAY	3	3
GRASS/PASTURE/ETC	89	112
SORGHUM/SMALL GRAINS	30	45

*Field reported may have contributed to inquiry field symptomology

**Includes unconfirmed but suspected Xtend soybeans fields

As noted above, application of these older higher volatility formulations over corn or small grains is allowed under those labels, but of course can result in visual symptomology to nearby soybean fields. These older dicamba formulations can be an order of magnitude or more volatile than Xtendimax, but no buffer is required nor are there any restrictions on application during inversions or periods of high wind, nor any requirements to use ultra-coarse nozzles to minimize drift or any restrictions on using tank mixtures that could increase drift and volatility.

It is reasonable to consider why such incidents would be appearing for the first time now, when old dicamba has been on the market for use on corn, small grains and pasture for decades. But it is important to recognize that Xtendimax has been the subject of unprecedented publicity and scrutiny. That scrutiny resulted in several positive outcomes, including: a significant drive to improve label compliance; unprecedented efforts to reduce pesticide drift; unprecedented grower training; and unprecedented recordkeeping to facilitate compliance and enforcement. But that scrutiny also appears to have resulted in growers noticing – and reporting for the first time – effects

ER 0322

that likely have been present for years as a result of off-target movement of other pesticides, old dicamba, and agronomic stress.

Second, and relatedly, in many instances (approximately 6 percent), Monsanto's in-depth inquiry revealed that no Xtend field was located near to the alleged incident. Again, however, other potential sources (including corn and small grains, where old dicamba can be sprayed) were located close to the field. An illustration of one such actual field is shown below (Map 2). (Yellow shading shows where corn fields are located; green represents trees and grass; red is LibertyLink soybeans; and purple is the LibertyLink soybeans that alleged an impact.)



Map 2: Example Inquiry Investigated by Monsanto showing surrounding crop fields

As noted above, it is likely that this type of visual symptomology had been occurring for years but was not widely recognized until the recent scrutiny of Xtendimax.

Third, the label enhancements and the training conducted in 2018 have had notable success in helping applicators reduce off-target movement. For example, only *eight* applicators inadvertently mixed AMS in the tank in 2018—a dramatic improvement from 2017. And overall, the incidences of non-compliance with the label were small—and substantially fewer than in 2017. Nonetheless, label non-compliance was responsible for approximately 66 percent of the incidents evaluated by Monsanto to date. The table below shows the types of applicator errors that have been identified in our investigations. (Note that more than one error could have been reported in a single incident.)

Application Requirements (Applicator Reported)	Compliant	Not Compliant	Information Not Provided
Use of Required Buffer	81	80	2
Tank Mix	115	45	2
Approved Nozzle	148	11	3
Boom Height @ Application	145	12	6
Wind Speed	153	0	10
Equipment Speed	51	0	1

Table 7: Results of inquiries evaluated by Monsanto – applicator label compliance (through July 19, 2018)

Fourth, a detailed review of the symptomology demonstrated, from non-applicator fields, that in 13 percent of cases, dicamba could not have been the cause of the alleged incident. For example, in some cases the symptomology was consistent with 2,4-D exposure.

Table 8: Results of inquiries evaluated by Monsanto of non-dicamba symptomology (through July 19, 2018)

Symptomology	Inquiry
2,4-D	19
Agronomic/Disease/Stress	16
Other Group 15	20

Fifth, system hygiene/contamination improved dramatically this year as a result of the increased training and the label enhancements, but remained the cause of approximately 5 percent of the reported incidents. For example, Monsanto has identified incidents where a tank mixture was refilled in-field from the supplier, and symptomology was exhibited uniformly across the field, but was identified where the sprayer skipped areas around the field edge. This area initiated further conversation with supplier and grower to determine hygiene issues with the bulk load(s).

Sixth, the overall number of acres with potential symptomology is low – only 14,345 acres as of July 19. Monsanto notes here that its detailed, site-specific evaluations provide the best evidence of actual acres potentially impacted. Although AAPCO has been tracking reported incidents by state, not all states are participating – and those states that do participate may report number of individual incidents but not the acres potentially impacted. And while Dr. Kevin Bradley has suggested larger numbers of potentially impacted acres by state, Dr. Bradley's estimates are admittedly anecdotal and do not identify any yield impacts – and in any event are generally not consistent with what those states have reported via AAPCO.

Seventh, Xtendimax volatility caused few if any incidents of off-target movement. Indeed, Monsanto has identified only eight incidents (less than 1%) where volatility even possibly could have been the cause - and none of those were confirmed to be caused by volatility as all eight incidents had other potential causes as well. The areas are limited to defined gradient from source field directly adjacent and could be a result of variable winds, sprayer velocity at head row, and/or boom height during turnaround. In none of these cases was uniform symptomology observed; all areas exhibiting symptomology we confined to near the field edge adjacent to source field. Moreover, any off-target movement of XtendiMax can be addressed effectively through additional grower training. In sum, the number of off-target movement inquiries reported to Monsanto has decreased in 2018 even as the number of dicamba-tolerant soybean acres planted doubled. And the number of reports of suspected off-target movement per acre of dicamba-tolerant soybean planted has declined by 54% from 2017 to 2018. Moreover, as in 2017, the state with the highest number of complaints of off-target dicamba damage in 2018 is Arkansas, where Xtendimax is not sold. Finally, it is important to recognize that even where a field exhibits symptomology consistent with dicamba exposure, that symptomology by itself does not mean that there will be an impact on yield. Indeed, as discussed above, 2017 saw record yields in much of the country - and particularly in areas that saw the highest numbers of dicamba-related complaints. Monsanto would be happy to provide EPA with more detail about the 2018 incident database, if requested.

<u>Finally</u>, it is important to note the tremendous benefits of XtendiMax, which is a key consideration in EPA's registration decision. In 2017, 97% of growers surveyed who applied XtendiMax were satisfied with weed control. (August 2017 survey of growers using XtendiMax). Moreover, in 2015 and 2016 Monsanto herbicide system trials, comparing the performance of the Xtend crop system to other competing weed control systems, the use of XtendiMax with Roundup Ready® Xtend soybeans yielded a 5.4 bushel per acre advantage over the leading alternative herbicide system.

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Photograph 1: 2,4-D leaf strapping symptomology on cotton



Photograph 2: Iron Chlorosis exhibited on young soybeans

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Photograph 3: Disease exhibited on Green Peas

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Photograph 4: Leaf puckering and drawstring affect from chloroacetamide application in soybeans



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

- Date: November 1, 2018
- Transmittal of "Summary of New Information and Analysis of Dicamba Use on SUBJECT: Dicamba-Tolerant (DT) Cotton and Soybean Including Updated Effects Determinations for Federally Listed Threatened and Endangered Species"
- Environmental Fate and Effects Division (7507P) Maruffe Scherer Office of Pesticide Programs (ODD) FROM:

TO: Michael Goodis, Director Registration Division (7505P) Office of Pesticide Programs (OPP)

As finalized October 31, 2018, please find attached the final document entitled, "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".

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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

October 31, 2018

Prepared by

OFFICE OF PESTICIDE PROGRAMS

U.S. Environmental Protection Agency 1200 Pennsylvania Ave., NW Washington, DC 20460

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1. Description of the Federal Action

In 2016, EPA issued a dicamba time-limited registration to Monsanto (now Bayer¹) for use on dicamba-tolerant soybean and cotton. The expiration on the 2016 registration is November 9, 2018. EPA received a request to amend this registration that included extending the registration to December 2020, as well as other labeling restrictions, as requested by EPA, to further minimize the potential for off-site movement of dicamba. In addition to the retention of the 110-foot downwind spray drift buffer currently on the Engenia, FeXapan and Xtendimax labels, which was an important component of earlier no effect determinations, additional label language and mitigations have been added to reduce the off-field movement of dicamba residues. These include the following changes from previous labels:

- 1. Restriction for use by certified applicators only (intended to increase label compliance).
- 2. Require dicamba specific training for all applicators (intended to increase label compliance).
- 3. Label language revision to improve label consistency and enforceability (intended to increase label compliance).
- 4. Revised language limiting dicamba application to an interval between 1 hour after sunrise and 2 hours before sunset (intended to reduce the potential for applications proximal to temperature inversion conditions).
- 5. Establishing the period of application limited to 45 days after soybean planting (or before R1 stage) and 60 days after cotton planting, with a maximum of 2 postemergent applications (intended to reduce the frequency of events that could potentially result in off-site movement).
- 6. Tank clean out instructions to include clean out of the entire application equipment (intended to reduce the potential for cross-contamination).
- Improve label description of sensitive crop/susceptible crop and sensitive areas (intended to improve label compliance and reduce the potential for dicamba application near sensitive non-target plants).
- 8. Enhance the label with pH advisory language to improve applicator awareness of the impact of low tank-mix pH on volatility of dicamba (expected to reduce the contribution of volatile dicamba to overall off-site exposure).

The above general label requirements are reasonably expected to improve pesticide applicator awareness of the potential for off-site dicamba movement and to further minimize dicamba movement potential. Additionally, all other previous label restrictions (*e.g.* nozzle restrictions, 110-ft downwind spray drift buffer, tank mix partner prohibitions etc.) remain in place.

¹ Fexapan and Engenia were registered after the Xtendimax Registration

The above list of label restrictions does not include any **additional** proposed mitigation to avoid effects to listed species. The effects determination in **Section 5** of this document, presents conclusions with and without mitigations in place.

The end-use products related to this decision are EPA Reg Nos. 524-617 (M1768 Herbicide, Xtendimax with VaporGrip Technology; Bayer CropScience, previously Monsanto Company), 7969-345 (Engenia Herbicide; BASF Corporation), and 352-913 (FeXapan Herbicide; Corteva Agriscience, previously Dupont).

This memorandum and effects determinations are for the 34 states that are currently registered for the dicamba over-the-top use pattern, as listed below:

Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, West Virginia and Wisconsin

2. Existing effects determinations

2.1. Previous Screening Level and Refined Ecological Risk Assessment Conclusions

In March 2016, EPA issued a Section 3 screening-level risk assessment for the use of diglycolamine salt of dicamba (dicamba DGA) on dicamba herbicide-tolerant cotton (USEPA, 2016a; D404823) and an addendum to the 2011 Section 3 screening-level Risk Assessment for the use of dicamba DGA on dicamba herbicide-tolerant soybeans (USEPA, 2016b; D426789). Concurrent with these two actions, EPA issued three addenda to the risk assessments (USEPA, 2016c-e; D416416+) that refined the screening-level risk assessments to include species-specific assessments for threatened and endangered (hereafter referred to as "listed") species present within the 34 states included in the Section 3 registrations on dicamba-tolerant crops (Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, West Virginia and Wisconsin).

The screening-level risk assessments concluded that potential direct risk concerns <u>could not be</u> <u>excluded</u> for:

• mammals (chronic, from the soybean use only, due to residues from dicamba's metabolite, DCSA, rather than from parent dicamba);

- birds (acute from parent dicamba for both soybean and cotton uses; chronic from DCSA residues only in soybean but not in cotton), considered surrogates for reptiles, and terrestrial-phase amphibians; and
- terrestrial plants (soybean and cotton uses)

In the screening-level risk assessments, indirect effect risk concerns for all taxa <u>were possible</u> for any species that have dependencies (e.g., food, shelter, and habitat) on mammals, birds, reptiles, terrestrial-phase amphibians, or terrestrial plants.

Additionally, the screening-level assessment showed that direct risk levels of concern were not exceeded for:

- mammals (acute) and (chronic—for the cotton use only);
- birds, reptiles, and terrestrial-phase amphibians (chronic from parent dicamba or DCSA degradate from use on cotton);
- terrestrial insects (acute and chronic);
- freshwater fish (acute and chronic);
- aquatic-phase amphibians (acute and chronic);
- estuarine/marine fish (acute and chronic);
- freshwater invertebrates (acute and chronic); estuarine/marine invertebrates (acute and chronic); and
- aquatic plants²

In the screening-level cotton risk assessment and soybean addendum as part of the earlier public comment process, EPA concluded that mitigation measures, including the use of rainfast mitigation to limit runoff exposure, limiting nozzles to those that restrict droplet spectra to extra-coarse and ultra-coarse, restricting applications under certain wind conditions (*i.e.* only apply when wind speeds are between 3 and 15 mph), and the use of a 110-foot buffer (for a 0.5 lb a.i./A application) in the direction of wind to account for spray drift and applying that buffer in every direction to account for potential volatilization (a discussion of the updates to this assessment is provided below), would limit any exposures beyond the treated field to levels below thresholds that would trigger any risk concerns for any taxa. These assessments concluded that by applying the rainfast mitigation and utilizing the spray drift and volatility buffer as setbacks from the edge of the field ("in-field buffers"), exposures that could potentially trigger risk concerns would be limited to the treated field. With these labeling restrictions, EPA determined that the vast majority of listed species would be off-field and therefore would not be part of the action area and consequently reached a No Effect decision for those species. Species that were potentially on the treated field or utilizing resources from

² The listed species LOC was exceeded for non-vascular aquatic plants; however, there are no listed species in this taxa.

the treated field and for which the screening-level risk assessment indicated concerns for that taxa underwent further refinement to determine the potential for risk.

Subsequent to the screening level risk assessments and refined endangered species addenda, EPA issued several additional addenda including the evaluation of field volatility (flux) studies for DGA formulations (USEPA, 2016f; D435792), bridging data and volatility analysis for dicamba BAPMA salt (USEPA, 2016g-h; D402518, D436905) and an additional refined endangered species addendum (USEPA, 2016i; D436602) that covered listed species that were newly listed between the Section 3 registrations of dicamba DGA salt on dicamba-tolerant soybeans and cotton and the Section 3 registration of dicamba BAPMA salt. The evaluation of the flux studies for DGA and the volatility analysis for both DGA and BAPMA concluded that volatility buffer setbacks were not needed to limit exposures off the field to below the threshold level (set by the listed species endpoint for the most sensitive plant species tested, soybean), though uncertainties were noted at that time including whether the submitted flux studies (MRIDs 49888401, 49888403, 49888501 & 49888503) adequately encompassed the extremes of conditions (*i.e.* when temperatures are greater than the low 90°s) that can increase the rate of volatility and the statistical uncertainty in the calculation of the risk quotient based upon the large 30x difference between the submitted vapor phase humidome NOAEC and LOAEC (MRID 49925703).

By limiting the action area to the treated field, the refined endangered species addenda (USEPA, 2016c-e, i; D416416+) concluded that all but 27 listed species were outside of the action area. Overall, of the remaining 27 species, one likely to adversely affect (LAA) determination was made, two not likely to adversely affect (NLAA) determinations were made, and no effect (NE) determinations were made for the remaining species (**Table 1**, reprinted from USEPA, 2016; D436602).

Species	Effects determination	Crops Pertinent to Effects Determination*	Areas of Concern
Indiana bat	NE	Cotton, Soybean	NA
Lesser long- nosed bat	NE	Cotton, Soybean	NA
Mexican long- nosed bat	NE	Cotton, Soybean	NA
Northern long-eared ba <u>t</u>	NE	Cotton, Soybean	NA
Ozark Bat	NE	Cotton, Soybean	NA
Virginia big- eared bat	NE	Cotton, Soybean	NA
Canada Lynx	NE	Cotton, Soybean	NA
Gray wolf	NE	Cotton, Soybean	NA

 Table 1. Summary of Previous Effects Determinations for Federally Listed Threatened or

 Endangered Species within the Action Area (USEPA, 2016i; D436602)

Species	Effects	Crops Pertinent to Effects	Areas of Concern	
	determination	Determination*		
Mexican wolf	NE	Cotton, Soybean	NA	
Red wolf	NE	Cotton, Soybean	NA	
Jaguar	NE	Cotton, Soybean	NA	
Gulf-Coast	NE	Cotton, Soybean	NA	
jaguarundi				
Ocelot	NE	Cotton, Soybean	NA	
Sonoran	NE	Cotton, Soybean	NA	
pronghorn				
antelope				
Whooping	NE	Cotton, Soybean	NA	
crane				
Attwater's	NE	Cotton, Soybean	NA	
greater				
prairie-				
chicken				
Eskimo	NLAA	NA	NA	
curiew				
Gunnison	NE	Cotton, Soybean	NA	
Sage Grouse		Cattan Saukaan		
Nilssissippi	INE	Cotton, Soybean	NA	
Audubop's		Cattan	Palm Boach County in	
Crested	INLAA	cotton	Faim Beach County in Florida	
Caracara	NE	Sovhean		
California	NE	Cotton Sovhean		
condor		cotton, soybean		
Fastern	NF	Cotton Soybean	NA	
Massasauga	112		10.	
rattlesnake				
Indigo snake	NE	Cotton, Soybean	NA	
Gopher	NE	Cotton, Sovbean	NA	
tortoise				
Houston toad	NE	Cotton, Soybean	NA	
American	NE	Cotton, Soybean	NA	
burying				
beetle				
Spring Creek	LAA	Cotton, Soybean	Wilson County in	
bladderpod			Tennessee	
NA – Not Applie	NA – Not Applicable as a No Effect determination has been reached or consultation has been			
concluded	concluded			
NE-No Effect				
NLAA- May Effe	NLAA- May Effect, Not Likely to Adversely Affect			
LAA- May Effect, Likely to Adversely Affect				

Species	Effects determination	Crops Pertinent to Effects Determination*	Areas of Concern	
*Considering soybeans and cotton, which are the focus of the previous assessments and this				
addendum.				

For the Eskimo curlew, EPA consulted with U.S. Fish and Wildlife Service and they concurred with the NLAA Effects Determination, and no further action was needed for this species (USEPA, 2016d-e).

The XtendiMax[™] With VaporGrip[™] Technology (EPA Reg. No. 524-617) product label included the following language:

"XtendiMax[™] With VaporGrip[™] Technology is approved by U.S. EPA to be used in the following states, subject to county restriction as noted: Alabama, Arkansas, Arizona, Colorado, Delaware, Florida (excluding Palm Beach County), Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Ohio, Pennsylvania, South Carolina, South Dakota, Tennessee (excluding Wilson County), Texas, Virginia, West Virginia, Wisconsin."

The Engenia[™] (7969-345) and FeXapan[™] herbicide plus VaporGrip[™] Technology (352-913) product labels contain identical county restrictions.

Based on the county prohibitions described above, these restrictions addressed the other NLAA and LAA determinations for the Audubon's caracara and the Spring Creek bladderpod, respectively. Therefore, these species were no longer inside the action area of the dicamba uses on cotton and soybean. Consequently, <u>no</u> Effects Determination were needed because they would have resulted in an ultimate conclusion of **No Effect**.

2.2. Re-consideration of listed species

The documentation leading to initial effects determinations in 2016, using the best available information of the time, concluded that, with selected mitigations in place, concern for listed species effects from uses of Xtendimax DGA salt (Monsanto, Reg No. 524-617) and Engenia BAPMA salt (BASF, Reg No. 7969-345) on genetically modified (GMO) dicamba-tolerant (DT) cotton and soybean fields was limited to the confines of the treated fields themselves (*i.e.* the action area was the treated fields; USEPA, 2016c-e,i; DP Barcodes 40138, 404806, 404823, 410802, 411382, 416416, 420160, 420159, 420352, 420518, 421434, 421723, 422305, 425049, 426789, 432752, 435892, 436602, 436905).

New information that is now available [FIFRA 6(a)(2) reporting, state agricultural lead agency and news reports] appears to show that dicamba emissions (through spray drift, volatile drift, or a combination) from Xtendimax- or Engenia-treated GMO cotton and soybean fields may have resulted in effects to non-target terrestrial plants offsite from the treated fields. This new information demonstrates the need to reevaluate the 2016 Endangered Species Act (ESA)

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effects determinations involving Federally listed threatened or endangered terrestrial plants for any new regulatory decision involving the use of Xtendimax or Engenia on GMO cotton and soybean fields. Specifically, the action areas (the areas where effects are reasonably expected to occur) may be larger than estimated with earlier datasets, encompassing more geographic areas, and so increasing the potential for overlap with identified locations of listed terrestrial plant species.

The purpose of this addendum is to review new information and to review which, if any, species that were not identified in the previous effects determinations as being within the action area (the treated field), could now potentially be located within an expanded action area. The conclusions from the previous listed species effects determinations made in the initial screening level risk assessments and the refined endangered species addenda (USEPA, 2016c-e, j; D416416+) are maintained for all taxa except listed non-monocot plants that may exist near the treated field, where levels of exposure could potentially result in effects and any newly listed species of terrestrial animals that may be present on the treated field that were not previously assessed. The action area has been set considering the established most sensitive tested plant, soybean, a dicot plant. The available terrestrial plant data set indicates that the dicot plant species are generally more sensitive than monocots, and that the most sensitive tested dicot, soybean, is substantially more sensitive than the most sensitive tested monocot, onion (DP Barcode 378444). Comparisons with other potentially sensitive taxa (e.g. aquatic plants), also indicate that the soybean endpoints (the most sensitive tested species) are highly protective (USEPA, 2016b, D426789, Appendix D). There are no incident information or other data available to suggest the potential for direct effects to other taxa except for non-monocot plants. Given the already protective nature of the existing 110-foot wind directional in-field buffers for monocots, and the far lower sensitivity of the most sensitive monocots compared to the most sensitive dicots (most sensitive tested monocot, onion, is four orders of magnitude less sensitive than the most sensitive dicot, with an IC₂₅ close to the field application rate; USEPA 2011; DP Barcode 378444), it is reasonable to exclude listed monocot plants and listed animal species from further effects determination efforts because all the available evidence suggests exposure off treated fields will be insufficient to trigger monocot or other listed animal taxa concerns.

3. Establishing Direct Effects Endpoints

3.1 EPA's use of Apical Endpoints in Risk Assessment

To assess the effects on aquatic and terrestrial organisms exposed to a chemical stressor, the Agency evaluates the available ecotoxicological literature to determine effects directly relating to an organism's fitness in the environment (*i.e.* apical effects based on effects reducing an organisms' survival, reproductive capacity and/or physiological growth; USEPA, 2004). These effects are based on direct inhibitions of an organism's ability to survive, reproduce, or grow. In the case of terrestrial plants, effects determinations center on plant height and weight (growth) that have meaning in the context of survival and reproductive potential of species in the

environment. Plant growth endpoints (*e.g.* height and weight) address the ability of plants to competitively exclude other plants' demands on resources, thereby enhancing survival, and achieving sufficient growth to obtain adequate resources for the increased energetic needs for reproduction. The previous issued effects determinations for listed species following the use of dicamba on dicamba tolerant (DT) crops (USEPA, 2016c-e, j; D416416+) have been based on the observed most sensitive effects to apical endpoints reported in the available suite of ecotoxicological data. More specific information on endpoints used in previous risk assessments is described below in **Sections 3.5** (toxicity endpoints used in comparisons with from vapor drift exposures).

3.2 Consideration of Previous Field Study Data

Many new and previously published field studies of dicamba investigating plant effects are based on measures of visual damage, height, or crop yield (seed mass produced). Anecdotal reports of off-site injury (primarily as visual signs of injury) suggest potential movement of dicamba at levels causing observable plant responses to dicamba exposures (AAPCO, 2017, 2018). These lines of evidence have caused us to reexamine our earlier determinations based on the previously submitted registrant studies, that dicamba exposures above threshold levels of concern remain confined to the treated field. Additional newly submitted flux and humidome data (described below in Sections 4.1 and 4.2) generally support the previous effects determinations that volatile drift alone would not reach levels that would trigger concerns for non-target plants, based on previously used modeling methodologies. In coming to the conclusion that under the 2017 terms of registration there is potential for dicamba exposures outside the treated field that are sufficient to cause effects to listed plant species, EPA considered additional lines of evidence that would assist in resolving the conflict between reported incidents, mass emissions, and the extent of the action area used for effects determinations (the area where effects are expected to occur). Quantitative incorporation of additional lines of information (such as new field study data), as discussed below, resulted in a revised action area for over-the-top use of dicamba DGA and dicamba BAPMA salts on DT cotton and soybeans. This approach is consistent with previous approaches in which field data were incorporated in the ecological risk assessments and effects determinations as lines of evidence to support the 110 foot in-field buffer in the direction of wind to decrease off-field exposures from spray drift below toxicity thresholds. Similarly, field data were also used in the previous effects determinations and addenda to the ecological risk assessments as lines of evidence that edge of field concentrations from volatility were below toxicity thresholds, supporting the previous conclusion that omnidirectional buffers around the field were not needed to restrict the action area.

This updated assessment reevaluates whether a new action area is necessary. This new determination is limited to the taxa and types of exposures suggested by the new information available in incident reporting from FIFRA 6(a)(2) documents, state reports, and meetings with stakeholders. These incidents involve direct toxic effects to non-target plants from reported alleged off-site exposure to dicamba from spray drift, volatile drift, or a combination of both.

While the available incident data suggests potential effects beyond the treated field can damage non-target plants, the available information is insufficient to precisely determine the distance from treatment sites over which effects are observed, given the lack of quantitative measurements regarding impacts to plant height, yield or survival described in the incident reports.

3.3 Field Studies in the context of effects to listed plant species

To evaluate the potential for effects to listed plant species, EPA typically uses measurements of apical endpoints (*e.g.* plant height) from laboratory studies conducted under conservative conditions that ensure exposure at measured doses as opposed to field studies that test phytotoxic effects under more variable environmental conditions. From these studies, EPA uses the NOAEC (No Observed Adverse Effect Concentration) associated with the most sensitive species' EC₂₅ value as the effect threshold to determine whether exposures are above the threshold level and consequently have the potential to cause risk to listed plant species. EPA also commonly calculates a regression estimate of the 5% effect level (EC₀₅) that is used in lieu of the NOAEC when a NOAEC cannot be determined from the study.

Many of the field studies of dicamba were not designed to capture a no-effect level (NOEL) for all measures of plant damage. Consistent with the EC_{05} growth endpoints typically used for effects determinations for listed species, based on guideline terrestrial plant studies when a NOEL is not reliably established, the Agency considered a 5% threshold interpolation (regression estimate when comparing distances or doses and biological effects) when evaluating the available field studies where effects on plant apical endpoints were measured.

3.4 Consideration of Field Measurement Data to Establish the Action Area

This effects determination considers the new and previously submitted field measurement data for soybean to establish the limit of the action areas. The available data include newly submitted field volatility (flux) studies (MRIDs 49899601, 49888603, 50578902, 50606801, and 50642801) and plant humidome data (MRID 50578901), both conducted to assess potential damage from vapor-phase exposures of dicamba and refine previously issued addenda assessing dicamba volatility exposure and effects (*e.g.* USEPA, 2016f; D435792).

To examine whether there was recent literature on potential impacts from volatility and/or spray drift of dicamba, EPA conducted a search for off-site transport and effects data through an on-line search of Google Scholar with the search terms: "dicamba" and any one of the following terms: "off-site transport", "volatility", "drift", and "non-target". EPA confined consideration of identified information to the years 2016-2018 since that time period presents the greatest opportunity to identify studies using the currently labeled Xtendimax and Engenia products. EPA also conducted a Google Scholar search with the terms "dicamba" combined with "visual signs of injury" and the term "height" or "yield". This latter search was used to inform analysis appearing in **Appendix A.** In addition, EPA considered additional field effects

data submitted to the Agency in 2018 from independent researchers and the registrants. These studies are discussed in **Section 4.4**. A tabulation of the results from all the available field studies considered is in **Appendix B**.

3.5 Focus on Non-Monocot Plant Species

As discussed above, the available terrestrial plant data set indicates that the dicot plant species are generally more sensitive than monocots, and that the most sensitive dicot, soybean, is substantially more sensitive than the most sensitive monocot, onion (DP Barcode 378444). Given the already protective nature of the existing in-field buffers for spray drift (110 feet) for monocots, and the far lower sensitivity of the most sensitive monocots compared to the most sensitive dicots (most sensitive monocot, onion, is approximately three orders of magnitude less sensitive than the most sensitive dicot, soybean; based on equivalent endpoints (e.g. NOAEC/IC₀₅) used to assess potential risk to listed species of 0.072-0.137 and 0.000261-0.0003 Ib ae/A, respectively for onions and soybean (MRIDs 47815102 and 48718015), it is reasonable to exclude listed monocot plants from further effects determination efforts because there is no evidence to suggest exposure off treated fields will be sufficient to trigger monocot concerns. Moreover, the initial screening level risk assessment on DT-soybeans (USEPA, 2011; D378444) demonstrates, even without in-field buffers, that off field movement was below the NOEC for the most sensitive monocot plants a scant 7 feet from the field edge with non-conservative drift estimates. This distance is within the margin of error for any overlap analysis and is essentially equivalent to only the treated field itself.

The vast majority of available field studies investigated the effects of dicamba exposure on nondicamba tolerant soybeans. Based on a comparison of EC₂₅ values across the standard suite of tested species, soybeans were determined to be the most sensitive species from the available laboratory toxicity assays (MRID 47815102 and 48718015 for dicamba DGA and BAPMA salt formulations, respectively). As such, they are utilized as a reliably representative species for evaluating potential effects to sensitive listed species. Additional field study data on other plant species were considered, where effects to apical endpoints were measured (*e.g.* Knezevic et al. 2018, discussed above).

4. Establishing the Distance from Treated Fields Where Plant Effects are Reasonably Expected to Occur

The previous effects determinations (USEPA, 2016c-e, j; D416416+) concluded that any potential effects following the use of registered dicamba products for over-the-top use on dicamba-tolerant plants would be limited to the treated field following the labeled mitigations to reduce spray drift (*e.g.* nozzles, wind speed restrictions) and the 110-foot spray drift buffer in the direction of wind at the time of application. Although the initial screening risk assessments (USEPA, 2016a-b) recommended the use of an omnidirectional buffer to preclude the potential for off-field dicamba exposures from volatility, further refinements based on submitted field flux data suggested that edge of field concentrations from vapor drift were expected to be

below any thresholds of concern (USEPA, 2016f; D435792 and USEPA, 2016h; D402518 for DGA and BAPMA salts, respectively).

As discussed above, complaints of alleged dicamba damage of off-site injury from a variety of sources including investigative reports from multiple states since 2016 suggest that movement of dicamba could be occurring at levels causing plant injury (visual signs, damage to fruit, etc.). Comparative flux emissions from new field studies would suggest, in some cases for both Engenia and Xtendimax products, that total flux emissions are of sufficient mass to meet or exceed thresholds of non-target plant effects under conservative exposure assumptions (see **Sections 4.1 & 4.4**). These lines of evidence call into question our earlier determinations based on the previously submitted registrant studies and modeling methodologies, that dicamba exposures above threshold levels of concern remain confined to the treated field. However, newly submitted flux and humidome data (described below in **Sections 4.1** and **4.2**) generally support the previous effects determinations that demonstrated that any concentrations of vapor drift were expected to be below thresholds of concern. EPA considered additional lines of evidence that assisted in resolving the uncertainties that have arisen due to differences in the multiple lines of evidence in order to determine the appropriate action area for making effects determinations (the area where effects are expected to occur).

4.1 New Registrant-submitted Field Volatility (Flux) Data

Since the development of the risk assessment in November 2016 that determined omnidirectional buffers were not needed (USEPA, 2016f; DP Barcode 435792), four additional field volatility studies (OCSPP Guideline 835.8100) have been submitted to further characterize potential emissions coming from a dicamba-treated field. A comparison of the new emission rates (*i.e.*, flux rates) to those used in the November 2016 risk assessment is provided in **Figure 1**. The GA Clarity, TX Clarity, GA Xtendimax, and TX Xtendimax flux rates (based on MRIDs 49888401, 49888403, 49888501 & 49888503) were used in the November 2016 analyses. The Engenia flux rates are also provided for comparison purposes.

The remaining flux rates (GA Xtendimax+R [MRID 49888601], TX Xtendimax+R [MRID 49888603], TX MON 76980/MON79789 [MRID 50578902], Australia MON 76980/MON78789 [MRID 50606801], and AZ MON 76980/MON78789 [MRID 50642801]) are based on recently submitted field volatility studies, new since the 2016 assessment, and are briefly discussed below. While flux rates derived from the recent trials are higher than the rates derived for the other studies conducted at an application rate of 0.5 lb ae/A (the post-emergent over-the-top application rate), the flux rates are lower than those used in the 2016 assessment (which were based on 1 lb a.e./A, the highest allowable pre-emergent application rate). The modeled air concentrations and the atmospheric deposition amounts at the edge of the field for these recent studies are still below the effects endpoints (17.7 ng/m3 and 2.61x10⁻⁴ lb ae/A for vapor and spray droplet exposures, respectively) used in the 2016 assessment (USEPA, 2016f; D435792) that concluded omnidirectional buffers were not needed. Consequently, the new information from these field flux studies would not alter the effects determinations made in the

2016 assessments. The analysis made in 2016 evaluated exposure routes singularly and did not consider the combined exposure pathways of spray drift and volatility, an attribute reflected in some of the recently available field studies discussed below.



Figure 1. Comparison of Registrant Submitted Flux Studies for Dicamba Applications

In May and June 2015, field volatility studies were conducted in Chula, GA (MRID 49888601) and Kendleton, TX (MRID 49888603), submitted to EPA in 10/2016 as part of a different new product registration application. These studies are also informative for the currently registered OTT dicamba products. The test substances used in the field phase of these studies were MON 76832, a Roundup Xtend formulation (Xtendimax with VaporGrip and glyphosate) containing a mixture of dicamba DGA salt (120 g a.e./L) and glyphosate (242 g a.e./L). The plot dimensions were approximately 384 feet by 384 feet (3.4 A) in GA and 648 feet by 648 feet (9.6 A) in TX. The test plot at the GA site was a bare ground site treated at a rate of 1 lb a.e./A, while the TX site was a field of cotton, planted with a variety of Bollgard II® XtendFlexTM Cotton, treated at a rate of 0.5 lb a.e./A.

The cotton was at the 6-8 leaf stage and roughly 11 inches in height, at the time of dicamba application. The boom height for the spray application was set at 14-18 inches above the canopy or ground height. The spray application was made to the GA test plot at 9:00 am on May 5th, while the application to the TX plot was in the afternoon at 2:45 pm on June 8th. In GA temperatures during the first 24 hours ranged from 59-86°F and 60-91°F on Day 2. Relative humidity in GA ranged from 10-94% and soil pH was 6.0. In TX, temperatures during the first 24 hours ranged from 22. Relative humidity in TX ranged from 18-97% and soil pH was 6.2. The maximum 95th percentile 24-hour average concentrations from air

modeling from PERFUM runs performed by the study authors were 3.2 and 16.1 ng/m³ for the bare and cotton fields, respectively, at the edge of the field. The maximum 90th percentile 24-hour total deposition values from AERMOD runs performed by the study authors were 1.2×10^{-5} and 4.1×10^{-5} lb a.e./A for the bare and cotton fields, respectively, at the edge of the field.

In October 2016, a field volatility study was conducted in Fort Bend, TX (MRID 50578902, submitted to EPA 07/23/2018). The formulation, MON 76980 (which is not registered in the United States but is similar to Xtendimax plus VaporGrip), contains dicamba in the form of its DGA salt (42.8% by weight, 28.9% a.e.). MON 79789, which is glyphosate in the form of its potassium salt (48.7% by weight, 39.6% a.e.), similar to Roundup Powermax, was added with MON 76980 to the tank mix. The product was applied at an application rate of 0.5 lb a.e./A on October 4, 2016 at noon to two different types of agricultural field test plots:

- 1. a fallow (bare ground), 4.6-acre field and,
- 2. a 9.1-acre field planted with herbicide-tolerant cotton.

The bare ground plot was defined as having stubble less than 7.5 cm (approximately 3 inches) in height in the area of application and measurement. Spray application to the cotton test plot was representative of typical post-emergence herbicide applications to cotton (2-leaf stage or greater at time of application). The boom height for the spray application was set at 50.8 cm (20 inches) above the cotton crop (24-26 inches above the soil surface, indicating the cotton crop was 4-6 inches in height). Temperatures during the first 24 hours ranged from 70-94°F and 72-96°F on Day 2. Relative humidity during application was approximately 57-59%. Soil pH was 5.5 on the bare ground field and 6.8 on the cotton field. The maximum 95th percentile 24-hour average concentrations from air modeling PERFUM runs performed by the study authors were 15.6 and 12.6 ng/m³ for the bare and cotton fields, respectively, at the edge of the field. The maximum 90th percentile 24-hour total deposition values from AERMOD runs performed by the study authors were 3.68x10⁻⁵ and 2.9x10⁻⁵ lb ae/A for the bare and cotton fields, respectively, at the edge of the field. EPA verified the concentration and deposition estimates derived by the study authors.

In December 2017, a field volatility study was conducted in Walgett Shire Australia (MRID 50606801, submitted to EPA 07/23/2018). The test substances used in the field phase of this study were MON 76980 and MON 79789. The formulation MON 76980 contains dicamba DGA salt (29.0% by weight, 28.9% a.e). The formulation MON 79789 contains glyphosate in the form of its potassium salt (39.8% by weight). In addition to the test substances, the tank mix contained Precision Laboratories Intact[™] (Lot # PLB-1709-24800-I), a drift control and foliar retention agent and deposition aid, at a rate of 0.5% v/v. Intact[™] contains polyethylene glycol, choline chloride, and guar gum as principal functioning agents that comprise 43.18% of the product. The plot dimensions were approximately 1280 feet in length and 1260 feet in width, for a total treated area of approximately 37 acres. The test plot and surrounding buffer zone was planted in a glyphosate, but not dicamba, tolerant variety of soybean. Soybean plants were roughly 6 inches in height. The boom height for the application was set at 24 inches above the soybean crop. The spray application was made to the test plot at 10:30 am on December 15,

2017. MON 76980 was applied at a target rate of 22 oz/A (0.5 lb a.e./A) and MON 79789 was applied at a target rate of 32 oz/A (1.125 lb a.i./A). Temperatures during the first 24 hours ranged from 76-106°F and 77-106°F on Day 2. Relative humidity during application was approximately 32%. Soil pH was 7.6. The maximum 95th percentile 24-hour average concentration from air modeling from PERFUM runs performed by the study authors was 4.4 ng/m³ for the soybean field at the edge of the field. EPA verified the concentration and deposition estimates derived by the study authors. The maximum 90th percentile 24-hour total deposition value from AERMOD runs performed by the study authors was 2.68x10⁻⁵ lb a.e./A for the soybean field at the edge of the field. This study is classified as supplemental because flux rates for Day 2 could not be calculated due to high wind conditions. Originally the study included plant effects measurements in an attempt to differentiate plant injury due to spray drift versus volatility. However, prior to study initiation, the study area and the surrounding area were damaged by 2,4-D spray drift. Additionally, residual isoxaflutole was measured in the soil, confounding plant damage measurements. As a result, an assessment of plant damage surrounding the treated area was not included in the study.

In May 2018, a field volatility study was conducted in Maricopa, AZ (MRID 50642801, submitted to EPA 08/23/2018). Approximately 27 acres (1050 ft in length and 1120 ft wide), in the center of a 33-acre agricultural field planted with non-tolerant soybean, was treated with Xtendimax with VaporGrip, RoundUp PowerMax, and Intact on May 8, 2018 at 4:15 pm. The test plot and surrounding buffer zone were planted in non-tolerant soybean on April 3, 2018. Test substance applications were made using a John Deere 4630 ground sprayer equipped with an 80 ft boom and Turbo TeeJet[®] Induction (TTI) 11004 nozzles. A spray drift test system consisted of three downwind transects (east side of field) spaced approximately 15 m apart perpendicular to the spray area near the middle of the spray swaths. Deposition collectors (Whatman #1 15 cm diameter filter papers) were placed on all three transects at 5, 10, 15, 20, 25, and 30 m away from the field. Deposition collectors were mounted on metal posts elevated to the soybean crop height (15 cm). Three upwind (west side of field) collectors were located along the depositional transects 30 m from the upwind edge of the spray area, and three were located 40 m from the upwind edge of the spray area. A volatilization test system, including both in-field and off-field (perimeter) sampling locations as well as flux meteorological stations for the test plot, was also implemented. Lastly, a plant effects test system, including a uniform stand planted with soybeans tolerant to glyphosate, but not dicamba (non-dicamba tolerant soybeans), was implemented upwind and downwind of the treated areas. Plant effect transects were planted perpendicular to the eastern (downwind) and western (upwind) edge of the applied area to a maximum distance of 30 m (3 downwind pairs and 2 upwind pairs) to evaluate volatility and spray drift exposure. Plant effects from volatility were evaluated by covering approximately 30 m by 3 m of non-tolerant soybean crop along the volatility transects during the application period to prevent exposure via spray drift. The covers were removed approximately 30 minutes after application. Plants were measured before application (five sets of ten plants) from downwind, upwind and within the designated treated area to better characterize the inherent variability across the field. Control (untreated/no visual dicamba injury observed) plant height measurements (ten sets of ten plants) were collected nonsystematically from areas further upwind of the upwind transects on the same day as plant

height assessments. At each study transect, plant heights were measured 15 and 28 days after treatment (DAT; post-application) on ten plants at each distance along each transect distance (5, 10, 15, 20, 25 and 30 m).

The wind directions at the time of application were variable within and outside of the target, with an orientation of 267°. Wind directions and wind speeds during the daytime (8:00 am to 8 pm) and nighttime during conduct of the study are provided in Figures 2 and 3. Temperatures for three days after application ranged from 18.5 to 40.4°C (65 to 105°F) and relative humidity ranged from 8.3 to 38.9%. Flux rates were estimated using the integrated horizontal flux technique, the aerodynamic method, and the indirect method. On-field wind speed samplers malfunctioned during the first 27 hours of sampling, so study authors used data from an offfield station to estimate the wind speeds that would be expected at the on-field samplers. While the flux rates estimated using the integrated horizontal flux method and the aerodynamic flux method, which used these estimated wind speeds, during this time were not significantly different than those estimated using the indirect method, the flux rates using the indirect method were higher and were considered more reliable. These were the flux rates used in the air modeling as well, which yielded a maximum 95th percentile 24-hour average concentrations from PERFUM runs performed by the study author of 3.6 ng/m³ for the soybean field at the edge of the field and a maximum 90th percentile 24-hour total deposition value from AERMOD runs performed by the study author of 1.00x10⁻⁶ lb a.e./A for the soybean field at the edge of the field. EPA verified the concentration and deposition estimates derived by the study authors.

Spray drift measurements indicated that dicamba residues were not detected in any of the upwind samples and were detected at levels below 24.5 μ g/m² (2.19 x 10⁻⁴ lb/A). It should be noted that wind directions at the time of application were variable within and outside the target orientation of 267°. Additionally, samples were collected 3 minutes after applications were complete, which may not have been sufficient time for airborne droplets to deposit. As such, deposition values are considered uncertain.



Figure 2. Wind Rose Plot, AZ Study, Daytime Hours



Figure 3. Wind Rose Plot, AZ Study, Nighttime Hours

Following 28 DAT, significant differences on plant height were observed between the downwind spray drift and volatility transects at 15 and 30 m; however, the study authors did not consider the differences treatment related as there was no clear dose response with respect to plant heights (**Figure 4**). For example, plant heights were significantly greater in the volatility transects at 15 m, whereas at 30 m plants were larger in the drift transects. Although attempts were taken to minimize variability, plant height differed across the field from the upwind to the downwind area (at Day 0, the average upwind plant height was 9.3 cm and the average downwind plant height was 7.64 cm). Therefore, due to the nonuniformity of plant height across the field, study authors did not perform a comparison of the plant height data to the upwind controls. At 28 DAT, no visual symptomology was reported in the downwind and upwind volatility transects off the treated field. Visual symptomology in the downwind spray drift transects decreased with increased distance from the treated area ranging from 30% at 5 m to a maximum of 5% at 30 m.



Figure 4. Plant Height Comparison, AZ Study

4.1.1 Placing all available flux studies into perspective

Using the results from the various field volatility studies, EPA examined the mass coming off the field in volatile form to determine if there was sufficient mass coming off the entire field to cause a concern from vapor drift exposure. To determine if this route could be excluded, EPA made a conservative assumption, for comparative purposes, that the available fugitive mass would be entirely deposited to a nearby field of the same dimensions (**Figure 5**). Because flux studies varied in application rate, it was necessary to normalize the resulting mass of dicamba leaving the treated fields to the labeled rate to 0.5 lb/A and the normalization process assumed that the total mass leaving the field linearly followed the change in application rate. While the assumptions made in this comparison are likely conservative, and do **not** accurately represent an aerial extent or distance down range over which effects might occur, the comparison does provide evidence that volatility remains an exposure route warranting further consideration.

Figure 5 suggests that a variety of field flux trials for Clarity, Engenia and Xtendimax produce enough field volatile emissions to trigger plant concerns, under a conservative assumption that mass emitted is subsequently deposited on an equivalent area of down range land. As noted above, this is based on conservative assumptions and not meant to be predictive of the actual expected adjacent field concentrations.



Figure 5. Comparisons of total emissions from various field volatility studies versus the listed species endpoint (0.00026 lb ae/A). All flux emissions are normalized to an application rate of 0.5 lb/A (labelled rate) and emissions are assumed to change linearly with application rate.

It should be noted that the studies were all conducted under varying field conditions and that a side-by-side comparison of Engenia releases and Xtendimax releases is not appropriate. The studies had variable meteorological conditions (*i.e.*, temperature and relative humidity), field conditions (*i.e.*, soil texture, temperature, moisture, and pH), and tank mix conditions (pH), all of which could increase or decrease the emissions from a treated field. The studies were designed to be done under real-world, conservative conditions with regards to temperature (*i.e.*, higher temperatures theoretically yielding higher emissions).

4.2 New Plant Humidome (Vapor Effects) Data

In EPA's 2016 assessment (USEPA, 2016f; DP Barcode 435792), EPA relied on a NOAEC of 17.7 ng/m³ and a LOAEC of 539 ng/m³ for vapor phase dicamba risk conclusions (MRID 49925703), but noted that "that the dose spacing in this study results in an approximately 30x difference between the NOAEC and LOAEC, creating uncertainty as to where effects to plants from vapor-phase exposure to dicamba may occur." Since the 2016 risk assessment was completed, a new study (MRID 50578901) has been submitted by a registrant to address this uncertainty. The explicit purpose of this study was "to examine the relationship between dicamba vapor concentration and plant response to identify a refined no observed effect concentration (NOEC) that can be used to support the risk assessment for dicamba use on dicamba-tolerant crops."

The biological results of this new study indicated that soybean height was not significantly reduced compared to control plants following 24 hours of exposure (at 85°F for 16 hours and 70°F for 8 hours with 40% relative humidity) to vapor-phase dicamba at concentrations less than or equal to 138 ng/m³; however, 24-hour exposure (at 85°F for 16 hours and 70°F for 8 hours with 40% relative humidity) to concentrations of vapor-phase dicamba greater than or equal to 238 ng/m³ significantly reduced soybean height (12%) compared to control plants (p<0.0001). As a result, EPA considers the new NOAEC to be 138 ng/m³ (an approximate 8-fold increase relative to previous NOAEC), and the predicted peak air concentrations of 60.3 ng/m^3 and 20.8 ng/m³ (for the Clarity and Xtendimax formulations, respectively) from the risk assessment would no longer exceed the NOAEC described in the 2016 addendum (USEPA, 2016f). Results from this new study fall within the range of the previous NOAEC and LOAEC endpoints, and with the refined dose spacing, there is greater certainty in the new NOAEC and LOAEC endpoints, compared to the previous vapor phase study. This new endpoint does not alter the previous effects determinations, though it does bolster the additional characterization of plant risks described in EPA's 2016 assessment and provides greater certainty surrounding the exposure levels necessary to result in damage to soybean apical endpoints from vapor exposure.

4.3 Studies Measuring Effects in the Field Evaluate the Combined Results of Multiple Routes of Exposure

As has been noted earlier in the document there are uncertainties as to why there are differences between previous risk assessment conclusions regarding the potential for off-site

terrestrial plant effects and reported complaints of non-target plant response to dicamba exposure off-field. It should be noted that reliance on spray drift calculations for exposure and flux-based vapor drift estimates using field flux data, the PERFUM model and humidome studies have the potential to not fully account for the possible combined exposure of off-site plants to multiple routes of dicamba transport (*e.g.* combined spray drift and volatility exposures).

To provide additional actual field representation for this effects determination, EPA investigated available data (i.e., registrant-submitted studies, open literature, and academic studies) involving the response of plants in actual areas near treated crops. Having the additional line of evidence being field testing, EPA can more fully account for the potential for plants to be exposed to a combination of dicamba from spray drift and volatile drift.

A tabulation of the results from all the available studies considered is in **Appendix B** and descriptions of each study are provided in the following sections.

4.4 Available Recent Field Studies

To examine whether there was recent literature on potential impacts from volatility and/or spray drift of dicamba, EPA conducted a search for off-site transport and effects data through an on-line search of Google Scholar with the search terms: "dicamba" and any one of the following terms: "off-site transport", "volatility", "drift", and "non-target". EPA confined consideration of identified information to the years 2016-2018 since that time period presents the greatest opportunity to identify studies using the currently labeled Xtendimax and Engenia product. EPA also sought out any field study data that may have been conducted over the last two years (*e.g.* using the registered formulations for dicamba use on dicamba-tolerant soybean and cotton) through contacts at academic institutions, scientific associations and agricultural extension experts. A discussion of all the field studies evaluated in this document is available in **Appendices A** and **B**.

An important aspect of confidently establishing field effects thresholds for height or yield effects is to consider the sensitivity of height and yield measures with respect to growth stage of the tested plant species. While it is important to realize that this effects determination is using soybeans as a sensitive surrogate plant to represent other non-monocot plants with varied schedules for growth and reproduction, it is also important to understand the limits of the empirical designs of studies as they relate to growth stages of soybeans. Field effects studies with soybeans are typically conducted using plants in either vegetative growth stage or reproductive stage. In vegetative (V) growth stages, the tested soybean plants are actively producing more vegetative mass and actively increasing in overall height. The vegetative phase involves exponential increase in biomass (Peterson, 2007). As the soybean plants enter reproductive (R) stages, energy is diverted from the production of vegetative mass to production of reproductive structures and offspring and the increase in biomass now takes on a linear rate (Peterson, 2007). This shift in energy allocations would suggest that measures of height effects on plants are likely to be more pronounced when exposures occur during the vegetative growth states of the plants, and that effects on yield are likely more pronounced

when the plants are shifting to reproductive development. Therefore, the concentration that causes a 5% reduction in plant height or yield would be lowest within the most sensitive growth stages for each.

4.4.1 Recent Large Scale Academic Field Studies

Large-scale trials were conducted by the University of Arkansas, University of Wisconsin-Madison, Purdue University, Michigan State University, and University of Nebraska. The protocol for these studies is provided in **Appendix B**. This series of field trials were designed to evaluate off-target movement via spray drift and volatility when applied to large areas (10 - 40acres). Applications were made under conditions consistent with the current XtendiMax label. Tank mixtures of XtendiMax + PowerMax (active ingredient glyphosate) + Intact (drift-reduction adjuvant) were applied consistent with labeled requirements for nozzles and wind speed restrictions. Off-target movement was assessed via air samplers, horizontal mylar sample collectors, and a bio-indicator crop of non-DT soybean.

Treated areas were planted with Roundup Xtend DT soybeans while the surrounding area was planted with a non-DT soybean of a similar maturity group. Applications are designed to target the largest soybean possible before reaching a flowering stage (~V5-V6). The treated areas were surrounded by non-DT soybean, such that samples could be taken for a minimum of 300 feet (91 m). Sample stations were located at various distances (4, 8, 16, 30.5, 45, 60, 75, 90, 105, 120 m) downwind of the application, determined by the available site-specific wind direction at the time of the study. Residues from sample collectors were sent to the University of Nebraska for analysis. To assess volatility, polyurethane foam (PUF) samples were collected and placed in uniquely labeled containers, to be analyzed by the Mississippi Department of Agriculture State Chemical Laboratory. The PUFs were collected approximately 6, 12, 24, 36, 48, 60, and 72 hours following completion of the application to the entire plot.

Spray drift impacts on non-DT soybean were assessed by comparing plant heights and visual plant response along transects perpendicular to the edges of the field to a distance of 100 m. Plant effects from vapor drift were assessed by covering a portion of the non-DT soybean crop during the application period to prevent exposure to spray drift. The cover was removed post-application. Plant heights were measured approximately 14 and 21 days post-application on ten plants at each distance along each transect. Control (untreated) plants were measured just prior to the application at each site as a measure of inherent variability in the plant sizes across the field. In addition, upwind plant height measurements were taken on the day assessments were made. These measurements were taken at least 50 to 100 m upwind of the "upwind edge" of each sprayed area and in areas where visual dicamba symptomology was not expected.

Visual plant response was assessed on a scale of 0 to 100 with 0 representing no visible plant response and 100 representing complete plant death. This plant response rating scale was conducted consistent with visual plant response ratings described in Frans (Frans, 1977), Behrens and Lueschen (Behrens, 1979), and Sciumbato et al. (Sciumbato et al., 2004). For

selected plots and timings, photographs were made to document the visual plant response symptoms, and severity at specified distances.

The sections below discuss the results of these large field studies. While air concentrations and deposition were measured using air samplers and mylar collectors, these values were not provided to EPA. Air sampler analysis was being conducted by the Mississippi Department of Agriculture State Chemical Laboratory, while deposition samplers were being analyzed by University of Nebraska. It is EPA's understanding that these samples are still being processed and will be submitted as soon as they are available. Deviations to the protocol in **Appendix B** were noted in the University of Arkansas study; responses to the deviations are discussed in further detail in **Appendix G**. The remaining study authors were contacted on October 11, 2018 to assess if any of the other large field studies had deviations to the protocol. The study authors (Dr. Werle, Dr. Young, Dr. Sprague, and Dr. Kruger) all responded by October 12, 2018, that there were not deviations from the protocol for their study site.

4.4.1.1 University of Arkansas Results

Dr. Norsworthy from the University of Arkansas (Norsworthy, 2018a) provided results for the field trial conducted in Arkansas, where a 38.5-acre field of DT soybean inside of a larger 240acre field of non- DT soybean was treated on 7/16/18 at 3 pm. Wind speed during the application varied from 1 mph to 6 mph, with wind direction varying from winds from the west (start) to winds out of the south (completion). As prevailing winds were described as coming from west to east, only one transect was used on the north and south sides of the field. However, based on the wind measurements during the first three days, the majority of the winds were from the south (Figure 6). The wind direction profile for the daytime (8 am to 8 pm) hours was consistent with the profile during the nighttime hours (8 pm to 8 am). It should be noted that for 7 days prior to the application, no sustained wind speeds above 3 mph (minimum wind speed limit on the label) were observed. In an effort to apply the Xtendimax before the R2 growth stage occurred (Xtendimax only allows applications up to the R1 growth stage), the application was made on July 16th. Winds after application continued to be low, with the majority of the wind speeds in the range of 0.5 to 2.1 m/s (1 to 5 mph). Buckets were placed on plants every 50 ft, and a 12 x 25 ft² tarp was placed on top of soybean plants outside the field to evaluate the impacts of secondary only drift. Air temperatures ranged from 75 to 92°F, soil temperatures were not provided. Relative humidity data during the course of the study were not provided. Plant height measurements along the transects were made at 15 and 22 DAT. There were no significant differences between the height of plants on the upwind and downwind sides of the treated field or with distance away from the field. As noted above, establishing plant height endpoint measurements is reliably established for V stage plants and not for R stage plants. Because the plants in this study were in R stage, height data was not considered reliable for establishing effects distances. At 22 DAT, visual injury was similar for plants exposed to primary spray and secondary volatility drift and those exposed to secondary drift alone. Twenty percent visual injury occurred out to a distance of 200-250 ft (61-76 m). At 29 DAT, 20% visual injury due to drift (it was not specified whether the damage was due to

primary or secondary drift) was reported along the east and south sides of the field at approximately 150 ft (46 m) and between 200 and 250 ft (61-76 m) along the west side. Forty percent visual damage along the north side of the field extended beyond 750 ft (229 m), but was attributed to runoff from flood irrigation.

Several deviations from the protocol (as described in **Appendix B**) were noted. UR110-10 nozzles were used instead of the TTI 11004. The UR110-10 are permissible according to the Xtendimax label. The product Warrant (a microencapsulation of acetochlor) was also added to the tank mix. The tank mix was held for 8 days, so the study might have been compromised because there is significant uncertainty as to whether the products were not properly mixed or could have degraded, potentially increasing the volatility of the tank mix, especially given that the Warrant label explicitly states that "Applications made using spray solutions of this product which have been allowed to stand or have been stored in application equipment or the mix tank for an extended period of time could result in crop injury." The label for Warrant also indicates that the product should not to be used with irrigation. After learning of this label deviation for this study, EPA considered whether any plant damage reported could be confused with damage allegedly from acetochlor and therefore call into question the study's utility for defining dicamba damage. Subsequent discussions (10/14/2018) with and information provided by Dr. Norsworthy (see Appendix G) suggested that the tank mix containing Warrant had no undue effects on the study results and that damage resulting from acetochlor would be easily distinguishable from that caused by dicamba (i.e., acetochlor damage results in a crinkling of the leaf and a wavy appearance, while dicamba damage results in a cupping of the leaf) and none was observed during the conduct of the study (Appendix G).



Figure 1. Wind Rose Plot, Norsworthy Study (direction from which wind was blowing)

4.4.1.2 University of Wisconsin-Madison Results

After EPA inquiries regarding additional field studies conducted using dicamba products, Dr. Werle from the University of Wisconsin-Madison also submitted data in support of the large field study effort (Werle, 2018). An 8-acre plot of soybeans at the V5 stage was treated on 7/11/18 from 10:50 to 11:17 am with Xtendimax plus PowerMax. The air temperature during the application was 81°F, while the soil temperature was 75°F. Winds during the application were out of the southeast at 3-6 mph. Temperature during the first 19 days of the study ranged from 49 to 90°F and relative humidity ranged from 42 to 100%. Inversion conditions appeared to occur during the evenings during the course of the study. Soybean was at the V5/V6 growth stage and was 13 inches tall. Three transects along the north side of the field and one transect along the south side were assessed for soybean plant height and visual injury. Plant height measurements along the transects were made at 14 and 28 DAT. This was also the case with for downwind transects with distances away from the field. However, an upwind transect (S-1) had a 5% reduction in height approximately 9 m from the edge of the field Along the north transects, 20% visual injury was reported out to about the 6th-9th row of soybeans at 14 DAT (Figure 7) and the 6th-14th row of soybeans at 28 DAT (Figure 8). At both times, visual damage for the uncovered plants tended to be higher than those that were covered, indicating that primary and secondary drift played more of a role in the visual damage than secondary drift alone. Each row was approximately 30 inches in width, so the distance would be, at a minimum, 15-23 ft (5-7 m) at 14 DAT and 15-35 ft (5-11 m) at 28 DAT. The south side did not indicate any visual injury to plants. However, it should be noted that winds didn't blow from the north, and blew from the northwest and northeast approximately 22% of the time (**Figure 9**), so it is uncertain if the plants along the single south transect were exposed.



Figure 7. Plant Damage at 14 Days After Treatment, Werle Study



Figure 8. Plant Damage at 28 Days After Treatment, Werle Study



Figure 9. Wind Rose Plot, Werle Study (direction from which wind was blowing)

4.4.1.3 Purdue University Xtendimax plus PowerMax Results

EPA inquired regarding additional field studies conducted using dicamba products and Dr. Young from Purdue University also submitted data in support of the large field study effort (Young, 2018a). A 20-acre plot (1000 ft x 2800 ft) of DT soybeans surrounded by 44 acres of non-DT soybeans at the R1 stage was treated on 8/9/18 with Xtendimax plus PowerMax. The air temperature during the application was 84°F and relative humidity was 64%. Winds during the application were out of the southwest at 1.5-7 mph. Temperature during the first 19 days of the study ranged from 53 to 88°F and relative humidity ranged from 48 to 100%. Soil temperature data were not provided. Inversion conditions appeared to occur during the evenings during the course of the study; in many cases the wind speeds during the inversions were recorded as 0 mph. Three transects along the east side of the field and one transect along the west side were assessed for soybean injury. Three separate transects, 8 ft x 50 ft, along the east side were covered by tarps to evaluate secondary volatility drift only. A series of controls were also assessed for primary (spray drift) and secondary (volatility) drift, but is unclear where these transects were located. Plant height measurements along the transects were made at 14 and 21 DAT. There were no significant differences between the height of plants on the upwind (west) and downwind (east) sides of the treated field or with distance away from the field. However, on the east side of the field, covered plants heights had plant height reductions where the plants that were uncovered did not (Figure 10). By 21 DAT, covered and uncovered plant heights were similar. Additionally, control plants showed significant plant height reduction at distances up to 10 ft, at which point the plant heights in the controls were the same as those in the east and west transects. As noted above, establishing plant height endpoint measurements is reliably established for V stage plants and not for R stage plants. Given the issues of control versus treatment initial condition and the field study using R stage plants, EPA concluded that direct measures on plant height for Young were unreliable for establishing distance to effect. Along the east transects, 20% visual injury was reported out to about the 15-20 ft at 14 DAT (Figure 11) and the 0-22 ft at 21 DAT (Figure 12). At both times, visual damage for the uncovered plants were higher than those that were covered, indicating that primary and secondary drift played more of a role in the visual damage than secondary drift alone. Covered plants did not show visual damage above 10%. Control plants showed significant visual damage inside of 15 ft at both 14 and 21 DAT, but showed similar visual damage to the plants along the east transects beyond 15 ft. The west side did not indicate any visual injury to plants. However, it should be noted that winds only blew out of the west 14% of the time and from the east 6% of the time (Figure 13), so it is uncertain how much exposure the plants along the east and west transects received.



Figure 10. Plant Height 14 Days After Treatment, Young Study

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Figure 11. Plant Damage at 14 Days After Treatment, Young Study



Figure 12. Plant Damage at 21 Days After Treatment, Young Study



Figure 13. Wind Rose Plot, Young Study (direction from which wind was blowing)

4.4.1.4 Michigan State Results

EPA inquired regarding additional field studies conducted using dicamba products and Dr. Sprague from the Michigan State University submitted data in support of the large field study effort (Sprague, 2018). A 53-acre plot of a 300-acre field was planted with DT soybeans surrounded by non-DT soybeans on May 4-6, 2018. Xtend soybeans were treated at the V3 stage on 6/12/18 with Xtendimax plus PowerMax between 10 and 11 am. The air temperature during the application was 71°F and relative humidity was 78%. Soil temperature data were not provided. Winds during the application were out of the east to southeast at 3-7 mph. Temperature during the first 9 days of the study ranged from 53 to 93°F and relative humidity ranged from 25 to 99%. It should be noted that air temperatures only exceeded 90F (when greater volatility and potential for secondary movement were to occur) for two short periods (4 hours) 5 and 6 days after application. It is uncertain if inversion conditions occurred during the study as temperature at different heights was not available. Winds were primarily out of the northeast and southwest during the study (**Figure 14**). Two transects 120 m in length along the north side of the field (Transects B and C) and one transect along the west side (Transect A), near the northwest corner of the field, were assessed for soybean injury. Tarped regions, 12 ft x 50 ft, near the three transects in the north and west, were covered to evaluate secondary drift only. A series of untarped and tarped upwind areas, 8 to 30 m from the field, were also assessed for primary and secondary drift. Plant height measurements along the transects were made at 14 and 21 DAT. Plants along Transect A appeared to show signs of reduced height (based on a comparison with other transects) up to approximately 25 ft (8 m) from the edge of the field at 14 and 21 DAT; transects to the north did not appear to show signs of plant height reductions except at a distance of between 246 to 344 ft (75 to 105 m) away where study authors noted a low area that appeared affected (**Figures 15** and **16**). Although EPA was unable to estimate plant height reductions using regressions(due to poor regression fit of the data), visual interpretation puts 21-DAT height inhibition for Transect A, relative to other transects at approximately 10 meters for Transect A. Note, the analysis of the data for this study does not necessarily establish a 5% plant height reduction endpoint for Transect A, but rather, a point of departure for plant height along Transect A, relative to transects showing no demonstrable height effect. EPA is using this point of departure as a surrogate for the 5% plant height threshold, which in turn is used as an endpoint when a NOAEC is not available.

Two of the transects, one in the north and the west transect, showed signs of visual injury, with distances to 20% visual injury reported out to about 13-26 ft (4-8 m) at 14 DAT (**Figure 17**) and 26-52 ft (8-16 m) at 21 DAT (**Figure 18**). At both times, tarped plants exhibited no signs of visual damage at 14 DAT and < 20% damage at 21 DAT for the entire 50 ft (16 m) distance, indicating that primary drift played more of a role in the visual damage than secondary drift alone. Upwind plants showed 20% visual injury at distances less than 2.5 ft (0.8 m) from field at 21 DAT. Substantial variability was observed across the other two transects. 21-DAT 10% visual injury, relative to controls, was observed out to approximately 25 meters in two transects, but only 5 meters in the third.



Figure 14. Wind Rose Plot, Sprague Study

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Figure 15. Plant height, 14 DAT, Sprague Study



Figure 16. Plant height, 21 DAT, Sprague Study

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Figure 17. Visual damage, 14 DAT, Sprague Study



Figure 18. Visual Damage, 21 DAT, Sprague Study

4.4.1.5 University of Nebraska Results

EPA inquired regarding additional field studies conducted using dicamba products and Dr. Kruger from the University of Nebraska also submitted data in support of the large field study effort (Kruger, 2018). A 30-acre plot of soybeans inside of a 150-acre field was treated on 7/10/18 from 8:46-9:09 am with Xtendimax plus PowerMax. Soybean was at the V5 growth stage and was 14 inches tall. The three downwind transects were placed to the north of the field and the upwind samplers were placed on the south. The wind direction was out of the south-southeast at the time of application. No precipitation occurred during the study. Air temperature and relative humidity data for the study were not available. Plant height effects at 21 days beyond 50 feet (15 m) were not observed, regardless of the direction from the application area. The average distance to 5% plant height reduction for the three transects was 10 m. Covered plants did not show a change in plant height with distance. Plots of visual injury with distance for the uncovered transects are provided in **Figure 19**. Slight visual symptomology was observed approximately 250 feet (76 m) beyond the edge of the field. Visual injury to covered plants at 21 days did not vary with distance for two of the transects, but did for the third. Visual injury ranged from 25-40% at 30 feet (9 m) from the treated field for covered plants.



Figure 19. Visual Injury, 21 DAT, Kruger Study

4.4.1.6 Purdue University, Engenia Results

EPA inquired regarding additional field studies conducted using dicamba products and Dr. Young from Purdue University also submitted data for DT soybeans treated with Engenia (Young, 2018b). Two separate plots, each 0.9 acres (200 ft x 200 ft) of DT soybeans in the center of a 15-acre field (800 ft x 800 ft) of non-DT soybeans at the V5 stage, were treated on 8/3/2018 at 3:30 pm. Plots were treated 24 and 48 inches above the canopy, using TTI11003 nozzles (it should be noted that the Engenia label specifies that the boom height should not exceed a height of 24 inches above the crop canopy). During the application, the air temperature was 87°F, the soil temperature was 95°F and the relative humidity was 56%. Winds during the application were out of the southwest at 1-5 mph. Temperature during the first 28 days of the study ranged from 51 to 91°F and relative humidity ranged from 34 to 100%. Wind speed and wind direction are depicted in Figure 20. The majority of the time the wind was blowing from the southwest. Meteorological data were not available to assess whether inversion conditions occurred during the study. Visual plant injury measurements were taken at 14 and 28 DAT every 40 ft on all sides of the field, with additional measurements along a 45 degree at each corner. Three measurements were taken along each transect; the distance to where the extent of symptoms > 30%; the distance to where the extent of >10% symptoms; and the distance to where no symptoms would be visible. Plant heights were not measured in this study. Visual injury results are provided in Table 2. At 14 DAT, the maximum average distance to greater than 30% visual injury occurred along the north side at 31 ft, with a maximum distance to greater than 30% injury at 82 ft (east side) for plot 1. At 28 DAT, the maximum average distance to greater than 30% visual injury occurred along the east side at 26 ft, with a maximum distance to greater than 30% injury at 108 ft for plot 1. Plot 2 results are also provided in Table 2, but these results were generated using a boom height 48 inches above the canopy, which is in violation of the label.



Figure 20. Meteorological Data, Young Engenia Study

	14 DAT				28 DAT	
Side/Transect	Averag	e Distant (Min	– Max)	Average Distant (Min – Max)		
	> 30%	10-30%	< 10%	> 30%	10-30%	< 10%
			Plot 1			
North	10 (3 – 21)	16 (5 – 43)	19 (6 – 50)	5 (2 – 18)	11 (4 – 19)	13 (5 – 23)
East	7 (1 – 25)	11 (1 – 33)	21 (5 – 34)	8 (0 – 33)	10 (1 – 33)	12 (1 – 34)
South	0 (0 - 1)	1 (0 – 2)	5 (2 – 8)	0 (0 – 1)	0 (0 - 1)	1 (0 – 3)
West	1 (1 – 3)	3 (2 – 5)	6 (3 – 7)	1 (0 – 3)	2 (1 – 4)	3 (1 – 5)
Diagonals	2 (0 – 5)	4 (1 – 8)	8 (2 – 11)	1 (0 – 3)	4 (0 - 8)	4 (1 – 9)
			Plot 2			
North	31 (1 - 80)	31 (11 – 55)	34 (16 – 59)	27 (1 – 79)	32 (3 - 80)	41 (10 - 81)
East	11 (2 – 16)	15 (2 – 21)	21 (5 – 29)	8 (1 – 12)	22 (8 – 29)	32 (8 – 44)

Table 2. Distance to Visual Injury (m) from Young (2018) under Engenia Application

South	51 (0 – 135)	34 (2 – 102)	65 (4 – 129)	17 (0 – 96)	20 (1 – 98)	34 (4 – 100)
West	1 (1 – 2)	2 (2 – 4)	4 (2 – 5)	1 (0 – 2)	2 (1 – 3)	3 (2 – 4)
Diagonals	(7 (0 - 26)	10 (1 – 36)	24 (3 – 52)	3 (0 - 10)	11 (1 – 39)	18 (2 -62)

4.4.1.7 2017 Field Studies

In 2017, a series of small-scale field studies (0.17 - 3.5 acres) were conducted in Nebraska, Indiana, Arkansas, Tennessee, and Missouri (Norsworthy, 2018b). Studies looked at plant effects (visual injury and plant height) to spray drift and volatility to soybean plants in the downwind direction from a field treated with Xtendimax or Engenia. A summary of the field conditions is provided in **Table 3**.

Application Info	NE	IN	AR	TN	МО
Study Conductor	Kruger	Young	Norsworthy	Steckel	Bradley
Application date	7/6/2017	8/27/2017	7/20/2017	7/27/2017	7/20/2017
Start time	11:00 AM	3:04 PM	11:56 AM	10:45 AM	11:00 AM
Stop time	11:19 AM	3:19 PM	12:19 PM	10:52 AM	11:20 AM
Avg. air temp during application (F)	88	79	94.2	84.2	88.9
Max. air temp day of application (F)	100.7	82.3	96.4	91.5	94.9
Relative humidity during application (%)	46.3	47	59.4	84	60
Avg. wind speed during application (mph)	5.25	4.2	2.9	3.3	5.3
Wind direction during application (degrees)	250	80	259	225	240

Table 3. Study Conditions, 2017 Small Scale Trials

Plant height data were only available for the Arkansas field trial. Height measurements for control plants were not provided, so the average height of the plants at the last three distances (85, 91, and 97 m) were used as a surrogate for controls to evaluate plant height effects with distance. For the Arkansas field trial, at 25 DAT, height effects were not significantly different across the transects or among them for the trial conducted using Xtendimax. For the trial conducted using Engenia, height effects were significantly different when comparing the plant heights at 3 to 9 m distances to the plant heights at distances greater than 60 m.

Based on an analysis of the visual injury reported versus distance for each trial, the distance to 20% visual injury is provided in **Table 4**. It should be noted that the trial conducted in Nebraska may have been compromised, as an application occurred to a nearby field that may have impacted the results.

	,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,		,	.,	,,		
Duradust			I	Distance (m))		
Product	Exposures	NE	IN	AR	TN	MO	
Xtendimax	Primary and Secondary Exposure	43	<10	31	5	19	
Xtendimax	Secondary Exposure only	35	<10	18	0	3	1

Table 4. Summary of Distances (meters) to 20% Injury for Primary and Secondary Exposures

Engenia	Primary and Secondary Exposure	36	<10	24	13	8
Engenia	Secondary Exposure only	29	<10	11	1	2

It should be noted that meteorological data for the duration of the study trials were not provided, so it is uncertain if the wind blew the majority of the time in the direction of the soybean plants that were analyzed. Completion of a review for these studies will require additional information, in the form of a study report, and a better understanding of the nature of the field trials.

4.4.3.8 Additional large field study data

In 2018, Gordon Travis Jones, a Master of Science in Crop, Soil, and Environmental Sciences student at the University of Arkansas, evaluated the effects of dicamba on soybean plants for his master's thesis. Jones (2018, chapter 4) conducted field experiments in 2015 and 2016. Glufosinate-resistant soybean (Bayer Credenz 4950LL) was planted in two adjacent 8-ha (19.8 A) fields on June 15, 2015, and June 13, 2016. Rows were bedded on 97-cm centers. A 38- by 38-m area (0.144 ha, 0.36 A) in the center of each field simultaneously received either DGA or BAPMA dicamba applied at 560 g ae/ha (0.5 lb ae/A) with Bowman Mudmaster high-clearance sprayers. Applications were made at the soybean V6/V7 growth stage in 2015 and the V4/V5 growth stage in 2016. Each sprayer was equipped with a broadcast boom having a 7.6-m swath tipped with TTI11003 nozzles (TeeJet Technologies) calibrated to deliver 94 L/ha (10 gal/A) at 275 kPa (40 psi) while traveling at 15 km/h (10 mph). Five passes were made simultaneously for each chemical to reduce variation in wind, humidity, and temperature. Wind speeds were recorded at 1-s intervals during the application. Relative humidity and temperature were recorded at the beginning and end of the application. Daily weather data (wind speed, wind direction, temperature, humidity) on a 15-s interval were recorded from 1 week before application to 3 weeks after application using a weather station placed between the two fields. Prior to application, transects were laid out in each of the eight cardinal directions extending to the edge of the field. Plots were established every 3 m from 3 to 12 m from the sprayed area, every 6 m from 12 to 36 m, every 9 m from 36 to 72 m, and every 12 m beyond 72 m until the edge of the field was reached. Two subplots consisting of four to five soybean plants per subplot were marked at each distance. The subplots consisted of soybean plants that were exposed to a) primary plus secondary drift or b) secondary drift only (any exposure more than 30 min after application). Immediately before application, 19-L buckets were placed over the soybean plants in subplots that were exposed only to secondary drift. Buckets were removed from these plants 30 minutes after completing the spray application (secondary drift only). The primary plus secondary drift subplot was never covered.

Additionally, metal rebar stands were erected with a 20 by 20 cm plywood platform affixed to the rebar at the height of the soybean canopy just before spraying. These stands were placed within the treated area and at each plot in 2015. In 2016, stands were again placed in the treated area but only in plots up to 30 m from the application. Four petri dishes (63 cm² in size) were placed on separate stands within the treated area to catch a full rate of dicamba. Mylar

cards were placed on the stands outside of the treated area to catch primary drift. In 2015, 100 cm² mylar cards were placed on stands at 3, 6, 9, and 12 m from the application. Mylar cards 400 cm² in size were used at plots starting at 18 m to the field border. In 2016, 400 cm² mylar cards were used from 3 to 30 m. In order to quantify primary drift, rhodamine dye (Sigma-Aldrich Company) was placed in each spray tank at 1 g/L. Petri dishes and mylar cards were removed from the field 30 min after application and placed in plastic bags indicating their location and then in a dark cooler to prevent photodegradation of the dye. Petri dishes and mylar cards were taken to the University of Nebraska Pesticide Application Laboratory in North Platte, NE, to quantify the amount of dye present on each surface using fluorimetry.

Injury to soybean within each subplot (primary plus secondary, secondary) was rated at 7, 14, and 21 days after application (DAA). Injury was rated on a 0 to 100% scale with 100% being plant death. There was no attempt to solely quantify primary drift because this would have required plants be covered for several days with buckets. Injury to soybean outside of the treated area was primarily in the form of leaf cupping, but also included leaf crinkling, epinasty, and terminal death. Two soybean plants exposed to primary plus secondary drift were harvested at 7 DAA in 2015 and four plants in 2016 directly adjacent to all distances that were rated for injury. Samples were transported on dry ice to the Arkansas State Plant Board in Little Rock, AR, and analyzed for dicamba remaining in the tissue. The method of dicamba extraction and quantification was GC/MS. The limit of detection was 1 ppb.

Jones reported that the ambient air temperature was 38°C (100°F) in 2015 and 30°C (86°F) in 2016 at the time of application whereas relative humidity was 44% in 2015 and 77% in 2016. These and other environmental conditions are considered typical for over-the-top applications, but not necessarily worst-case conditions, especially for 2016 when the temperature was cooler than 2015. Wind speed ranged from 4 to 12 km/h (2.5 to 7.5 mph) in 2015 and 10 to 16 km/h (6.2 to 10 mph) in 2016. Winds were primarily in a north/northeastern direction during and for 48 h after application both years; therefore, soybean injury was mainly confined to the north, northeast, and east transects.

Injury resulting from primary plus secondary drift generally occurred along transects at further distances following application of the DGA (Clarity) than the BAPMA (Engenia) salt of dicamba in 2015. In the 2015 experiment, the maximum distance to 5% injury from primary and secondary drift was 30 m for DGA and 24 m for BAPMA. The maximum distance to 5% injury from secondary drift alone was 12 m for DGA and BAPMA. In 2016, the maximum distance to 5% soybean injury from primary and secondary drift was 168 m for the DGA salt and 96 m for the BAPMA salt. The maximum distance to 5% soybean injury from secondary drift alone of the DGA salt (120 m) was over twice as far as the BAPMA salt (54 m). However, it is unclear what impact primary and secondary drift had on crop yield or pod malformation, as these effects were not evaluated. The droplet spectrum difference in VMD was 13 microns between DGA (757 μ m) and BAPMA dicamba (744 μ m). In addition, the percentage of fines (droplets < 210 μ m) was equivalent for the two formulations (1.57% of total spray volume).

Measurements of primary drift using mylar cards resulted in only two positive readings in 2015 and nine positive readings in 2016. Either the use of mylar cards in combination with fluorimetry does not appear accurate enough to quantify the extremely low rates of primary dicamba drift capable of causing injury to soybean, or observed effects in this study were primarily a result of secondary drift.

Results from the rate response (see discussion in Section YY) experiment indicate that soybean is equally sensitive to DGA and BAPMA dicamba. It should also be noted that six to eight hours after application of the large drift trial in 2015, a rain event occurred, potentially limiting volatility by incorporating some of the herbicide into the soil.

4.4.4 Analysis Summary of Academic Field Studies

Table 5 provides a summary of the effects observed in the 2018 large, 2017 small field trials, and Jones 2018, relative to whether the damage occurred via secondary drift alone, or due to a combination of primary and secondary drift. From an analysis of the data summarized in the table, it appears that while secondary drift alone does cause visual damage to plants surrounding a treated field, in most cases primary plus secondary drift results in greater damage. Data are only available for two of the studies such that plant height reduction could be assessed for secondary drift only. In those cases, secondary drift alone did not appear to cause plant height reductions.

		Visual	Injury	Plant Heigh	nt Reduction
Study	Product Used	Secondary Drift Only Effects?	Primary + Secondary Drift Effects?	Secondary Drift Only Effects?	Primary + Secondary Drift Effects?
		2018 Larg	ge Field Studies		
Norsworthy (AR)	Xtendimax	Yes	Yes	Not reliable	Not reliable
Werle (WI)	Xtendimax	Yes, lower than combined primary + secondary	Yes	No	Upwind transect only
Young (IN)	Xtendimax	Yes (<10%), lower than combined primary + secondary	Yes	Not reliable	Not reliable
Sprague (MI)	Xtendimax	Yes (<20%), lower than combined primary + secondary	Yes	No	Downwind transect along west side
Kruger (NE)	Xtendimax	Yes, lower than combined primary + secondary	Yes	No	Yes

Table 5. Summary of Results from Large and Small Field Trials

		Visual	Injury	Plant Heigh	t Reduction
Study	Product Used	Secondary Drift Only Effects?	Primary + Secondary Drift Effects?	Secondary Drift Only Effects?	Primary + Secondary Drift Effects?
Young (IN)	Engenia	Damage observed around entire field, not just wind direction during application	Yes	Not assessed	Not assessed
		2017 Sma	all Field Studies		
Kruger (NE)	Xtendimax & Engenia	Not assessed	Yes	Not provided	Not provided
Young (IN)	Xtendimax & Engenia	Not assessed	Yes	Not provided	Not provided
Norsworthy (AR)	Xtendimax & Engenia	Yes, wind blew to northeast during application, and east later ¹	Yes, winds blew to northeast during application, and east later ¹	Not provided	Yes
Steckel (TN)	Xtendimax & Engenia	Not assessed	Yes	Not provided	Not provided
Bradley (MO)	Xtendimax & Engenia	Not assessed	Yes	Not provided	Not provided
		Open	Literature		
Jones (AR	Engenia	Yes, lower than combined primary + secondary	Yes	Not assessed	Not assessed

1. Based on presentation depicting extent of damage around treated fields, not on submitted visual injury data.

Table 6 provides a listing of the strengths and weaknesses of the approach taken in the large and small field studies. While the studies provide a real-world evaluation of the combined effects of primary and secondary drift to non-target plants, the varying meteorological and field conditions lend uncertainty to comparing results across the different studies.

Table 6. Strengths and	l Weaknesses	for Field	Studies
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Strengths	Weaknesses
Evaluation of effects from spray drift and	Varied meteorological conditions, confound
volatility	comparisons between sites.
Field studies showing real-world effects	Most studies used transects of plants in
	downwind/upwind direction. No evaluation
	of plant impacts when wind changes.
Studies reflect areas reporting significant	Use of tarps may have resulted in plant
number (43%) of incidents in 2018	damage
Studies done under same protocol to allow	Some studies were done at R growth stage,
for comparison across regions	making plant height measurements

	unreliable. These were not included in any
	distance analyses. For R stage, plant yield
	would be the preferred measurement, but
	was not available for any study.
Large field studies more reflective of what	No measurement of yield for R growth stage
occurs in environment	studies
	Most studies done when temperatures were
	in the low 90s
	Visual damage is subjective measurement,
	which is why plant height was preferred for V
	stage trials when both were available in the
	study.

Based on the majority of the studies, the 110 ft (33.5 m) in-field, unidirectional buffer appears to be sufficient to protect off-site plants from reductions in plant height due to primary drift. However, it is evident from a subset of the field studies that secondary drift also occurs. Because these data suggest an off-site secondary drift potential, EPA considered whether an omni-directional approach to establishing an effects distance (contributing to action area and mitigative buffers) was necessary to account for herbicide transport from the field for time periods following the application.

The only study reporting 5% plant height effects from primary and secondary drift beyond 33.5 m is the Norsworthy 2017 study, which had a transect reporting plant height impacts out to 55 m. However, the average distance for this study was 24 m.

Additional information on other factors influencing the potential for off-site vapor drift is discussed in **Appendix H**.

4.4.5

4.5 Distributional approach to establishing an action area off-field distance.

EPA's routine exposure estimation methods for assessing the potential for effects to listed species involves the use of a reasonable upper bound estimate for establishing exposure levels. This approach is used for exposure estimation in 1) aquatic phase organisms using the PWC model and 2) refined spray drift exposure for terrestrial and aquatic organisms using the AgDRIFT model. In addition, previous effects determinations for dicamba used a reasonable upper bound estimate for volatile drift exposure for using the PERFUM model. For the current effects determination, considering both spray drift and volatile drift exposure to terrestrial plants in the off-site areas, EPA has explored the establishment of a reasonable upper bound estimate for the field using a distributional approach combining the effects to distance data for all the available field studies (see **Appendix B**).
The Agency created probability distribution for the following variable and data sets:

- 1. Distance from the treatment field edge to a point related to direct estimate of 5% height for all field studies reporting height in V stage plants.
- 2. Distance from the treatment field edge to a point related to direct estimate of 5% height for Engenia field studies reporting height in V stage plants.
- 3. Distance from the treatment field edge to a point related to direct estimate of 5% height for Xtendimax field studies reporting height in V stage plants.
- 4. Distances evaluated for the VSI approach for height and yield approximation are provided in **Appendix A**.

EPA used Crystal Ball add-in software to Excel to fit distribution functions to the data sets. Crystal Ball enables the user to fit various probability distribution functions to a data set and then sample those distributions thousands of times using Monte Carlo probabilistic algorithms to test the extent to which the selected distributions tend to over or underestimate any segment of the distribution of the variable. Because EPA is interested in reasonable upper bound estimates for the purposes of the effects determination distance to effects analysis, the Agency selected a distribution to fit to the data that would be a more accurate representation of the dispersion of data at the upper limits of the distribution. In the case of the height measurement distributions, the number of available data points was too limited for Crystal Ball to directly fit a distribution (Crystal Ball requires at least 15 discrete values for its software to operate). In those cases, EPA first looked at the summary statistics of the data sets to confirm the comparison of mean and median estimates were sufficiently shifted to suggest a nonnormal distribution, and then fit a log normal distribution to the data sets using the mean and standard deviation of the data set as the fitment parameters.

EPA then tested the predictive quality of the distributions by sampling the distributions using Crystal Ball's Monte Carlo random sampling algorithms (random seed, Monte Carlo sampling). EPA then compared the upper quantiles of the data, the fit distribution, and the distribution of randomly sampled values to see if the results produced inconsistent upper quantile values (70%, 80% and 90%). The fitment was considered reasonable if the comparison of the data, the fit distribution and the distribution of randomly sampled values were consistent.

Appendix C provides the Crystal Ball output for each distribution. Good agreement between data, fit distribution, and resampled distribution was found in all cases up through the 90th percentile. **Table 7** below summarizes the findings of the height-based evaluations of distance to effects.

Percentile	All products (n=15)	Engenia (n=4)	Xtendimax (n=11)
95%	17.45	47.89	7.47
90%	15.06	39.60	6.71
85%	13.62	34.85	6.21
80%	12.57	31.50	5.86

Table 7. Distances (m) to 5% Plant Height Reduction Effect for Dicamba Products

75%	11.76	29.10	5.56
70%	11.11	26.99	5.32
65%	10.52	25.24	5.09
60%	9.99	23.61	4.88
55%	9.53	22.15	4.70
50%	9.09	20.78	4.53
45%	8.65	19.48	4.37
40%	8.22	18.29	4.20
35%	7.82	17.15	4.03
30%	7.43	16.01	3.86
25%	7.05	14.88	3.68
20%	6.60	13.72	3.48
15%	6.11	12.50	3.26
10%	5.53	11.09	3.02
5%	4.79	9.29	2.71
0%	2.10	3.21	1.39

4.6. Uncertainties Associated with Establishment of Distances to Effect

Below is a list of uncertainties associated with the plant effects studies and field studies assessed by EPA:

- 1. The field studies only measured plant height and visual signs of injury. While this is appropriate for studies of V stage plants, for studies with R stage plants, yield is the more appropriate measure. There were no studies that assessed yield. While this does not impact those studies that were conducted at the vegetative growth stage, there is no corresponding apical endpoint for consideration for those studies conducted at the reproductive stage. Therefore, there is some uncertainty as to whether the measures being relied upon will be effective at protecting plants in the reproductive stage.
- 2. Plant height measurements were provided for a limited number of studies (n=4), three of which were conducted using Xtendimax and one conducted with Engenia, with plant height effects evaluated using soybeans. As such, there is statistical uncertainty in whether this limited number of studies is sufficiently robust enough to reflect potential variance in the effects to plant height in the field.
- 3. Only one study (Norsworthy 2018) provided measurements that was in some direction other than downwind from treatment, where the downwind direction was established at the time of application. Therefore, measures of effects from volatile emissions are limited to the downwind and upwind transects.
- 4. Effects on plants in the field studies only used soybeans for evaluation. While soybeans are considered the most sensitive plant, based on laboratory studies submitted to the Agency, there is uncertainty as to how representative these results are for other plant species with different growth and reproduction strategies. This is an inherent uncertainty for all surrogate species-based risk assessments

- 5. As the volatility of dicamba increases with temperature, particularly above 90°F, there is uncertainty in the field study results as only 3 studies (MRIDs 50578902, 50606801, and 50642801) had sustained temperatures during the day above 90°F. However, the studies were representative of the warmer temperatures experienced in the areas growing soybeans and using dicamba OTT products.
- 6. Only one study reported the pH of the tank mixture (MRID 50642801). As a result, there is uncertainty as to how the various tank mixtures in the field studies may have had depressed pH values, resulting in increased volatility.
- 7. A limited number of large field studies were conducted using Engenia. Therefore, there is some uncertainty as to how representative the large field studies conducted using Xtendimax are for Engenia applications.
- 8. Field studies were conducted primarily in areas with high levels of alleged incidents. As a result, there is uncertainty in whether the results from these studies can robustly account for the variability of dicamba movement and attendant effects for non-target species located across other landscapes proximal to sites of dicamba use.

4.7 Final Selection of off-field distance necessary to establish the limits of the action area.

EPA considered a variety of lines of evidence when determining the appropriate reasonable distance for defining the action area and what, if any, risk mitigation was necessary for this federal action to make no effects for any overlap of action area and listed species. This action involves the consideration of an application to amend the current registrations of dicamba products for the over-the-top use on cotton and soybean genetically modified to be resistant to dicamba to extend the registration to December 20, 2020 as well as include further labeling and registration restrictions as discussed earlier in this assessment to avoid overlapping with listed species locations and critical habitat. These analyses and the addition of terms to the registration, in combination, allow EPA to make no effects determinations for the species of concern.

EPA considered different approaches for making effects determinations. EPA considered existing guidance set forth in the Overview Document related to consideration of effects measurement endpoints that are not direct measurements of survival, growth or reproduction in effects determinations when provided a plausible and quantifiable expression of the relationship between the measurement endpoint and endpoints related to survival, growth or reproduction is established (USEPA 2004, 2015). EPA also considered the Agency's guidance on the use the 5% effect endpoint (EC₀₅) for growth measures (*e.g.* height) in situations where no observed adverse effects concentrations cannot be established for plants because of study design and performance limitations (USEPA, 2011).

Applying the policies discussed above, two types of methodologies were considered to determine how to establish distances to a threshold for plant effects given the best available data for defining the action area:

- 1. Direct Field Study Approach (discussed in this section): Direct field chemical drift studies that involve measurements of effects on plant height at 21 or 28 days after treatment or plant yield. These measurements directly inform the endpoints related to survival, growth and reproduction.
- 2. VSI approach (discussed in Appendix A)

Considerations of the Direct Field Study Measures Approach

Although the studies are limited, there is confidence in the direct measurements of height effects themselves. The measurements are the product of replicate sampling and are the objective measurement of an endpoint directly applicable to the effects determination, consistent with guidance laid out in the Overview Document (USEPA, 2004).

Additionally, using direct measurements of the height endpoint is preferred to a more complicated and potentially uncertain mathematical relationship, *e.g.*, scoring levels of VSI and applying a relationship factor to approximate a threshold for height effects as was performed in the VSI approach discussed in a subsequent section.

The data set for reliable measures of any reduction in plant height in response to dicamba exposure is limited in number of studies (which affects the ability to represent a variety of conditions), number of transects (which affects the ability to capture or describe the distribution of possible outcomes directionally or omnidirectionally), and the geographical areas of investigation. There is one study available to measure plant height with the formulation Engenia and it looked at a total of four transects. For Xtendimax, there are three studies available constituting eight transects in all. In some cases (*e.g.* Sprague, Young using Xtendimax), the available transect data did not extend in sufficient directions from the treated field to cover any possible volatile dicamba deposition occurring at time periods after the initial spray of dicamba. Although having direct measurements of plant height is very informative (particularly for plants in vegetative growth stages), there is uncertainty because this approach does not provide for an evaluation of effects on plant reproduction through consideration of effects on yield.

EPA intends to establish a reasonable distance to effect for the purposes of establishing an action area which is reasonably protective of listed plant species. Therefore, the analysis considered the number and distribution of the studies into consideration when establishing a distance to effect with this method.

EPA considered the distribution of the total available transect predicted distances to the 5% height effect for all formulations, as well as distributions segregated by formulation. EPA focused on the all-formulation distribution because the distributions for each formulation had too few measurements to be reliable.

Accounting for the small number of studies and limited geographic distribution, EPA elected to evaluate the distribution of the direct measurement approach distances at the 95%-tile to calculate a reasonable and protective distance to the 5% effects threshold. The 95%-tile corresponds to a distance of 57 feet for determining the action area.

Further Consideration of Spray and Vapor Drift

EPA notes that the results of some field studies indicate that vapor drift can be a contributing factor to overall off-field plant exposure. In fact, one of the primary reasons for performing the new effects determination was the fact that previous determinations considered spray drift and volatile drift, separately. In the interest of providing reasonably protective effects determination and for establishing a reasonable exposure mitigation measure for the dicamba products in areas where proximity to listed species is a concern, EPA concludes that the 17.5 m (57 ft) distance to effects threshold be appropriately considered omnidirectional, not just downwind from the treatment site at the time of application. Additionally, the 110 ft downwind buffer is retained to protect from primary drift.

Setting the Action Area Distance.

With a distance for plant effects established at 57 feet, EPA next determined how this distance would be used in setting the limits of the action area beyond the treated cotton or soybean fields. This is then used to determine the degree of overlap with listed species ranges. While the effects distance of 57 feet is the predicted zone of effects beyond the treated fields, EPA understands that the geographical information of species and use-site information is limited to a spatial resolution of 30 m Therefore, the action area for this federal action is the cotton and soybean fields in states of proposed use extended outward by 30 m in all directions. This is a conservative representation of the action area limited by data resolution and EPA expects that it will serve to include more species ranges in the overlap analysis with the action area.

Using the 57 feet Distance as Risk Mitigation

The 57 feet off-field distance to plant effects can be used to mitigate risk to listed species. This risk reduction can occur using 57 feet as a no spray buffer within the treat field. This buffer, when applied omnidirectionally to treated fields 57 feet or less distant from sensitive areas within listed species ranges and in combination with the retention of the 110 foot in-field wind-directional spray drift buffer already on the registered labels, serves to limit the dicamba effects zone to an area within the treated field in those selected areas of dicamba use. Where the best available information for a listed species indicates that it would not occur on a treated field, this mitigation would place the effects border outside of the listed species' range, achieving a No Effects determination.

5. Establishing the Action Area and Making Effects Determinations

5.1 Background

Previous effects determinations (USEPA, 2016c-e,i) concluded that, with selected mitigations in place (*e.g.* 110- foot wind-directional buffer at the time of application), concern for listed species effects from the uses of Xtendimax and Engenia on dicamba-tolerant (DT) cotton and soybean fields were limited to the confines of the treated fields themselves (*i.e.*, the action area was the treated field, itself). New information that is now available, including FIFRA 6(a)(2) reporting, state agricultural investigative reports and media reporting, appear to show that dicamba emission ((through spray drift, volatile drift, or a combination) from the use of these registrations on DT-cotton and soybean fields has resulted in effects to non-target terrestrial plants offsite from the treated fields. This new information demonstrated the need to reevaluate the 2016 Endangered Species Act (ESA) effects determinations involving Federally listed threatened or endangered terrestrial plants for any new regulatory decision involving the use of these registrations on DT-cotton and soybean fields.

In establishing the action area and completing this effects determination, EPA considered the following information:

- 1. The analysis of available laboratory and field volatility and effects data summarized in earlier sections of this document (see **Sections 4.1-4.5** above).
- 2. The suite of general and proposed specific label statements and requirements intended to reduce off-field transport of dicamba (discussed immediately below).
- 3. EPA determination that 57 feet is the appropriate buffer (see Section 4.7 above)

Suite of general and proposed specific label statements and requirements

In addition to the retention of the 110-foot downwind spray drift buffer currently on the Engenia, Xtendimax, and FeXapan labels, which was an important component of earlier no effect determinations, the new labels will have the following general label requirements (for use in all states):

- 1. Restriction for use by certified applicators only (intended to improve label compliance).
- 2. Require dicamba specific training for all applicators (intended to improve label compliance).
- 3. Label language revision to improved label consistency and enforceability (intended to improve label compliance).
- 4. Revised language limiting dicamba application to an interval between 1 hour after sunrise and 1 hour before sunset (intended to reduce the potential for applications proximal to inversion conditions).
- 5. Establishing the period of application limited to 45 days after soybean planting (or before R1 stage) and 60 days after cotton planting (limiting the extent of the growing season where dicamba is applied and potentially reducing applications during periods of high temperature).

- 6. Tank clean out instructions to include clean out of the entire application equipment (intended to reduce the potential for cross-contamination).
- Improve label description of sensitive crop/susceptible crop and sensitive areas (intended to improve label compliance and reduce the potential for dicamba application near sensitive non-target plants).
- 8. Enhance the label with pH advisory language to improve applicator awareness of the impact of low tank-mix pH on volatility of dicamba (expected to reduce the contribution of volatile dicamba to overall off-site exposure).

The above general label requirements are reasonably expected to improve pesticide applicator awareness by instructing them in methods expected to reduce dicamba movement potential and to further minimize the potential for off-site dicamba movement.

In addition to the general label requirements listed above this effects determination will evaluate the changes to species effects determinations as a result of additional label requirements to address potential effects to federally listed threatened and endangered species. These include:

1. Generic Bulletins Live! statement on the product label directing applicators to consult the Bulletins Live! application for additional application instructions for their intended location for dicamba application. These include:

"It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. To obtain Bulletins, no more than six months before using this product, consult <u>http://www.epa.gov/espp/</u> or call 1-844-447-3813. You must use the Bulletin valid for the month in which you will apply the product."

- 2. In areas pertinent to the Bulletins Live! instructions the applicator will be instructed to establish an additional omnidirectional in-field buffer of 57 feet from identified sensitive areas in addition to the wind directional 110-foot buffer.
- Prohibition of dicamba application in areas where a federally listed threatened or endangered non-monocot plant may reasonably be expected to occur on treated fields (a scenario where elimination of concerns for plants effects off the field is insufficient to protect individuals of the species on the field).

5.2 Establishing the Geographic Extent

EPA established the geographic extent of the potential action area using the for expected terrestrial plant effects combined with multi-year aggregate (2010-2016) of the Cropland Data Layer (CDL) information into Use Data Layers (UDL) for the 34 labeled states for dicamba uses on GMO cotton and soybean (AL, AZ, AR, CO, DE, FL, GA, IL, IA, IN, KS, KY, LA, MD, MI, MN, MS, MO, NE, NM, NJ, NY, NC, ND, OH, OK, PA, SC, SD, TN, TX, VA, WV, WI).

The UDL data layer was extended outwards 30 m (98 feet) in all directions to incorporate the off-site distance of 57 feet or a minimum resolution distance for species action area overlap, whichever is greater. As discussed in the uncertainties section above, the resolution of the UDLs is 30 m and distances below 30 m cannot accurately be calculated. As discussed in the uncertainties section below, the resolution of the UDLs is 30 m and distances below 30 m cannot accurately be calculated. As discussed in the uncertainties section below, the resolution of the UDLs is 30 m and distances below 30 m cannot accurately be calculated. Use of this 30-m buffer on the UDLs sets a conservative boundary to the action area. This action area, without any further label mitigation measures, is then compared with range and critical habitat information for listed species. The spatial analysis makes conservative assumptions related to extent and distribution to be protective of the species when assessing the relationship of the species range to the action areas; the impacts of the uncertainties in data are discussed in more detail in the uncertainty section.

5.3. Listed Species of Concern Within the Action Area

The action area has been set considering the established most sensitive plant, soybean, a dicot plant. The available terrestrial plant data set indicates that the dicot plant species are generally more sensitive than monocots, and that the most sensitive dicot, soybean, is substantially more sensitive than the most sensitive monocot, onion (DP Barcode 378444). Given the already protective nature of the existing in-field buffers for monocots, and the far lower sensitive monocot is four orders of magnitude less sensitive than the most sensitive dicot, DP Barcode 378444), it is reasonable to exclude listed monocot plants from further effects determination efforts because there is no evidence to suggest exposure off treated fields will be sufficient to trigger monocot concerns. Moreover, DP Barcode 378444 demonstrates, even without in-field buffers, off field movement was below the NOEC for the most sensitive monocot plants a scant 7 feet from the field edge with non-conservative drift estimates. This distance is within the margin of error for any overlap analysis and is essentially equivalent a treated field itself.

With an action area conservatively established, EPA compared this geographic area with the known listed terrestrial plant species range map information (USFWS, 2017). First, all species with greater than 1% overlap³ of a species range with the action area were identified. Next, all counties with a species from the first step and greater than 1% overlap with the action area in the county were established as the area where overlap is reasonably certain to occur. The species meeting these conditions are found inside the action and identified as "may affect". Species are considered to be outside the action area and "no effect" if these conditions are not met after accounting for significant digits.

³ EPA has used this 1% overlap criteria because a known source of error within spatial datasets is positional accuracy and precision. The National Standard for Spatial Data Accuracy outlines the accepted method for calculating the horizontal accuracy of a spatial dataset (FGDC, 1998). To prevent false precision when calculating area and the percent overlap, only two significant digits should be considered for decision purposes given the reported 60 meters of horizontal accuracy for the CDL.

A list of all of the additional species of concern (non-monocot plants) within the expanded action area (treated field + 30 m spatial buffer to estimate the 57-foot buffer is provided in **Appendix D**, including the effects determination with no modification of the federal action for each species. EPA also analyzed whether any additional animal species beyond those previously assessed could now be present on the treated field. EPA compared the list of previously assessed species by comparing scientific name and/or species entity id to an updated table of listed species addressing slight variations on scientific name due to updates or multiple populations. With no modification of the federal action, 69 listed dicot plant species were found to be within the action area. If a 57-foot omnidirectional in-field buffer (in addition to the 110-foot wind directional in-field spray drift buffer already on the label) were to be imposed as a label mitigation, then all but one species would be excluded from the action area (*i.e.* the action area would be limited to the treated field). The remaining species is the spring creek bladderpod (*Lesquerella perforata*), endemic to Wilson County, TN. County exclusions are already specified on the label for Wilson County, TN. No additional animal species were found to overlap with the treated field.

5.4 Uncertainties Associated with the Spatial Analysis

The overlap analysis was based on the species location provided by the US Fish and Wildlife Service (USFWS, 2017). Species range is defined as the geographical area where a species could be found in its lifetime. Produced and managed by the species experts with jurisdiction of the Endangered Species Act (ESA) these data are the best available information for species range, however, there are several uncertainties worth noting. The range information is not subdivided into additional qualifiers such as current/historical locations or temporal information to account for distribution variations relating to timing such as seasons. Without additional distribution information, EPA applies certain additional conservatisms: specifically, a uniform distribution within the range is assumed, meaning the species is assumed to be present in all sections of the range at all times of the year. Further, this distribution assumption is applied to full extent of the species range, which is an additional conservatism because this distribution is unlikely to actually occur based a species life history. Other sources of species range information, such as NatureServe, indicated more refined extents for range based on known observations for a species. However, these surveys are not exhaustive, and therefore only indicated known species locations.

Other commonly known and related sources of uncertainty for GIS data generally are related to accuracy and precision. Accuracy can be defined as how well information on a map matches the values in the real world. Precision relates to how well the description of the data matches reality, based on closeness of repeated sets of measurements. Some sources of inaccuracy and imprecision in GIS data are obvious while others are difficult to identify. It is important to consider these sources of error as GIS software can make users think data is accurate and precise beyond the limits of the data. When conducting this spatial analysis to assess the relationship between the species range and agricultural locations conservative assumptions are made related to the accuracy and precision of the available data. These assumptions impact the uncertainty of the relationship, and in most cases potentially overestimate the relationship between of species range and agricultural locations.

To address classification accuracy and positional accuracy of the agricultural GIS data used by EPA, multiple years were combined into a Use Data Layer (UDL) for a crop to represent anywhere the crop could be found. However, this is likely an overestimate of where a crop is found in any given year due to common agricultural practices such as rotation. Data resolution or the smallest difference between features that could be recorded is related to accuracy. The raster land cover data used to identify agricultural land, the Cropland data layer (CDL) produced by United States Department of Agriculture (USDA), has a resolution of 30 meters. A raster data set can be re-sampled into small increments but this does not improve the resolution or accuracy of the dataset. For this reason, values falling between the resolution value cannot accurately be determined and distances below 30 meters cannot be calculated.

Common sources precision errors can be introduced when formatting data for processing. Formatting changes can include changes to scale, reprojections of data, and data format conversions (raster to vector or vice versa). Sources of errors that are not as obvious can include those originating from the initial measurements, digitizing of data, and using different versions of a dataset. These types of precision error may introduce edge effect, or misaligned dataset when conducting the spatial analysis. Borders following the general shape of the county boundaries but do not align exactly in range information used could be result of this type of precision error.

These uncertainties impact the relationship between the agricultural areas and species locations. The spatial analysis makes conservative assumptions to err on the side of the species when assessing the relationship of the species range to agricultural land. This relationship may be overestimated when the range is larger than the actual area occupied and the additional area includes agricultural use or where edge effects were introduced. County or state boundaries can be used as a conservative estimate for species range but species and natural habitats are not expected to follow man-made boundaries, which will include agricultural lands. Underestimates of the relationship between species range and agricultural use can occur if the range represents a large area but the species occupies a refined area adjacent to agricultural land. In this situation, the conservative species boundaries may dilute the relationship. While this underestimation is possible, the additional conservative assumptions for agricultural land UDLs and the use of the best available information as defined by the species experts attempts to minimize this possibility.

5.5 Effects Determinations and the Impact of Modifications to the Federal Action

For each species with range overlap within the action area (**Appendix D**), EPA made an effects determination for each of three scenarios. The results of these effects determinations are provided in **Appendix D**.

Under Scenario 1, the effects determination is based on the federal action as initially described in Section 1.0 of this document. No mitigations beyond that which is described in Section 1.0 were considered. If the species overlap analysis places portions of the species range within the

action area, it is conservatively presumed that individuals of the species within that overlap area are, according to the best information available, reasonably expected to be affected by the federal action (May Affect).

With Scenario 2, EPA assumes that the federal action is modified to require the EPA established 57-foot omnidirectional in addition to the retained 110-foot spray drift buffer in the direction of the wind in-field application offset buffer in areas proximate to the locations of species overlap (at the county or subcounty level of resolution). The in-field buffer is intended to move the boundary of the action area away from the locations of species overlap, back toward the treated field boundary. This avoids overlap of the listed species' range with the area where effects to plants are reasonably expected to occur. By using this buffer mitigation to eliminate overlap of the species with the action area, EPA can confidently determine the action as modified will have no effect on listed species (No Effect). The spatial data layer used for the action area has a resolution of 30 m, therefore a 30-m buffer was used in the spatial analysis to estimate the 57-foot buffer. Appendix C reflects the changes in effects determinations as a result of this modification to the federal action.

Finally, Scenario 3 applies to species where overlap with the action area includes expected occurrence of the species on the treated cotton or soybean fields themselves. In these circumstances, a buffer designed to limit dicamba exposure to the margin of the treated field is insufficient to preclude effects to individuals of the species that might occur within the treated cotton or soybean field. Therefore, this scenario includes an additional mitigation that modifies the federal action with a labeled zone where dicamba application in prohibited. This prohibition zone may either be at the county level of resolution or at a sub-county level, where best available information provides more refined spatial resolution. By removing that area from dicamba application altogether, EPA can confidently determine that individuals of the species will not be affected by the federal action (No Effect).

Initially, the spatial extent of the modification is set based on location files provided by USFWS in 2017 and the results of the overlap analysis. If the location file is at the county level, the modification/limitation extent will follow the county boundary, if sub-county sections are present, the extent of the modification/limitation with follow the sub-county boundary with a buffer of 57 feet, see column 'Counties with overlap' of **Appendix D**. The final spatial extent of the modification/limitation may change under the following conditions.

• Updated information related to counties within the species range documented in the publicly available spatial files in ECOS; remaining counties found in column 'Accounting for ECOS updates'.

5.6 Critical Habitat Determinations

In addition to the species-specific effects determinations discussed above in Section 6, EPA also conducted the same overlap analysis to the critical habitat map information and identified new critical habitat within the expanded action area for listed terrestrial species as described in Section 6 (USFWS, 2017). Critical habitat with less than 1% overlap after accounting significant

digits are outside the actions and not considered further, critical habitat greater than 1% overlap are inside the action area and the modification analysis conducted. The critical habitat modification analysis is based on an assessment of how dicamba DGA and/or BAPMA salts would affect the U.S. Fish and Wildlife Service or National Marine Fisheries Service (the Services) established principle constituent elements (PCE's) of the designated habitat as well as how direct species effects outcomes would impact critical habitat's present and future utility for promoting the conservation of a particular listed species. The Agency will conclude "modification" of designated critical habitat based on the results of the overlap analysis for the available critical habitat maps found in the states subject to the Federal action and one or more of the following conditions exist:

- The available Services' information indicates that cotton or soybean fields or areas within 30 meters (spatial estimate of the EPA established 57-foot buffer) of these fields are habitat for the species and there is a "may affect" determination for the species associated with exposure to dicamba DGA/BAPMA salts or the degradate, DCSA, as labeled.
- The available Services' information indicates that the species uses cotton or soybean fields or non-monocot species within X meters of these fields and one or more effects on taxonomic groups predicted for dicamba DGA/BAPMA salts or the degradate DCSA, on cotton and soybean fields would modify one or more of the designated PCEs.

If neither of the above conditions are met, EPA concludes "no modification."

The list of species with critical habitats and the attendant determinations of modification for all of the additional terrestrial critical habitats of concern within the expanded action area (treated field + 30-meter spatial buffer to approximate the 57-foot buffer) are presented in **Appendix E**. Designated critical habitats for 14 species were found to be co-located with the action area described as treated cotton and soybean fields with an additional omnidirectional 30 m boundary. 12 of these critical habitats would be "Modification" with no additional mitigation and 2 critical habitats would be "No Modification" by virtue of not having PCEs related to non-monocot plant species. With the imposition of a 17.5 m (57 feet) omnidirectional in-field buffer (in addition to the already labeled 110-foot wind directional spray drift in-field buffer), then all critical habitats would be excluded from the action area.

The spatial extent of the modification for critical habitat will be set based on location files provided by USFWS in 2017 and the results of the overlap analysis.

6. Summary

Previous effects determinations concluded that, with selected mitigations in place (*e.g.* 110foot wind-directional buffer at the time of application), concern for listed species effects from the uses of Xtendimax, FeXapan and Engenia on dicamba-tolerant (DT) cotton and soybean

fields were limited to the confines of the treated fields themselves (*i.e.*, the action area was the treated field, itself). New information that is now available, including FIFRA 6(a)(2) reporting, state agricultural investigative reports and media reporting, appear to show that dicamba emission ((through spray drift, volatile drift, or a combination) from the use of these registrations on DT-cotton and soybean fields has resulted in effects to non-target terrestrial plants offsite from the treated fields. This new information demonstrated the need to reevaluate the 2016 Endangered Species Act (ESA) effects determinations involving Federally listed threatened or endangered terrestrial plants for any new regulatory decision involving the use of these registrations on DT-cotton and soybean fields.

EPA evaluated new data, including field volatility and vapor exposure toxicity studies submitted by the registrants and large field studies conducted by academic researchers. Additionally, as much of the incident and some of the field study data described effects solely in terms of visual signs of damage, rather than effects to apical endpoints such as plant height and yield, EPA considered open literature data relating visual signs of damage to these apical endpoints.

EPA concluded that the new information supported the need for an additional in-field 57-foot omnidirectional buffer in areas where listed dicot plant species are present to support the previous No Effect calls. This buffer determination was based on a distributional approach combining the direct effects (based on the most sensitive endpoint of plant height) to distance data for all the available field studies. Accounting for the small number of studies and limited geographic distribution, EPA decided to evaluate the distribution of the direct measurement approach distances at the 95%-tile to calculate a reasonable and protective distance to the 5% apical effects threshold.

EPA established the geographic extent of the potential action area using the for expected terrestrial plant effects into Use Data Layers (UDL) for all of the 34 labeled states for dicamba uses on GMO cotton and soybean. The UDL data layer was extended outwards 30 meters in all directions to incorporate the off-site distance of 57 feet or a minimum resolution distance for species action area overlap, whichever is greater. This area was then compared with the geographic area for the known listed terrestrial plant species ranges and all counties with a species with greater than 1% overlap with the action area in the county were established as within the action area and identified as "may affect."

Of the 69 listed species co-located with the action area described as treated cotton and soybean fields with an additional omnidirectional 30-meter boundary;

- 1. 69 species would be may-affect with no additional mitigation,
- 2. 1 species (the spring creek bladderpod) would be May Affect and 68 species would be No Effect with the imposition of a 57-foot omnidirectional in-field buffer and
- all 69 species would be No Effects with the imposition of the 57-foot buffer and the continued labeled county prohibition for Wilson County, Tennessee (for the endemic spring creek bladderpod)

Of the 14 designated critical habitats co-located with the action area described as treated cotton and soybean fields with an additional omnidirectional 30-meter boundary;

- 12 critical habitats would be "Modification" with no additional mitigation and 2 critical habitats would be "No Modification" by virtue of not having PCEs related to nonmonocot plant species
- 2. 14 critical habitats would be "No Modification" with the imposition of a 57-foot omnidirectional in-field buffer

These effects determinations, critical habitat modifications, and mitigation measures have considered the uncertainties in the analysis as noted throughout the document. These included, but are not limited to interpreting the incident data (largely due to the nature of incident observations being limited to visual signs of injury), field study limitations (*e.g.* varying environmental conditions in field studies, nature of subjectivity in VSI estimates between different observers, etc.), and geospatial analysis (*e.g.* species are presumed to be distributed throughout their range at all times of the year).

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Appendix A. Relating Visual Signs of Injury to Apical Endpoints

As discussed above in **Section 3.1**, EPA typically considers direct effects to apical endpoints (survival, growth and reproduction) to assess risks to aquatic and terrestrial organisms. EPA routinely considers information in the open literature when determining endpoints for risk assessment. A number of dicamba field effects studies present results in terms of measurements of visual signs of injury. EPA commonly uses effects endpoints in effects determinations that consist of measures of plant growth. While these measurement endpoints are routinely used to calculate the risk quotients that support effects determinations, generally EPA has taken the position that they do not represent a limitation on the types of toxicity endpoints that may be considered (USEPA 2004,

<u>https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf</u>). The assessor may encounter other effects data that provide insight on endpoints not routinely considered for calculation; professional judgment is used and documented by the assessor to determine whether and how available data on other toxicological endpoints are included in the risk assessment. Following the recommendations of the National Academy of Sciences, EPA released a document on interim approaches for national-level pesticide endangered species act assessments (USEPA 2015, <u>https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf</u>) that provides useful guidance on applying professional judgement to the utilization of other effects endpoints. The interim approach states "For plants, endpoints that can be quantitatively or strongly qualitatively linked to effects on growth, the level corresponding to a reproduction/growth no observed adverse effect concentration or level (i.e., NOAEC/NOAEL) for the most sensitive species will be used."

Many of the available field studies investigating plant response to off-field dicamba exposure report visual signs of injury (VSI), with many studies sharing the same protocol and recommended scoring system, as the only measurement endpoint for the study. EPA investigated multiple lines of evidence to inform a policy decision regarding the use of such information in this effects determination. The lines of evidence included:

- the dicamba herbicidal mechanism and whether VSI and height or yield effects are grounded in a common biologically relevant mechanism;
- the biological implications of growth stage of tested plants and the reasonableness of establishing relationships of VSI to other effects; and
- an evaluation of VSI observations relative to observations of height and yield effects in dose:response studies to explore the potential for establishing a quantitative link between VSI and height or yield effects.

The discussion below describes the VSI data and analysis. While informative, EPA has chosen to rely on measurements of plant height because these are direct measures of apical endpoints. This avoids the establishment of mathematical relationships between other endpoints (*e.g.* VSI and plant height or yield). The use of plant height data eliminates the uncertainty associated with the subjective nature of VSI measurements. However, as with all limited field study data,

relying on the plant height data from four field studies has uncertainties related to study conduct as well as geographical and environmental variability.

A.1 Considering the Dicamba Herbicidal Mechanism

EPA evaluated whether there is a plausible mechanistic link between VSI responses and impacts on growth or yield. Dicamba is an auxin (indole-3-acetic acid) mimicking compound (Kelley and Riechers 2007). Auxin governs dynamic cellular processes involved at several stages of plant growth and development and dicamba is a benzoate auxin herbicide that acts by mimicking indole-3-acetic acid. Although the precise mechanism of action of auxin herbicides is not fully understood, the mechanism appears to involve a stimulation of ethylene production leading to an accumulation of abscisic acid and/or cyanide resulting in abnormal growth. At sufficiently high levels of exposure, the abnormal growth is so severe that vital functions cannot be maintained and the plant dies. The differential toxicity of dicamba to various plant species is based on variations in the ability of different plants to absorb, translocate, and degrade the herbicide. The mode of action—the induction of hormonal imbalance—is specific to plants and does not affect animals (USDA, 2004; available at:

https://www.fs.fed.us/foresthealth/pesticide/pdfs/112404_dicamba.pdf

The most typical injury symptom of dicamba is epinasty, or curved and twisted stems and leaves. This is one of the primary symptoms observed and used when scoring visual signs in injury. Derr et al. (no publication data ,

http://pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/PPWS/PPWS-77/PPWS-77P-pdf.pdf) suggests this abnormal growth is caused by the auxin-mimicking effect of the herbicide stimulating growth on different sides of an organ. In addition, dicamba injury is also manifested in the form of meristematic inhibition. This is also a symptom used for injury scoring, where leaf edge meristems are inhibited by dicamba, and often force the leaf to form a cup-shape. This cupping is often associated with a darker green color and a bunched, or puckered, appearance (Iowa State University, no date, http://agron-

<u>www.agron.iastate.edu/~weeds/Ag317/manage/herbicide/dicamba.html</u> and Cornell University, no, date <u>https://weedecology.css.cornell.edu/herbicide/herbicide.php?id=2</u>).

In summation, the mechanism that causes epinasty and meristematic inhibition, rapid abnormal growth through the auxin-like characteristics of dicamba, is the same mechanism that ultimately disrupts the nutrient flow of the plant leading to reduced growth and ultimate starvation.

A.2 Considering the Biology of Growth Stage

An important aspect of establishing relationships of visual signs of injury to height or yield effects is to consider the sensitivity of height and yield measures with respect to growth stage of the tested plant species. While it is important to realize that this effects determination is using soybeans as a sensitive surrogate plant to represent other non-monocot plants with

varied schedules for growth and reproduction, it is also important to understand the limits of the empirical designs of studies as they relate to growth stages of soybeans. Field effects studies with soybeans are typically conducted using plants in either vegetative growth stage or reproductive stage. In vegetative growth stages, the tested soybean plants are actively producing more vegetative mass and actively increasing in overall height. The vegetative phase involves exponential increase in biomass (Peterson 2007). As the soybean plants enter reproductive stages, energy is diverted from the production of vegetative mass to production of reproductive structures and offspring and the increase in biomass now takes on a linear rate (Peterson 2007). This shift in energy allocations would suggest that measures of height effects on plants are likely to be more pronounced when exposures occur during the vegetative growth states of the plants, and that effects on yield are likely more pronounced when the plants are shifting to reproductive development. Therefore, the concentration that causes a 5% reduction in plant height or yield would be lowest within the most sensitive growth stages for each. Because plant injury isn't linked to these same shifts in plant growth stages, the relationship of injury does not markedly change and thus the concentrations required to impart a relative level of injury to the plant do not significantly change based on growth stage either. Consequently, establishing relationships between visual injury and plant height effects are best performed using plants in vegetative (V) growth phases while visual signs of injury related to yield relationships are best investigated with plants in the reproductive (R) stages.

Several available field studies of dicamba effects to non-target plants only measure the extent of VSI against either the distance from a treated plot or to a received dose of dicamba.

A.3 Evaluation of the Available VSI to Height and/or Yield Relationship Studies

Brief discussions of the studies reviewed for estimating the VSI to height or yield are provided below. The estimated ratios are presented in **Table A.1**. The Excel file titled (Open Literature Evaluations 10-26-18.xlsx, found on the docket) provides the calculations and equations for each of the ratio estimates.

Kniss (2018, prepublication) provided information related to soybean exposures associated with a 5% yield loss for soybeans. The analysis encompassed 11 primary publications and spanned the years 1978 to 2016. As expected based on the considerations discussed above regarding exposure timing effects on yield, the reproductive phases of soybean exposure were more sensitive than the vegetative phases, with R1 to R2 exposures of 0.15 to 14 g/ha (1.34×10^{-4} to 1.25×10^{-2} lb a.e./A) producing 5% yield loss with an across study pooled mixed model estimate of 5% yield effect value of 0.89 g/ha (7.94×10^{-4} lb a.e./A). This estimate approaches the listed species endpoint used in the effects determinations (0.00026 lb ae/A). Vegetative phases V1 to V3 exhibited 5% yield loss at dicamba exposures ranging from 1.6 to 24 g/ha (1.43×10^{-3} to 2.14×10^{-2} lb a.e./A) with a pooled across study mixed model estimate of 1.9 g/ha. Growth stages V4 to V7 showed 5% yield loss at an exposure ranging from 1.2 g/ha to 47 g/ha (1.07×10^{-3} to 4.19×10^{-2} lb a.e./A) with a pooled across study mixed model estimate of 5.7 g/ha (5.26×10^{-3} lb a.e./A

Silva et al. (2018) was also reviewed to make comparisons of height and yield with visual signs of toxicity. In this field trial, dicamba was directly applied to dicamba sensitive soybean at 0, 3.7, 7.4, 14.9 and 29.8 g a.e./ha. Spray applications were made at the V5 or R2 growth stages in separate experiments. Visible estimates of soybean injury were collected at four weeks after treatment on a 0 to 100% scale relative to untreated plots (method/scale used for injury was not reported). In addition, five random plants in each treatment were selected for soybean height, which measured distance from the ground to the tip of the topmost fully expanded leaf. At harvest, the two center rows of each plot were harvested manually and grain yield (total grain weight) was recorded and normalized to a constant water content. Application rate was regressed against visual injury, height and yields. From these regressions, an estimated dicamba treatment corresponding to a 5% yield reduction at harvest were 3.49 and 1.03 g a.e./ha (3.1 x10⁻³ and 9.2 x 10⁻⁴ lb a.e./A, respectively), for dicamba treatment to V5 and R2 growth stage soybean, respectively. The estimated dicamba treatment corresponding to a 5% reduction in plant height was 0.86 and 0.45 g a.e./ha (7.67 x 10⁻⁴ and 4.01 x10⁻⁴ lb a.e./A, respectively) for V5 and R2 growth stages, respectively.

Foster and Griffin 2018, another study reporting field response of soybean to a dose progression of dicamba treatments was also reviewed. This field study evaluated the impact on non-dicamba resistant soybean (three cultivars: Pioneer 94Y80, Terral REV 51R53, and Asgrow 4835, one for each of the three years of the experiment) from direct spraying of dicamba. The dicamba DGA salt (Clarity[®] herbicide; BASF Corp., Research Triangle Park, NC) was applied to soybean at V3/V4 (third/fourth node with two to three fully expanded trifoliates) or at R1/R2 (open flower at any node on main stem/open flower at one of the two uppermost nodes on main stem). Dicamba rates included 0.6, 1.1, 2.2, 4.4, 8.8, 17.5, 35, 70, 140, and 280 g ae/ha (1/1,000 to 1/2 of the manufacturer's use rate of 560 g/ha). Nonionic surfactant at 0.25% vol/vol was added to all treatments, and a nontreated control was included for comparison. A randomized complete block design with a factorial arrangement of treatments (growth stage by dicamba rate) and four replications were used each year. Plants were evaluated for severity of % injury and percent reduced height at 7 and 15 days after treatment (DAT), mature plant height prior to harvest, and grain yield (moisture adjusted) at harvest. While the manuscript did not provide 5% effect levels, EPA used the equations that were provided in the manuscript to estimate the concentration causing a 5% effect on mature plant height and grain yield (see Open Literature Evaluations 10-26-18.xlsx).

5% Grain Yield Reduction

R1/R2 Exposure = 1.24 g ae/ha (1.11 x 10⁻³ lb ae/A)

5% Mature Plant Height Reduction

V3/V4 Exposure = 2.02 g ae/ha (1.80 x 10⁻³ lb ae/A)

These results are consistent with those of Silva et al. (2018) with height being more sensitive following applications during the rapid growth phases (V3/V4) and yield being more sensitive when applications are made during bloom (R1/R2). The resulting 5% effect concentrations are

greater than those relied upon in the dicamba risk assessments (regulatory listed species endpoints: 0.34 g ae/ha (0.00030 lb ae/A) for the BAPMA form; MRID 48718015).

Robinson et al. 2013 conducted field experiments at the Dow AgroSciences Midwest Research Center (MRC) near Fowler, IN in 2009. The authors planted Beck's brand '342NRR' soybeans in 38-cm rows at a density of 430,000 seeds/ha. Dicamba (diglycolamine salt) was applied at rates of 0, 0.06, 0.2, 0.6, 1.1, 2.3, 4.5, 9.1, and 22.7 g/ha at V2, V5, or R2 soybean growth stages. The applications were made to plots which were 3.1 m wide and 9.1 m long and consisted of a 3.1m-long and 1.5-m-wide buffer to reduce the possibility of off-target movement into adjacent plots. All dicamba treatments were applied in 140 L/ha carrier volume using a CO2-pressurized backpack sprayer with a 3.1 m-wide boom and XR11002 flat fan nozzles (TeeJet Spraying Systems Company, Wheaton, IL 60189) at 138 kPa. Wind speeds at application were less than 5 km/h. The authors reported visual estimates of percentage of soybean injury at 14 and 28 DAT using a scale of 0 to 100%, where 0% = no crop injury and 100% = complete plant death (no additional details were provided). Plant height was also reported based on three plants sampled at the R8 growth stage. Additionally, 10 plants from the middle two rows of each treatment were arbitrarily selected to determine the following reproduction endpoints: yield (seed mass g/100 seeds), #seeds/m, #seeds/pod, #pods/m, #main-stem reproductive nodes/m, #pods/reproductive node, #mainstem nodes/m, and percentage of reproductive nodes. Plants were harvested with a plot combine and seed yield was adjusted to 13% moisture. Oil and protein concentrations were determined from machine-harvested seed using near-infrared reflectance spectroscopy at the Purdue University Grain Quality Laboratory.

EPA's review of the study results focused on the plant reported yield effects and their relationship to plant injury. The regression equations provided in Figure 5 of the study provided sufficient information to estimate the VSI to plant yield ratio (**Table A.1**). These results reflect the combination of the study sites presented in the study, however the individual study sites result in similar relationships and support the combined analyses presented. The derived ratio is also within the range of those estimated from the other studies discussed in this section and **Table A.1**.

Growe (2017) also evaluated the effects of sub-lethal rates of dicamba on five maturity group VI soybean cultivars at vegetative and reproductive growth stages. The design was a factorial arrangement of 80 treatments in a randomized complete block with four replications and three factors consisting of dicamba rate, soybean cultivar, and soybean growth stage. Trials were conducted near Kinston, Lewiston, and Rocky Mount, NC. In each trial, five soybean varieties were planted using a two-row cone planter. The DGA salt formulation of dicamba (Clarity) was applied to soybean at 1.1, 2.2, 4.4, 8.8, 17.5, 35, and 70 g/ha (1/512 to 1/8 of the labeled 560 g/ha use rate for weed control in dicamba-tolerant soybean) when soybeans reached V4 (three completely unrolled trifoliates) or R2 (full bloom) growth stages. A non-treated control was included for each variety. Plot dimensions were 3.65 m wide by 9 m long. After each application, effects of dicamba were determined by collecting visual injury ratings at 7, 14, and 28 DAT using a scale of 0 (no injury) to 100% (complete death). Soybean height was recorded 0, 14, and 28 DAT by randomly selecting four plants from each plot and measuring from the soil

surface to the terminal bud. The treated rows for each plot were mechanically harvested and yields were adjusted to 13% moisture.

While the manuscript did not provide 5% effect levels, EPA used the equations that were provided in the manuscript to estimate the concentration causing a 5% effect on mature plant height and grain yield.

5% Grain Yield Reduction (based on combined harvest) Kinston, R2 Exposure = 1.30 g ae/ha (1.16 x 10^{-3} lb ae/A) Lewiston, R2 Exposure = 0.90 g ae/ha (8.04 x 10^{-4} lb ae/A) Rocky Mount, R2 Exposure = 2.05 g ae/ha (1.83 x 10^{-3} lb ae/A)

5% Mature Plant Height Reduction

Kinston, V4 Exposure = 0.81 g ae/ha (7.23 x 10^{-4} lb ae/A) Lewiston, V4 Exposure = 2.46 g ae/ha (2.20 x 10^{-3} lb ae/A) Rocky Mount, V4 Exposure = 0.265 g ae/ha (2.37 x 10^{-4} lb ae/A)

Growe (2017) also reported results of another dose based study (chapter 2). However, the results of this study were not presented in a format to discern the height data from vegetative stage exposures from those following reproductive stage exposures. Therefore, the chapter 2 results were excluded from further review.

Jones (2018, Chapter 1) evaluated the impact on non-dicamba resistant soybean from nearby dicamba applications, such as those made to nearby dicamba tolerant soybean and cotton in a series of separate but interrelated experiments (presented in separate chapters). Presented in Chapter 1 are the results of twenty-five field experiments conducted in 2014 and 2015 in Keiser and Marianna, Arkansas. These experiments were conducted using Clarity® (BASF Corporation) at 560 g a.e./ha (maximum labeled field rate for over the top application) applied during the reproductive stages of R1 through R6. Plots extended along transects until no injury was observed or the end of the field was reached. Soybean injury and three canopy heights were recorded at 28 DAA for each plot. A visual scale from 0 to 100%, with 100% being plant death, was used to estimate soybean injury (no further details on the visual scale method were provided). The percent of pods malformed and the height to the terminal of three individual plants per plot were recorded at soybean maturity. Additionally, a small-plot combine was used to harvest plots, and grain yields (based on weight) were corrected to 13% moisture before being converted to a percentage yield relative to uninjured plots.

These data were reviewed by EPA to explore the ratio of visual signs of injury (VSI) to percent yield reduction at the 5% threshold. While instances of height reduction (5%) differed among growth stages were reported, the exposure was timed at the R1 through R5 growth stages and thus, height impacts were determined by EPA to be less informative than the yield results. Furthermore, the results for pod malformation and seed germination were not considered further due to their relative insensitivity as compared to yield. Percent Yield

reduction and percent injury regression equations, provided by Jones, were used to estimate the corresponding level of visual injury that was observed at the same distance as 5% reduction of yield. This established a ratio of visual injury percentage to 5% reduction in yield. The average ratio for of all trials was 5.1 (0.6-8.8). In other words, for a 5% reduction in yield a 26% rate of visual injury would be expected on average.

Jones (2018, Chapter 4) also conducted a small field study where DGA and BAPMA forms of dicamba were directly applied to a sensitive soybean variety. Applications were made on the same day and growth stage as the large field drift experiment presented in Chapter 4. Row spacing, irrigation, and weed control measures were also the same as in the large field experiment. Ten dicamba doses (56, 17.5, 5.6, 1.75, 0.56, 0.175, 0.056, 0.0175, 0.0056, and 0.00175 g ae/ha) for each formulation were applied to the center two rows of each four-row plot using a CO_2 -pressurized backpack sprayer with a 1.5-m spray boom equipped with four AIXR110015 nozzles (TeeJet Technologies) with an output of 143 L/ha (15.3 gal/A) at 275 kPa (40 psi). Treatments were arranged in a randomized complete block design and included four replications. Injury ratings were taken 7, 14, and 21 DAA. Data were subjected to a two-way ANOVA to test for effects of rate, formulation, and the interaction between rate and formulation as related to injury at 21 DAA. Injury data were also subjected to regression analysis to determine goodness of fit. For each year, a model describing the natural logarithm of the dose (g ae/ha) as a function of injury (%) at 21 DAA was produced. Plant heights were also collected 21 DAA and subjected non-linear regression analysis. Various exponential models were tested and goodness of fit was decided. EPA reviewed the regressions and empirical measurements reported by Jones and concluded that injury to height ratios would fall within the range of values presented in Table A.1 for other studies (~1-3). However, there was low confidence in the estimates at the 5% effect level due to extrapolation below the lowest tested dose and poor fit of the model at these levels

EPA also included the review of another field study (Knezevic et al. 2018) which evaluated the impact on tomato and grape plants after direct spraying of dicamba (three different formulations) in the field. Tomatoes and grapes were treated at five different rates (0.56, 1.12, 5.6, 11.2, 56 g ae/ha) of three dicamba-based products (Clarity, Engenia, and XtendiMax). Each species of plant was treated at two different stages of growth (based on tomato height and grape vine length). Separate experiments were conducted over two years. Plants were evaluated for severity of % injury (7, 14, 21, and 28 days after treatment (DAT)), tomato height/grape vine length (14 and 28 DAT), and plant biomass (14 and 28 DAT). Analysis of the data calculated the Effective Dose (ED) at 10, 20 and 50 % effect for each measured variable.

Length (i.e., tomato shoot height and grape vine length), was analyzed by the study author in terms of individual dicamba products. However, biomass estimates were combined across products in the study report. EPA estimated 5% and 25% Inhibition Concentrations (IC₀₅ and IC₂₅) values to compare with results from registrant-submitted toxicity studies on dicamba. Regressions were carried out in Excel using linear, exponential, and power regression of the reported ED_x values for length and biomass. Linear regressions (intercept set to zero) were generally judged poor fits and were therefore excluded as reviewer calculated IC₀₅ values

typically exceeded the reported ED_{10} values. The power and logistic regressions each fit the data well ($r^2 > 0.98$), and the power regression results were selected based on their r-squared estimates.

Based on comparisons of the tomato height DGA and BAPMA IC_{25s}, Knezevic et al. (2018) results (IC25s = 1.579 and 2.527 g ae/ha for DGA and BAPMA, respectively) are more sensitive than the height endpoints reported for both DGA (3.25 g ae/ha) and BAPMA (2.77 g ae/ha) in greenhouse studies using tomato (MRIDs 47815102 and 48718015 respectively). The corresponding tomato IC₀₅ height estimates for Knezevic et al. (2018; DGA IC₀₅ = 0.086 g ae/ha; BAPMA IC₀₅ = 0.55 g ae/ha) were also more sensitive than the greenhouse tomato IC₀₅ (0.65 g ae/ha) for DGA and is slightly higher than the BAPMA estimate (IC₀₅ = 0.386 g ae/ha).

Because the biomass ICx estimates were based on the combined results from multiple experiments and are not specific to DGA or BAPMA, it is not possible to directly compare against the DGA and BAPMA products individually. However, the reviewer's IC₂₅ estimate (1.836 g ae/ha) suggest that the tomato biomass IC₂₅ for DGA in the registrant submitted greenhouse study (0.59 g ae/ha) was more sensitive (MRID 47815102). The registrant submitted BAPMA IC25 for biomass was 4.52 g ae/ha. Therefore, the combination of DGA and BAPMA data in Knezevic et al. (2018) likely represents a similar distribution of effects, adding to uncertainty in the relative sensitivity in comparison to the DGA greenhouse result.

The results for grape indicate that based on the observed dicamba effects on vine length and biomass, the tomato was more sensitive of the two crops.

In comparison to the established regulatory endpoints for DGA and BAPMA from the registrant submitted greenhouse studies (MRID 47815102 and 48718015), the Knezevic IC₂₅ estimates are less sensitive in terms of the IC₂₅. However, the tomato IC₀₅ estimates (DGA IC₀₅ = 0.086 g ae/ha; BAPMA IC₀₅ = 0.55 g ae/ha) are below the regulatory endpoint selected from soybean for DGA (0.293 g ae/ha) and slightly higher than the BAPMA endpoint (0.336 g ae/ha). In keeping with Agency policy, the selection of the most sensitive endpoint for is first determined based upon the IC₂₅ (USEPA, 2005), where there is greater confidence in the regression estimate since the estimates are bounded by the data; therefore, the established regulatory endpoint is unchanged.

The following table provides a summary of available studies containing simultaneous scoring of visual signs of injury and measures of height or yield. These studies were all effects studies conducted as dose response studies where measurements of VSI, height and yield were made at a number of dicamba exposure levels (g/ha). Some studies (*e.g.,* Jones 2018, Silva et al. 2018, and Knezevic et al. 2018) measured each variable and established separate regressions of effects without relating VSI to height or yield. In other cases (*e.g.,* Foster and Griffin 2018, Growe 2017 and Robinson et al. 2013) the authors set out from the initiation of the study to establish relationships between VSI and other effects endpoints. In still others, the authors (Kniss 2018) performed a metadata analysis of other research for the express purpose of relating VSI levels to other effects endpoints. Lastly, registrant submitted laboratory vegetative

vigor studies (MRIDs 47815102 and 48718014) contain sufficient information for EPA to directly compare VSI effects recorded in the observations with the effects endpoints commonly measured for growth (*e.g.*, plant height).

With the exception of the Kniss (2018) metadata analysis where the ratio of VSI to 5% yield was established in the publication, EPA evaluated each study with a common approach. First the Agency established the dicamba dose associated with either a 5% height or 5% yield reduction (effects determination endpoints) from the study's available dose response data. EPA then consulted the dose response relationship of VSI from the same study and growth stage and determined the level of VSI that corresponds with the dose shown to cause the 5% reduction in height or yield. EPA then established a ratio of % visual injury to % reduction in height or yield by dividing the VSI% by the 5% level of height or yield. The reader will note that, in accordance to the biological basis for utilizing data appropriate to the life stage of the plant (see sections above) EPA limited these comparisons to height or yield as appropriate for the V or R stage growth phases, respectively. **Table A.1** provides the ratios for each study while the within data range deciles are shown in **Table A.2**.

Table A.1. Relationship of Visual Signs of Injury to Plant Height or Plant Yield Effects from
Peer Reviewed Publicly Available Literature

Study ID Product ¹	Number of Data Points	Growth Stage	Ratio of % visual injury to % reduction in height	Ratio of % visual injury to % reduction in yield	Estimation Method
		Vegetative Growth	Stage		
Silva et al. (2018) TEP not reported	1	Soybean (V5)	6.7	Not reliable at this growth stage	Regression- based value at 5% reduction in height
Foster and Griffin (2018) <i>Clarity</i>	1	Soybean (V3/V4)	9.4	Not reliable at this growth stage	Regression- based value at 5% reduction in height
Growe (2017) Clarity	3	Soybean (V4)	3.2 4.3 1.0	Not reliable at this growth stage	Regression- based value at 5% reduction in height

Study ID Product ¹	Number of Data Points	Growth Stage	Ratio of % visual injury to % reduction in height	Ratio of % visual injury to % reduction in yield	Estimation Method
Knezevic et al. (2018) Clarity ¹ , Engenia, XtendiMax	2	Tomato	0.7 (Xtendimax) 1.5 (Engenia)	Not reliable at this growth stage	Regression- based value at 5% reduction in height
Knezevic et al. (2018) Clarity ¹ , Engenia, XtendiMax	2	Grape	2.3 (Engenia) 5.8 (Xtendimax)	Not reliable at this growth stage	Regression- based value at 5% reduction in height
MRID 47815102- Laboratory Test (Clarity)	1	Soybean (V3/V4)	2.1	Not reliable at this growth stage	Regression- based value at 5% reduction in height
MRID 48718014- Laboratory Test (<i>Engenia</i>)	1	Soybean (V3/V4)	2.5	Not Reliable at this growth stage	Regression- based value at 5% reduction in height
		Reproductive Growt	h Stage		
Kniss (2018) TEP not reported	4	Soybean (R1/R2)	Not reliable at this growth stage	3.6 2.2 2 2.4	Regression- based value at 5% reduction in yield
Silva et al. (2018) TEP not reported	1	Soybean (R2)	Not reliable at this growth stage	2.2	Regression- based value at 5% reduction in yield
Foster and Griffin (2018) <i>Clarity</i>		Soybean (R1/R2)	Not reliable at this growth stage	6.7	Regression- based value at 5% reduction in yield

Study ID Product ¹	Number of Data Points	Growth Stage	Ratio of % visual injury to % reduction in height	Ratio of % visual injury to % reduction in yield	Estimation Method
Growe (2017) <i>Clarity</i>	1	Soybean (R2)	Not reliable at this growth stage	1.5	Regression- based value at 5% reduction in yield
Robinson et al. (2013) <i>Clarity</i>	1	Soybean (R2)	Not reliable at this growth stage	4	Regression- based value at 5% reduction in yield
Jones (2018) Chapter 1 trials <i>Clarity</i>			Not reliable at this growth stage	7.18	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	7.1	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	6.45	Regression- based value at 5% reduction in yield
	18	Soybean (R1)	Not reliable at this growth stage	8.36	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	7.16	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	2.13	Regression- based value at 5% reduction in yield
		Soybean (R2)	Not reliable at this growth stage	0.58	Value discarded because yield for entire trial was reduced

Study ID Product ¹	Number of Data Points	Growth Stage	Ratio of % visual injury to % reduction in height	Ratio of % visual injury to % reduction in yield	Estimation Method
			Not reliable at this growth stage	5.44	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	Not calculable	No yield loss reported
			Not reliable at this growth stage	8.9	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	Not calculable	No visible injury reported
			Not reliable at this growth stage	Not calculable	No yield loss reported
			Not reliable at this growth stage	4.83	Regression- based value at 5% reduction in yield
		Soybean (R3)	Not reliable at this growth stage	3.09	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	Not calculable	No yield loss reported

Study ID Product ¹	Number of Data Points	Growth Stage	Ratio of % visual injury to % reduction in height	Ratio of % visual injury to % reduction in yield	Estimation Method
			Not reliable at this growth stage	1.95	Regression- based value at 5% reduction in yield
			Not reliable at this growth stage	Not calculable	No yield loss reported
			Not reliable at this growth stage	1.84	Regression- based value at 5% reduction in yield
		Soybean (R4)	Not reliable at this growth stage	Not calculable	No yield loss nor injury reported
		Soybean (R5)	Not reliable at this growth stage	Not calculable	No yield loss reported

¹ As the registered products for dicamba use on dicamba-tolerant crops are Xtendimax and Engenia formulations, where studies used multiple TEP, including the registered products, EPA focused the analysis on the relevant registered products. However, if only unregistered formulations for over the top use (*e.g.* Clarity) data were available, then EPA used this data.

Percentile Range	Vegetative Growth Stage VSI:Height Ratios	Reproductive Growth Stage VSI:Yield Ratios
5%	1.33	1.5
10%	1.66	1.84
15%	1.99	1.95
20%	2.18	2
25%	2.3	2.13
30%	2.42	2.2
35%	2.57	2.2
40%	2.78	2.4
45%	2.99	3.09
50%	3.2	3.6
55%	3.53	4
60%	3.86	4.83
65%	4.19	5.44
70%	4.78	6.45
75%	5.5	6.7
80%	6.22	7.1
85%	6.97	7.16
90%	7.78	7.18
95%	8.59	8.36

Table A.2. Within Soybean Range Ranked Percentiles for VSI:Effects Ratios

A.4 VSI:Effects Ratio Uncertainties, Limitations, and Conclusions

There is considerable overlap in the ranges of VSI:Effect ratio for both V-stage plant height and R-stage plant yield measures suggesting that the selection of a ratio for each relationship of VSI with an appropriate effects determination measurement endpoint can be selected in common.

Potential contributing factors for the range in observations across the studies within each VSI:Effect ratio calculation may be the effects of factors that affect overall growth and maturation of soybeans. These may include soybean cultivar, meteorological conditions (*e.g.*, temperature and rainfall) and soil conditions (*e.g.*, soil fertility and moisture holding). The effects of these environmental variables among the studies cited in **Table A.1** is not quantitatively known. The available data show that the range for field-derived studies encompasses the ratios derived for the two laboratory studies (MRID 47815102 and 48718014), where environmental conditions were selected to optimize growth.

One uncertainty with using this dataset is that none of these studies, with the possible exceptions of Silva *et al* (2018) and the registrant-submitted study using BAPMA salt (MRID 48718014) used the currently registered dicamba formulations for DT-crops (Xtendimax or Engenia). It is unknown the exact impact that the formulation used might have on the nature and extent of toxicity or on the ratio of VSI to apical endpoint. However, it is notable that in the registrant-submitted laboratory studies with DGA (Clarity™) and BAPMA salts (MRIDs 47815102

and 48718014, respectively, both conducted at the same laboratory, but in different years), the formulation used appeared to have near negligible impacts on the toxic effects observed. For example, an application of 0.00026 lb ae/A Clarity[™] resulted in a 9.2% inhibition of soybean plant height, relative to controls, while an equivalent rate of BAPMA salt (0.0003 lb ae/A) had a 4.8% inhibition of soybean plant height, relative to controls. Similarly, the ratio of %VSI to %plant height effects was 2.1 and 2.5, respectively for the DGA and BAPMA salt formulations. This suggests that the impact of formulation on toxic effects may be a limited source of variability compared to other factors (*e.g.* study site, researcher, differing study protocols, etc.)

The limited data available in **Table A.1** for tomatoes and grapes suggest that other plant species have the potential to fall within the bounds of VSI:effects relationships. But again, just as growing conditions and cultivars yield varying relationships between VSI and height or yield effects, it is reasonable to also expect these confounding effects in other non-target plants. The data for tomatoes and grapes was therefore not included in the calculation of equivalent percentile ranks presented for soybean in **Table A.2**.

In summary, the consideration of the data in **Table A.1** for the evaluation of VSI observations in other field studies of primary and secondary drift of dicamba should:

- 1. Assign VSI ratios appropriate for the growth stage of the plant
- 2. Consider the potential uncertainty surrounding the subjective nature of VSI scoring; inconsistencies are likely, in the absence of standardized VSI scoring across studies.
- 3. Recognize that the growth stages of listed plants in the wild will likely not always coincide with that of soybeans or other agricultural crops
- 4. The ratio between VSI and height or yield for wild plants may occur across the distribution of values identified to date, and may indeed go higher or lower.
- 5. The environmental conditions affecting plant growth for the soybeans studies in the data in **Table A.1** are likely also important drivers for other plant species
- 6. Formulation is not expected to be a confounding factor when establishing plant responses to known dicamba doses.

A.5 Considerations of the VSI Approach

The VSI approach has the advantage (related to the direct effects measurement approach) of having a larger pool of data that encompasses more field trials, under more variable environmental conditions and performed in more geographic locations. Over a dozen studies measured visual signs of injury for both V and R stage plants. Forty-five separate transects were measured in all (21 for Engenia and 24 for Xtendimax). Where height measures were simultaneously measured these were included in the results. All levels of VSI were related to thresholds of height or yield effects using the distribution analysis of VSI relationships on over multiple published effects studies with simultaneous measures at appropriate growth stages.

However, with these advantages comes the uncertainties associated with the available data used to establish VSI:Effects ratios. Notable is the uncertainty associated with the subjective nature of the VSI scoring procedure compounded by the lack of performance criteria to evaluate the consistency of such scoring efforts across the field studies. The likely net effect of this uncertainty is an increase in the breadth of reported ranges, because of the variability in scoring the VSI portion of the ratio. For a discussion on the uncertainties associated with the field studies that report VSI measures used in approach, see Section 4.6.

In interpreting this VSI threshold for distance from the field to effects, EPA considered the predicted distance to a 20% level of VSI as the surrogate for a 5% effect on height or yield for many field-study transects. In cases where a field study measured effects to plant height directly (there were no yield measures), the distances to the 5% height were used in place of the distance predicted for a 20% level of VSI.

A distribution-based analysis was performed for all of the predicted distances to a 20% level of VSI or a 5% level of height, when measured in the study. This was performed for all available transects combined or the transects associated with field studies for each formulation alone (Engenia or Xtendimax).

EPA's routine exposure estimation methods for assessing the potential for effects to listed species involves the use of a reasonable upper bound estimate for establishing exposure levels. This approach is used for exposure estimation in 1) aquatic phase organisms using the PWC model and 2) refined spray drift exposure for terrestrial and aquatic organisms using the AgDRIFT model. In addition, previous effects determinations for dicamba used a reasonable upper bound estimate for volatile drift exposure for using the PERFUM model. For the current effects determination, considering both spray drift and volatile drift exposure to terrestrial plants in the off-site areas, EPA has explored the establishment of a reasonable upper bound estimate for the distance from the field using a distributional approach combining the effects to distance data for all the available field studies (see **Appendix B**).

The Agency created probability distribution for the following variable and data sets:

- Distance from the treatment field edge to a point related to 10% VSI for all field studies reporting visual signs of damage (10 % VSI selected to represent 5% effects on height or yield)
- 2. Distance from the treatment field edge to a point related to 10% VSI for Engenia field studies reporting visual signs of damage.
- 3. Distance from the treatment field edge to a point related to 10% VSI for Xtendimax field studies reporting visual signs of damage.
- 4. Distance from the treatment field edge to a point related to 20% VSI for all field studies reporting visual signs of damage. (20 % VSI selected to estimate 5% effects on height or yield)
- 5. Distance from the treatment field edge to a point related to 20% VSI for Engenia field studies reporting visual signs of damage.

- 6. Distance from the treatment field edge to a point related to 20% VSI for Xtendimax field studies reporting visual signs of damage.
- 7. Distance from the treatment field edge to a point related to direct estimate of 5% height for all field studies reporting height in V stage plants.
- 8. Distance from the treatment field edge to a point related to direct estimate of 5% height for Engenia field studies reporting height in V stage plants.
- 9. Distance from the treatment field edge to a point related to direct estimate of 5% height for Xtendimax field studies reporting height in V stage plants.

When establishing the VSI distributions, and to maintain the use of direct measures whenever practical and robust, if a study reported both VSI and plant height data, the Agency made a decision to rely on the distance to 5% height reduction because it was a direct measure of the apical endpoint used in risk assessment and did not include the subjective nature inherent in VSI scoring. EPA used Crystal Ball add-in software to Excel to fit distribution functions to the data sets. Crystal Ball enables the user to fit various probability distribution functions to a data set and then sample those distributions thousands of times using Monte Carlo probabilistic algorithms to test the extent to which the selected distributions tend to over or underestimate any segment of the distribution of the variable. Because EPA is interested in reasonable upper bound estimates for the purposes of the effects determination distance to effects analysis, the Agency selected a distribution to fit to the data that would be a more accurate representation of the dispersion of data at the upper limits of the distribution. For the VSI-based calculations, where the number of studies allowed Crystal Ball to directly fit the distribution, EPA fit the data to exponential functions. In the case of the height measurement distributions, the number of available data points was too limited for Crystal Ball software to directly fit a distribution. In those cases, EPA first looked at the summary statistics of the data sets to confirm the comparison of mean and median estimates were sufficiently shifted to suggest a non-normal distribution, and then fit a log normal distribution to the data sets using the mean and standard deviation of the data set as the fitment parameters.

EPA than tested the predictive quality of the distributions by sampling the distributions using Crystal Ball's Monte Carlo random sampling algorithms (random seed, Monte Carlo sampling). EPA then compared the upper quantiles of the data, the fit distribution, and the distribution of randomly sampled values to see if the results produced inconsistent upper quantile values (70%, 80% and 90%). The fitment was considered reasonable if the comparison of the data, the fit distribution and the distribution of randomly sampled values were consistent.

Appendix C provides the Crystal Ball output for each distribution. Good agreement between data, fit distribution, and resampled distribution was found in all cases up through the 90th percentile. **Table A.3** below summarizes the findings of the VSI-based and height-based evaluations of distance to effects. As was discussed in earlier sections, the uncertainties associated with VSI scoring, would suggest a reasonable selection from the distribution of distances to VSI effects from the upper bound of the central portion of the available distributions (i.e., ~70-75th %-ile). This avoids potentially unrealistic predictions towards the tails of the distribution which are further confounded by the uncertainties. The 70-75%-tile

yields a predicted distance to a reasonably expected effects threshold of 20% VSI (or 5% height when measured) of 17-20 meters. Furthermore, it is also reasonable to expect that the distances measured to a 20% VSI threshold, based on the critical relationships established in Table A.3 will also be protective of the reproductive endpoint because there is a high degree of similarity of VSI ratios for both height and yield.

Percentile	All products (n=47)	Engenia (n=22)	Xtendimax (n=25)
	Distance to	20% VSI (m)	
95%	43.24	44.18	42.77
90%	34.08	34.12	33.02
85%	27.88	27.99	27.44
80%	23.77	23.73	23.30
75%	20.21	20.43	20.15
70%	17.67	17.62	17.64
65%	15.51	15.36	15.38
60%	13.46	13.45	13.36
55%	11.77	11.77	11.58
50%	10.20	10.24	10.11
45%	8.81	8.84	8.58
40%	7.54	7.56	7.32
35%	6.35	6.38	6.17
30%	5.24	5.24	5.09
25%	4.21	4.12	4.02
20%	3.23	3.20	3.06
15%	2.33	2.36	2.21
10%	1.48	1.52	1.43
5%	0.70	0.74	0.69
	Distance to 5% Plant	Height Reduction (m)	
Percentile	All products (n=15)	Engenia (n=4)	Xtendimax (n=11)
95%	17.45	47.89	7.47
90%	15.06	39.60	6.71
85%	13.62	34.85	6.21
80%	12.57	31.50	5.86
75%	11.76	29.10	5.56
70%	11.11	26.99	5.32
65%	10.52	25.24	5.09
60%	9.99	23.61	4.88
55%	9.53	22.15	4.70
50%	9.09	20.78	4.53
45%	8.65	19.48	4.37
40%	8.22	18.29	4.20

Table A.S. Comparison of Distances to Effect for Dicampa Products	Table A.3. Com	parison of	Distances to	Effect for	Dicamba	Products
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35%	7.82	17.15	4.03
30%	7.43	16.01	3.86
25%	7.05	14.88	3.68
20%	6.60	13.72	3.48
15%	6.11	12.50	3.26
10%	5.53	11.09	3.02
5%	4.79	9.29	2.71
0%	2.10	3.21	1.39

Appendix B. Field Studies Data

B1. Protocol for Academic Large-Scale Off-Target Movement Assessment of Dicamba Methods

A series of trials were designed to evaluate off-target movement (OTM) via physical drift and volatility when applied to large areas (10 – 40 acres). Applications were made under conditions consistent with the current XtendiMax label. Tank mixtures of XtendiMax + PowerMax + Intact were applied in an application volume of 15 GPA from a commercial sized sprayer traveling no more than 15 MPH. The treatments were applied with TTI 11004 spray nozzles with a sprayer traveling approximately 10 MPH. Applications were made between sunrise and sunset while winds speeds were between 3 and 10 MPH. Off-target movement was assessed via air samplers, horizontal mylar sample collectors, and a bio-indicator crop of non-Xtend soybean. These large-scale trials were conducted by the University of Arkansas, University of Wisconsin-Madison, Purdue University, Michigan State University, and the University of Nebraska

Treated areas were planted with Roundup Xtend soybeans while the surrounding area was planted with a non-Xtend soybean of a similar maturity group. Applications are designed to target the largest soybean possible before reaching a flowering stage. In the south this would approximate a soybean application at V5-V6, where plants are approximately 10-12 inches tall. The treated areas were surrounded by non-Xtend soybean, such that samples could be taken for a minimum of 300 feet.

Figure B.1 provides a schematic of the sampling regime for the large-scale studies. Horizontal sample collectors were collected and placed in uniquely labeled containers following application of the test substances and then sent to the University of Nebraska for analysis. Downwind sample stations were located at various distances (4, 8, 16, 30.5, 45, 60, 75, 90, 105, 120 m) downwind of the application, determined by the available site-specific wind direction at the time of the study. The field line was defined as the edge of the spray from the furthest downwind nozzle on the boom. Three such lines of sample collectors were used for each treatment, spaced a minimum of 15 m apart, as appropriate for the test site and local landscape, with the center line located from the midpoint of the spray swath length, as appropriate for the site being used. A Mylar collector was placed at each location for collecting

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samples of the test substance. Each sample station used a horizontal structure to mount the collectors at crop height. Downwind sample collectors were collected 30 minutes after the spray application concluded. Additionally, three upwind sample collectors were collected, each located on the depositional sample transects at 30 m from the upwind edge of the application area. This is consistent with the trials that were conducted by the Spray Drift Task Force in the 1990s.

To assess volatility, PUF samples were collected and placed in uniquely labeled containers, to be analyzed by the Mississippi Department of Agriculture State Chemical Laboratory. Two preapplication air samples were collected using air sampling equipment placed near the in-field air monitoring location (center of plot) of the test plot. The samples were collected 24 – 48 hours prior to the start of the application. The pre-application air monitoring event lasted approximately 6 hours. These samples were used to determine the level of background dicamba within the application area. In-field air samplers were placed in the approximate center of the treated area and in each of 8 directions from the treated area. Samplers were turned on 30 minutes after completion of the application to the entire plot. The in-field air profile monitoring station in the plot consisted of air samplers mounted on a sampling mast located at the approximate center of the plot. The samplers located outside the treated area were located at a distance of 15 meters from the treated area. All air samplers will be located on the sample mast at approximately 0.33 m above the crop canopy. After application, PUFs were collected from the sample mast. The PUFs were collected approximately 6, 12, 24, 36, 48, 60, and 72 hours following completion of the application to the entire plot.

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Figure B.1. Large Area Applications, Field Layout

Spray drift impacts on non-tolerant soybean were assessed by comparing plant heights and visual plant response along transects perpendicular to the edges of to a distance of 100 m. Plant effects from volatility were assessed by covering a portion of the soybean crop during the application period to prevent exposure to spray drift. The cover was removed post-application. Plant heights were measured approximately 14 and 21 days post-application on ten plants at each distance along each transect. Plants were selected non-systematically and without measuring the same plant more than once. Height was measured by holding a plant upright and measuring the distance between the ground and the tip of the most recently emerged apical bud. Where multiple shoots were present, measurements along the main shoot were taken. Measurements were made to the nearest one-half cm using a standard ruler. Control (untreated) plants were measured just prior to the application at each site as a measure of inherent variability in the plant sizes across the field. Control measurements prior to application were taken non-systematically across the field in areas where spray treatments were to be made as well as upwind and downwind areas. In addition, upwind plant height

measurements were taken on the day assessments were made. These measurements were taken at least 50 to 100 m upwind of the "upwind edge" of each sprayed area and in areas where visual dicamba symptomology was not expected.

Visual plant response was assessed on a scale of 0 to 100 with 0 representing no visible plant response and 100 representing complete plant death. This plant response rating scale was conducted consistent with visual plant response ratings described in Frans (Frans, 1977), Behrens and Lueschen (Behrens, 1979), and Sciumbato et al. (Sciumbato et al., 2004). For selected plots and timings, photographs were made to document the visual plant response symptoms, and severity at specified distances.

Appendix B2. Table of Results for All Field Data Considered

					Average	Average	Average	Average Distance	Average Distance
Study ID	Location	Acres	Date of	Field condition	Distance (m) to	Distance (m) to	Distance (m) to	(m) to 5%	(m) to 5%
Study 12	Location	treated	Application		10% visual injury	20% visual injury	40% visual injury	reduction in height	reduction in yield
					(min – max)	(min – max)	(min – max)	(min – max)	(min – max)
					Field Studies				
					Product = Engen	ia			
Jones	AR		7/6/16	Soybean (V5), N	59	38	17	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), NE	57	36	15	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), E	37	24	12	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), SE	21	0	0	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), S	9	3	0	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), SW	0	0	0	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), W	6	2	0	Not assessed	Not assessed
Jones	AR		7/6/16	Soybean (V5), NW	11	0	0	Not assessed	Not assessed
Young ¹	IN	0.9	8/3/18	Soybean (V5)	12 (0 – 34)	10 (1 – 33)	8 (0 – 33)	Not assessed	Not assessed
Norsworthy	AR	3.5	7/20/17	Soybean (V3/V4)	40	24	7	24 (1 – 55)	Not assessed
Kruger ²	NE	0.17	7/6/17	Soybean (V5/V6/R2)	67	36	11	Not assessed	Not assessed
Young	IN	3.0	8/27/17	Soybean (V2/V3)	<10	<10	<10	Not assessed	Not assessed
Steckel	TN	2.0	7/27/17	Soybean (V5/V6)	27	13	3	Not assessed	Not assessed
Bradley	MO	2.6	7/20/17	Soybean (R1/R2)	28	8	1	Not assessed	Not assessed
					Product = Xtendin	nax			
49888501	GA	3.4	5/5/15	Bare	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
49888503	TX	9.6	6/8/15	Cotton	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
Norsworthy	AR	3.5	7/20/17	Soybean (V3/V4)	52	31	10	< 3	Not assessed
Kruger ²	NE	0.17	7/6/17	Soybean (V5/V6/R2)	69	43	18	Not assessed	Not assessed
Young	IN	3.0	8/27/17	Soybean (V2/V3)	<10	<10	<10	Not assessed	Not assessed
Bradley	MO	2.6	7/20/17	Soybean (R1/R2)	41	19	4	Not assessed	Not assessed
				Proc	duct = Xtendimax + I	Roundup			
49888601	GA	3.4	5/5/15	Bare	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
49888603	ТХ	9.6	6/8/15	Cotton	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
50578903	ТХ	4.6	10/4/16	Bare	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
50578903	ТХ	9.1	10/4/16	Cotton	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
50606801	Australia	37	12/15/17	Soybean (V4?)	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed
50642801	AZ	27	5/8/18	Soybean (V2)	8 (0 – 25)	4 (0 – 15)	0	Not reliable	Not assessed
Norsworthy ³	AR	38.5	7/16/18	Soybean (R1/R2)	34 - 136	20 – 82	7 - 29	Not reliable	Waiting on data

		Acros	Data of		Average	Average	Average	Average Distance	Average Distance
Study ID	Location	treated	Application	Field condition	10% visual injury	20% visual injury	40% visual injury	reduction in height	reduction in yield
					(min – max)	(min – max)	(min – max)	(min – max)	(min – max)
Werle ⁴	WI	8	7/11/18	Soybean (V5)	15 (12 – 17)	9 (7 – 10)	3 (3 – 4)	0 - 9	Not assessed
Young⁵	IN	20	8/9/18	Soybean (R1)	14 (6 - 20)	4 (1 – 6)	0	Not reliable	Not assessed
Sprague ⁶	MI	53	6/12/18	Soybean (V3)	16 (2 – 25)	7 (0 – 19)	4 (0 – 12)	0 - 10	Not assessed
Kruger	NE	30	7/10/18	Soybean (V5)	>15	>15	>15	10 (9 – 12)	Not assessed
Steckel	TN	2.0	7/27/17	Soybean (V5/V6)	18	5	0	Not assessed	Not assessed

1. Distance to 10% damage not provided in study. Values represent distance to < 10%, 10-30%, and > 30% along East side of field, side with largest values, at 28 days after treatment.

2. The Kruger, 2017 results may have been confounded by nearby application of dicamba during study.

3. According to protocol, TTI11004 nozzles were supposed to be used. UR11010 was used and is allowed on the label. Height data were collected, but because the growth stage was reproductive, the results were not considered reliable.

4. Transect that reported height damage showed no visual signs of injury, while transects that showed no plant height reductions showed visual injury.

5. In Young, 2018, drift transects were along the East and West directions, but a review of the meteorological data indicated winds were primarily out of South. Height data were collected, but because the growth stage was reproductive, the results were not considered reliable.

6. In Sprague, 2018, drift transects were along North and West directions, but a review of the meteorological data indicated winds were primarily out of Northeast and Southwest.

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There is no figure for yield as none of the studies provided measured yield values.

Appendix C. Crystal Ball Outputs

Worksheet. Report percentiles provided from input fit distribution

Assumption: Assumption_for_plant_height_for_all_formulations



Assumption: Assumption_for_plant_height_for_all_formulations (cont'd)

Cell: B18

Cell:

B18

Percentile		
s:	Assumption values	Distribution
0%	2.10	0.00
5%	4.79	4.81
10%	5.53	5.53
15%	6.11	6.07
20%	6.60	6.54
25%	7.05	6.98
30%	7.43	7.39
35%	7.82	7.80
40%	8.22	8.20
45%	8.65	8.62
50%	9.09	9.04
55%	9.53	9.49
60%	9.99	9.97
65%	10.52	10.48
70%	11.11	11.06
75%	11.76	11.71
80%	12.57	12.49
85%	13.62	13.46
90%	15.06	14.79
95%	17.45	17.00
100%	37.30	Infinity

Assumption: Assumption_for_plant_height_for_Engenia

Assumption_for_plant_height_for_Engree

Cell:

B20

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Percentile		
s:	Assumption values	Distribution
0%	3.21	0.00
5%	9.29	9.12
10%	11.09	10.94
15%	12.50	12.36
20%	13.72	13.63
25%	14.88	14.81
30%	16.01	15.97
35%	17.15	17.11
40%	18.29	18.28
45%	19.48	19.48
50%	20.78	20.75
55%	22.15	22.09
60%	23.61	23.54
65%	25.24	25.15
70%	26.99	26.96
75%	29.10	29.05
80%	31.50	31.58
85%	34.85	34.81
90%	39.60	39.34
95%	47.89	47.17
100%	137.75	Infinity

Assumption: Assumption_for_plant_height_for_Engenia (cont'd)

Assumption: Assumptions_for_plant_height_Xtendimax

Assumptions_for_plant_bright_Xandmax

Assumption: Assumptions_for_plant_height_Xtendimax (cont'd)

Percentile		
s:	Assumption values	Distribution
0%	1.39	0.00
5%	2.71	2.70
10%	3.02	3.02
15%	3.26	3.26
20%	3.48	3.47

Cell: B22

Cell: B22

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25%	3.68	3.65
30%	3.86	3.83
35%	4.03	3.99
40%	4.20	4.16
45%	4.37	4.33
50%	4.53	4.50
55%	4.70	4.68
60%	4.88	4.87
65%	5.09	5.08
70%	5.32	5.30
75%	5.56	5.56
80%	5.86	5.85
85%	6.21	6.22
90%	6.71	6.71
95%	7.47	7.52
100%	13.57	Infinity

Assumption: Assumption for 20% VSI for all formulations \cdot 1

Assumption for 20% V3H for all formulations -1

Percentile

s:	Assumption values	Distribution
0%	0.00	0.00
5%	0.74	0.74
10%	1.53	1.53
15%	2.32	2.36
20%	3.15	3.24
25%	4.12	4.18
30%	4.99	5.18
35%	6.10	6.26
40%	7.26	7.42
45%	8.47	8.68
50%	9.91	10.07
55%	11.46	11.60
60%	13.09	13.31
65%	14.92	15.24
70%	17.11	17.48
75%	19.80	20.13
80%	22.99	23.37
85%	26.97	27.55
90%	33.03	33.44
95%	43.51	43.50
100%	181.75	Infinity

Cell: B12

Assumption: Assumption for 20% VSI Xtendimax · 1

Assumption: Assumption for 20% VSI Xtendimax · 1 (cont'd)

Assumption: Assumption for 20% VSI for Engenia · 1 (cont'd)			
Percentile			
s:	Assumption values	Distribution	
0%	0.00	0.00	
5%	0.83	0.76	
10%	1.66	1.55	
15%	2.47	2.39	
20%	3.27	3.29	
25%	4.31	4.24	
30%	5.37	5.25	
35%	6.49	6.35	
40%	7.62	7.52	
45%	8.81	8.81	
50%	10.21	10.21	
55%	11.77	11.76	
60%	13.54	13.50	
65%	15.43	15.46	
70%	17.74	17.73	
75%	20.30	20.42	
80%	23.60	23.71	
85%	27.92	27.94	
90%	33.84	33.92	
95%	44.46	44.13	
100%	143.37	Infinity	

Assumption for 20% VSI Xtendimax 1

Assumption: Assumption for 20% VSI for Engenia · 1

Assumption for 20% VSI for Engenia 1

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Cell: B16

Cell: **B16**

Cell: B14

Cell:

B14

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Percentile		
s:	Assumption values	Distribution
0%	0.00	0.00
5%	0.78	0.74
10%	1.60	1.51
15%	2.44	2.33
20%	3.35	3.20
25%	4.25	4.12
30%	5.26	5.11
35%	6.32	6.18
40%	7.38	7.32
45%	8.65	8.57
50%	9.99	9.94
55%	11.52	11.45
60%	13.25	13.14
65%	15.11	15.05
70%	17.39	17.26
75%	20.25	19.88
80%	23.64	23.08
85%	27.97	27.20
90%	33.58	33.01
95%	43.52	42.95
100%	154.26	Infinity

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Worksheet B2. Crystal Ball Report Forecasts. Percentiles Provided From Sampling of the Assumed Distribution

Forecast: Distribution_for_plant_height_for_all_formulations

Summary:

Entire range is from 2.10 to 37.30 Base case is 0.00 After 10,000 trials, the std. error of the mean is 0.04



Statistics:	Forecast values
Trials	10,000
Base Case	0.00
Mean	9.83
Median	9.09
Mode	
Standard Deviation	4.01
Variance	16.11
Skewness	1.31
Kurtosis	5.88
Coeff. of Variation	0.4084
Minimum	2.10
Maximum	37.30
Range Width	35.20
Mean Std. Error	0.04

Forecast: Distribution_for_plant_height_for_all_formulations (cont'd)

Percentiles:	Forecast values
0%	2.10

5%	4.79
10%	5.53
15%	6.11
20%	6.60
25%	7.05
30%	7.43
35%	7.82
40%	8.22
45%	8.65
50%	9.09
55%	9.53
60%	9.99
65%	10.52
70%	11.11
75%	11.76
80%	12.57
85%	13.62
90%	15.06
95%	17.45
100%	37.30

Forecast: Distribution_for_plant_height_for_Engenia

Summary: Entire range is from 3.21 to 137.75 Base case is 0.00 After 10,000 trials, the std. error of the mean is 0.12



Statistics:	Forecast values
Trials	10,000
Base Case	0.00
Mean	23.57

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Median	20.78
Mode	
Standard Deviation	12.47
Variance	155.58
Skewness	1.68
Kurtosis	7.96
Coeff. of Variation	0.5293
Minimum	3.21
Maximum	137.75
Range Width	134.55
Mean Std. Error	0.12

Forecast: Distribution_for_plant_height_for_Engenia (cont'd)

Percentiles:	Forecast values
0%	3.21
5%	9.29
10%	11.09
15%	12.50
20%	13.72
25%	14.88
30%	16.01
35%	17.15
40%	18.29
45%	19.48
50%	20.78
55%	22.15
60%	23.61
65%	25.24
70%	26.99
75%	29.10
80%	31.50
85%	34.85
90%	39.60
95%	47.89
100%	137.75

Forecast: Distribution_for_plant_height_Xtendimax

Summary:

Entire range is from 1.39 to 13.57 Base case is 0.00 After 10,000 trials, the std. error of the mean is 0.01



101

Statistics:	Forecast values
Trials	10,000
Base Case	0.00
Mean	4.74
Median	4.53
Mode	
Standard Deviation	1.50
Variance	2.24
Skewness	0.9539
Kurtosis	4.65
Coeff. of Variation	0.3159
Minimum	1.39
Maximum	13.57
Range Width	12.18
Mean Std. Error	0.01

Forecast: Distribution_for_plant_height_Xtendimax (cont'd)

Percentiles:	Forecast values
0%	1.39
5%	2.71
10%	3.02
15%	3.26
20%	3.48
25%	3.68
30%	3.86
35%	4.03
40%	4.20
45%	4.37
50%	4.53
55%	4.70
60%	4.88
65%	5.09
70%	5.32
75%	5.56
80%	5.86
85%	6.21
90%	6.71
95%	7.47

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100%

13.57

Forecast: Assumption for 20% VSI for all formulations · 3

Summary:

Entire range is from 0.00 to 181.75 Base case is 0.00 After 10,000 trials, the std. error of the mean is 0.14



Statistics:	Forecast values
Trials	10,000
Base Case	0.00
Mean	14.33
Median	9.91
Mode	
Standard Deviation	14.48
Variance	209.69
Skewness	2.08
Kurtosis	10.04
Coeff. of Variation	1.01
Minimum	0.00
Maximum	181.75
Range Width	181.75
Mean Std. Error	0.14

Forecast: Assumption for 20% VSI for all formulations · 3 (cont'd)

Percentiles:	Forecast values
0%	0.00
5%	0.74
10%	1.53

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15%	2.32
20%	3.15
25%	4.12
30%	4.99
35%	6.10
40%	7.26
45%	8.47
50%	9.91
55%	11.46
60%	13.09
65%	14.92
70%	17.11
75%	19.80
80%	22.99
85%	26.97
90%	33.03
95%	43.51
100%	181.75

Forecast: Assumption for 20% VSI for Engenia · 3

Summary:

Entire range is from 0.00 to 143.37 Base case is 0.00 After 10,000 trials, the std. error of the mean is 0.15



Statistics:	Forecast values
Trials	10,000
Base Case	0.00
Mean	14.79
Median	10.21
Mode	

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Standard Deviation	14.79
Variance	218.87
Skewness	2.04
Kurtosis	9.27
Coeff. of Variation	1.00
Minimum	0.00
Maximum	143.37
Range Width	143.37
Mean Std. Error	0.15

Forecast: Assumption for 20% VSI for Engenia · 3 (cont'd)

Percentiles:	Forecast values
0%	0.00
5%	0.83
10%	1.66
15%	2.47
20%	3.27
25%	4.31
30%	5.37
35%	6.49
40%	7.62
45%	8.81
50%	10.21
55%	11.77
60%	13.54
65%	15.43
70%	17.74
75%	20.30
80%	23.60
85%	27.92
90%	33.84
95%	44.46
100%	143.37

Forecast: Assumption for 20% VSI Xtendimax · 3

Summary:

Certainty level is 100.00% Certainty range is from -Infinity to 431.12 Entire range is from 0.00 to 154.26 Base case is 0.00 After 10,000 trials, the std. error of the mean is 0.15



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Statistics:	Forecast values
Trials	10,000
Base Case	0.00
Mean	14.57
Median	9.99
Mode	
Standard Deviation	14.54
Variance	211.44
Skewness	2.01
Kurtosis	9.22
Coeff. of Variation	0.9981
Minimum	0.00
Maximum	154.26
Range Width	154.26
Mean Std. Error	0.15

Forecast: Assumption for 20% VSI Xtendimax · 3 (cont'd)

Percentiles:	Forecast values
0%	0.00
5%	0.78
10%	1.60
15%	2.44
20%	3.35
25%	4.25
30%	5.26
35%	6.32
40%	7.38
45%	8.65
50%	9.99
55%	11.52
60%	13.25
65%	15.11
70%	17.39
75%	20.25
80%	23.64
85%	27.97
90%	33.58
95%	43.52

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100%

154.26

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Appendix D Effects Determinations Summary for all dicot and new animal species

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
513	Star cactus (Astrophytum asterias)	OFF	Hidalgo, TX, Starr, TX	Hidalgo, TX, Starr, TX	May Affect	No Effect	Not Applicable
568	Spring Creek bladderpod (Lesquerella perforata)	ON	Wilson, TN	Wilson, TN	May Affect	May Affect	No Effect
569	Zapata bladderpod (Lesquerella thamnophila)	OFF	Starr, TX	Starr, TX	May Affect	No Effect	Not Applicable
620	Northern wild monkshood (Aconitum noveboracense)	OFF	Allamakee, IA, Clayton, IA, Delaware, IA, Dubuque, IA, Hardin, IA, Jackson, IA, Grant, WI, Monroe, WI, Richland, WI, Sauk, WI, Vernon, WI	Allamakee, IA, Clayton, IA, Delaware, IA, Dubuque, IA, Hardin, IA, Jackson, IA, Grant, WI, Monroe, WI, Richland, WI, Sauk, WI, Vernon, WI	May Affect	No Effect	Not Applicable
624	South Texas ambrosia (Ambrosia cheiranthifolia)	OFF	Cameron, TX, Jim Wells, TX, Kleberg, TX, Nueces, TX	Cameron, TX, Jim Wells, TX, Kleberg, TX, Nueces, TX	May Affect	No Effect	Not Applicable
627	Tobusch fishhook cactus (Sclerocactus brevihamatus ssp. tobuschii)	OFF	Medina, TX	Medina, TX	May Affect	No Effect	Not Applicable
628	Price's potato- bean (Apios priceana)	OFF	Calloway, KY	Calloway, KY	May Affect	No Effect	Not Applicable
630	Braun's rock- cress (Arabis perstellata)	OFF	Henry, KY, Rutherford, TN, Wilson, TN	Henry, KY, Rutherford, TN, Wilson, TN	May Affect	No Effect	Not Applicable
636	Mead's milkweed (Asclepias meadii)	OFF	Ford, IL, Iroquois, IL*, Will, IL, Anderson, KS, Barton,	Ford, IL, Iroquois, IL*, Will, IL, Anderson, KS, Barton,	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
			MO, Harrison, MO, Johnson, MO, Pettis, MO, Vernon, MO, Columbia, WI, Dane, WI, Grant, WI, Green, WI	MO, Harrison, MO, Johnson, MO, Pettis, MO, Vernon, MO, Columbia, WI, Dane, WI, Grant, WI, Green, WI			
651	Texas poppy- mallow (Callirhoe scabriuscula)	OFF	Coke, TX, Mitchell, TX, Runnels, TX	Coke, TX, Mitchell, TX, Runnels, TX	May Affect	No Effect	Not Applicable
655	Small-anthered bittercress (Cardamine micranthera)	OFF	Forsyth, NC, Stokes, NC	Forsyth, NC, Stokes, NC	May Affect	No Effect	Not Applicable
677	Cumberland rosemary (Conradina verticillata)	OFF	White, TN	White, TN	May Affect	No Effect	Not Applicable
682	Lee pincushion cactus (Coryphantha sneedii var. leei)	OFF	Eddy, NM	Eddy, NM	May Affect	No Effect	Not Applicable
683	Sneed pincushion cactus (Coryphantha sneedii var. sneedii)	OFF	Do\xc3\xb1a Ana, NM, El Paso, TX	Do\xc3\xb1a Ana, NM, El Paso, TX	May Affect	No Effect	Not Applicable
702	Black lace cactus (Echinocereus reichenbachii var. albertii)	OFF	Jim Wells, TX, Kleberg, TX, Refugio, TX	Jim Wells, TX, Kleberg, TX, Refugio, TX	May Affect	No Effect	Not Applicable
709	Gypsum wild- buckwheat (Eriogonum gypsophilum)	OFF	Eddy, NM	Eddy, NM	May Affect	No Effect	Not Applicable
716	No common name (Geocarpon minimum)	OFF	Henry, MO, Jasper, MO	Henry, MO, Jasper, MO	May Affect	No Effect	Not Applicable
734	Dwarf-flowered heartleaf (Hexastylis naniflora)	OFF	Catawba, NC, Cleveland, NC, Iredell, NC, Lincoln, NC	Catawba, NC, Cleveland, NC, Iredell, NC, Lincoln, NC	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
739	Slender rush-pea (Hoffmannseggia tenella)	OFF	Kleberg, TX, Nueces, TX	Kleberg, TX, Nueces, TX	May Affect	No Effect	Not Applicable
750	Lyrate bladderpod (Lesquerella lyrata)	OFF	Colbert, AL*, Franklin, AL*, Lawrence, AL*	Colbert, AL*, Franklin, AL*, Lawrence, AL*	May Affect	No Effect	Not Applicable
763	Walker's manioc (Manihot walkerae)	OFF	Hidalgo, TX	Hidalgo, TX	May Affect	No Effect	Not Applicable
764	Mohr's Barbara's buttons (Marshallia mohrii)	OFF	Calhoun, AL*, Cherokee, AL	Calhoun, AL*, Cherokee, AL	May Affect	No Effect	Not Applicable
789	Papery whitlow- wort (Paronychia chartacea)	OFF	Jackson, FL	Jackson, FL	May Affect	No Effect	Not Applicable
818	Bunched arrowhead (Sagittaria fasciculata)	OFF	Henderson, NC	Henderson, NC	May Affect	No Effect	Not Applicable
819	Green pitcher- plant (Sarracenia oreophila)	OFF	Cherokee, AL, DeKalb, AL, Etowah, AL, Jackson, AL*, Marshall, AL*	Cherokee, AL, DeKalb, AL, Etowah, AL, Jackson, AL*, Marshall, AL*	May Affect	No Effect	Not Applicable
831	Fringed campion (Silene polypetala)	OFF	Jackson, FL	Jackson, FL	May Affect	No Effect	Not Applicable
835	Short's goldenrod (Solidago shortii)	OFF	Harrison, IN, Fleming, KY, Harrison, KY, Meade, KY	Harrison, IN, Fleming, KY, Harrison, KY, Meade, KY	May Affect	No Effect	Not Applicable
836	Gentian pinkroot (Spigelia gentianoides)	OFF	Calhoun, FL, Jackson, FL, Washington, FL	Calhoun, FL, Jackson, FL, Washington, FL	May Affect	No Effect	Not Applicable
843	Texas snowbells (Styrax texanus)	OFF	Uvalde, TX	Uvalde, TX	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
852	Cooley's meadowrue (Thalictrum cooleyi)	OFF	Mitchell, GA, Worth, GA, Brunswick, NC, Columbus, NC, Onslow, NC, Pender, NC	Mitchell, GA, Worth, GA, Brunswick, NC, Columbus, NC, Onslow, NC, Pender, NC	May Affect	No Effect	Not Applicable
872	Large-fruited sand-verbena (Abronia macrocarpa)	OFF	Robertson, TX	Robertson, TX	May Affect	No Effect	Not Applicable
875	Sensitive joint- vetch (Aeschynomene virginica)	OFF	Salem, NJ*, Beaufort, NC, Craven, NC, Hyde, NC, Lenoir, NC	Salem, NJ*, Beaufort, NC, Craven, NC, Hyde, NC, Lenoir, NC	May Affect	No Effect	Not Applicable
891	Decurrent false aster (Boltonia decurrens)	OFF	Bureau, IL, Cass, IL, Fulton, IL, Greene, IL, Jersey, IL, LaSalle, IL, Marshall, IL, Marshall, IL, Morgan, IL, Peoria, IL, Pike, IL, Randolph, IL*, St. Clair, IL, Scott, IL, Tazewell, IL, Woodford, IL, Cape Girardeau, MO, Dunklin, MO, Lincoln, MO, Mississippi, MO, Pike, MO, St. Charles, MO	Bureau, IL, Cass, IL, Fulton, IL, Greene, IL, Jersey, IL, LaSalle, IL, Marshall, IL, Marshall, IL, Morgan, IL, Peoria, IL, Pike, IL, Randolph, IL*, St. Clair, IL, Scott, IL, Tazewell, IL, Woodford, IL, Cape Girardeau, MO, Dunklin, MO, Lincoln, MO, Mississippi, MO, Pike, MO, St. Charles, MO	May Affect	No Effect	Not Applicable
905	Pitcher's thistle (Cirsium pitcheri)	OFF	Brown, WI*	Brown, WI*	May Affect	No Effect	Not Applicable
920	Leafy prairie- clover (Dalea foliosa)	OFF	LaSalle, IL, Will, IL	LaSalle, IL, Will, IL	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
945	Schweinitz's sunflower (Helianthus schweinitzii)	OFF	Anson, NC, Davidson, NC, Randolph, NC, Rowan, NC, Stanly, NC, Surry, NC, Union, NC	Anson, NC, Davidson, NC, Randolph, NC, Rowan, NC, Stanly, NC, Surry, NC, Union, NC	May Affect	No Effect	Not Applicable
957	Prairie bush- clover (Lespedeza leptostachya)	OFF	Cass, IL, Champaign, IL, Fayette, IL, Jo Daviess, IL, Lee, IL, McHenry, IL, Ogle, IL, Winnebago, IL, Brown, MN, Cottonwood, MN, Dakota, MN, Dodge, MN, Goodhue, MN, Jackson, MN, Moder, MN, Mower, MN, Nobles, MN, Nobles, MN, Nobles, MN, Nobles, MN, Nobles, MN, Nobles, MN, Redwood, MN, Renville, MN, Rice, MN, Reck, MN, Steele, MN*, Dane, WI, Grant, WI, Green, WI, Pierce, WI, Rock, WI, Sauk, WI	Cass, IL, Champaign, IL, Fayette, IL, Jo Daviess, IL, Lee, IL, McHenry, IL, Ogle, IL, Winnebago, IL, Brown, MN, Cottonwood, MN, Dakota, MN, Dodge, MN, Goodhue, MN, Dodge, MN, Goodhue, MN, Jackson, MN, Martin, MN, Mower, MN, Nobles, MN, Nobles, MN, Nobles, MN, Nobles, MN, Redwood, MN, Renville, MN, Rice, MN, Rice, MN, Rice, MN, Rock, MN, Steele, MN*, Dane, WI, Grant, WI, Green, WI, Pierce, WI, Rock, WI, Sauk, WI	May Affect	No Effect	Not Applicable
959	Heller's blazingstar (Liatris helleri)	OFF	Burke, NC	Burke, NC	May Affect	No Effect	Not Applicable
960	Pondberry (Lindera melissifolia)	OFF	Bolivar, MS, Coahoma, MS, Leflore, MS, Sunflower,	Bolivar, MS, Sunflower, MS, Sampson, NC, Clay, AR,	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
			MS, Washington, MS, Sampson, NC, Clay, AR, Craighead, AR, Crittenden, AR, Cross, AR, Jackson, AR, Poinsett, AR, Prairie, AR, Woodruff, AR	Craighead, AR, Crittenden, AR, Cross, AR, Jackson, AR, Poinsett, AR, Prairie, AR, Woodruff, AR			
967	Rough-leaved loosestrife (Lysimachia asperulaefolia)	OFF	Beaufort, NC, Bladen, NC, Columbus, NC, Craven, NC, Cumberland, NC, Harnett, NC, Darlington, SC	Beaufort, NC, Bladen, NC, Columbus, NC, Craven, NC, Cumberland, NC, Harnett, NC, Darlington, SC	May Affect	No Effect	Not Applicable
976	Canby's dropwort (Oxypolis canbyi)	OFF	Florence, SC, Horry, SC, Orangeburg, SC	Florence, SC, Horry, SC, Orangeburg, SC	May Affect	No Effect	Not Applicable
977	Fassett's locoweed (Oxytropis campestris var. chartacea)	OFF	Portage, WI, Waushara, WI	Portage, WI, Waushara, WI	May Affect	No Effect	Not Applicable
978	Blowout penstemon (Penstemon haydenii)	OFF	Custer, NE, Lincoln, NE	Custer, NE, Lincoln, NE	May Affect	No Effect	Not Applicable
982	Godfrey's butterwort (Pinguicula ionantha)	OFF	Calhoun, FL	Calhoun, FL	May Affect	No Effect	Not Applicable
991	Harperella (Ptilimnium nodosum)	OFF	Dooly, GA	Dooly, GA	May Affect	No Effect	Not Applicable
992	Michaux's sumac (Rhus michauxii)	OFF	Cumberland, NC, Johnston, NC, Nash, NC, Robeson, NC, Union,	Cumberland, NC, Johnston, NC, Nash, NC, Robeson, NC, Union,	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
			NC, Wilson, NC	NC, Wilson, NC			
994	Alabama canebrake pitcher-plant (Sarracenia rubra ssp. alabamensis)	OFF	Autauga, AL*, Chilton, AL*, Elmore, AL*	Autauga, AL*, Chilton, AL*, Elmore, AL*	May Affect	No Effect	Not Applicable
996	American chaffseed (Schwalbea americana)	OFF	Burlington, NJ*, Ocean, NJ*, Florence, SC, Horry, SC	Burlington, NJ*, Ocean, NJ*, Florence, SC, Horry, SC	May Affect	No Effect	Not Applicable
1003	Houghton's goldenrod (Solidago houghtonii)	OFF	Genesee, NY	Genesee, NY	May Affect	No Effect	Not Applicable
1019	Seabeach amaranth (Amaranthus pumilus)	OFF	Sussex, DE*, Monmouth, NJ*, Hyde, NC, Horry, SC	Sussex, DE*, Monmouth, NJ*, Hyde, NC, Horry, SC	May Affect	No Effect	Not Applicable
1036	Ruth's golden aster (Pityopsis ruthii)	OFF	Polk, TN	Polk, TN	May Affect	No Effect	Not Applicable
1041	Running buffalo clover (Trifolium stoloniferum)	OFF	Dunklin, MO	Dunklin, MO	May Affect	No Effect	Not Applicable
1045	Texas prairie dawn-flower (Hymenoxys texana)	OFF	Fort Bend, TX	Fort Bend, TX	May Affect	No Effect	Not Applicable
1048	Alabama leather flower (Clematis socialis)	OFF	Cherokee, AL, Etowah, AL, Floyd, GA	Cherokee, AL, Etowah, AL, Floyd, GA	May Affect	No Effect	Not Applicable
1058	Mountain golden heather (Hudsonia montana)	OFF	Burke, NC, McDowell, NC	Burke, NC, McDowell, NC	May Affect	No Effect	Not Applicable
1059	Lakeside daisy (Hymenoxys herbacea)	OFF	Clinton, IL, Tazewell, IL, Will, IL, Erie, OH, Ottawa, OH	Clinton, IL, Tazewell, IL, Will, IL, Erie, OH, Ottawa, OH	May Affect	No Effect	Not Applicable
EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
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1064	Kral's water- plantain (Sagittaria secundifolia)	OFF	DeKalb, AL	DeKalb, AL	May Affect	No Effect	Not Applicable
1077	Texas ayenia (Ayenia limitaris)	OFF	Cameron, TX, Hidalgo, TX, Willacy, TX	Cameron, TX, Hidalgo, TX, Willacy, TX	May Affect	No Effect	Not Applicable
1087	Guthrie's (=Pyne's) ground-plum (Astragalus bibullatus)	OFF	Davidson, TN, Rutherford, TN	Davidson, TN, Rutherford, TN	May Affect	No Effect	Not Applicable
1096	Morefield's leather flower (Clematis morefieldii)	OFF	Jackson, AL, Madison, AL* , Franklin, TN, Grundy, TN	Jackson, AL, Madison, AL* , Franklin, TN, Grundy, TN	May Affect	No Effect	Not Applicable
1150	Leedy's roseroot (Rhodiola integrifolia ssp. leedyi)	OFF	Fillmore, MN, Olmsted, MN	Fillmore, MN, Olmsted, MN	May Affect	No Effect	Not Applicable
1191	Florida torreya (Torreya taxifolia)	OFF	Jackson, FL, Decatur, GA, Seminole, GA	Jackson, FL, Decatur, GA, Seminole, GA	May Affect	No Effect	Not Applicable
1209	Alabama streak- sorus fern (Thelypteris pilosa var. alabamensis)	OFF	Winston, AL*	Winston, AL*	May Affect	No Effect	Not Applicable
1678	Bracted twistflower (Streptanthus bracteatus)	OFF	Medina, TX, Uvalde, TX, Williamson, TX	Medina, TX, Uvalde, TX, Williamson, TX	May Affect	No Effect	Not Applicable
1710	Fleshy-fruit gladecress (Leavenworthia crassa)	OFF	Cullman, AL*, Lawrence, AL*, Morgan, AL*	Cullman, AL*, Lawrence, AL*, Morgan, AL*	May Affect	No Effect	Not Applicable
1831	Short's bladderpod (Physaria globosa)	OFF	Posey, IN, Maury, TN, Montgomery, TN	Posey, IN, Maury, TN, Montgomery, TN	May Affect	No Effect	Not Applicable
1881	Whorled Sunflower (Helianthus verticillatus)	OFF	Cherokee, AL, Floyd, GA, Chester, TN, McNairy, TN, Madison, TN	Cherokee, AL, Floyd, GA, Chester, TN, McNairy, TN, Madison, TN	May Affect	No Effect	Not Applicable

EntityID	Species	On/Off Field	Counties with overlap	Accounting for ECOS updates**	No change to Federal Action effects determinations	Infield omni- directional buffer of distance 57 feet change to Federal Action effects determinations	County prohibition of use change to Federal Action effects determinations
7167	Kentucky glade cress (Leavenworthia exigua laciniata)	OFF	Bullitt, KY, Jefferson, KY	Bullitt, KY, Jefferson, KY	May Affect	No Effect	Not Applicable
8392	Missouri bladderpod (Physaria filiformis)	OFF	Dade, MO, Lawrence, MO	Dade, MO, Lawrence, MO	May Affect	No Effect	Not Applicable

* Sub-county information available in this county (Bold) ** Dropped counties based on available spatial information provided documented in ECOS

Appendix E Determination for all Dicot and New Animal and Non-Monocot Species Critical Habitat Modification.

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
1	Indiana bat (Myotis sodalis)	PCE not specified - Critical habitat designations are either mines or caves.	No GIS file due to sensitivity - overlap is assumed	no	no	no	no	n/a
41	Alabama beach mouse (Peromyscus polionotus ammobates)	PCE includes: contiguous mosaic of early-late successional scrub vegetation and dune habitat; primary- secondary dunes dominated by sea oats; scrub dunes dominated by scrub oak; and, unobstructed habitat connections.	Baldwin, AL	no	no	γes	yes	omni- directional buffer of distance 57 feet
67	Whooping crane (Grus americana)	"All areas proposed in this rule would provide food, water, and other nutritional or physiological needs of the whooping crane during spring or fall migration.	Buffalo, NE, Kearney, NE, Phelps, NE	no	γes	yes	yes	omni- directional buffer of distance 57 feet

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
		Consumption of some cereal crops in adjacent croplands during migration period." Direct relatable resources to agricultural field possibly treated with 2,4-D choline.						
149	Southwester n willow flycatcher (Empidonax traillii extimus)	PCE includes riparian habitat along a dynamic river or lakeside in a natural or manmade successional environment (for nesting, foraging, migration, dispersal and shelter) comprised of trees and shelter) comprised of trees and shrubs (include willow species, boxelder, tamarisk, etc.) and dense riparian shrub/tree thicket interspersed with small openings of	Graham, AZ	no	no	yes	yes	omni- directional buffer of distance 57 feet

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
		open water or marsh or shorter vegetation.						
194	San Marcos salamander (Eurycea nana)	PCE not specified - Critical habitat defined simply as Spring Lake and its outflow, the San Marcos River, downstream roughly 50 meters from the Spring Lake Dam (Texas).	Hays, TX	no	no	no	no	n/a
558	Pecos (=puzzle =paradox) sunflower (Helianthus paradoxus)	PCE include desert wetland or riparian habitat components that provide a low proportion of woody shrub or canopy cover, and other abiotic conditions.	Chaves, NM, Pecos, TX	yes	no	yes	yes	omni- directional buffer of distance 57 feet
569	Zapata bladderpod (Lesquerella thamnophila)	PCE not specified - typical habitat described as open cenzino shrub community that grades into an blackbrush	Starr, TX	γes	no	yes	yes	omni- directional buffer of distance 57 feet

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
		shrub community; these communities apparently dominate upland habitats on shallow soils near the Rio Grande.						
1030	Huachuca water-umbel (Lilaeopsis schaffneriana var. recurva)	PCE includes a temporally stable riparian plant community; relatively stable stream channel subject to periodic flooding that provides rejuvenation of the riparian plant community and produces open microsites for Lilaeopsis expansion.	Cochise, AZ	yes	no	γes	yes	omni- directional buffer of distance 57 feet
1710	Fleshy-fruit gladecress (Leavenworth ia crassa)	PCE includes glade habitats (i.e, shallow- soiled, open areas with exposed limestone bedrock or gravel dominated by herbaceous vegetation) protected	Morgan, AL	yes	no	γes	yes	omni- directional buffer of distance 57 feet

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Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
		from invasive or weedy plants.						
1881	Whorled Sunflower (Helianthus verticillatus)	PCE includes: sites with no forest canopy, or where woody vegetation is present in sufficiently low densities to provide full or partial sunlight to the understory, and which support vegetation characteristic of moist prairie communities; as well as occupied sites in which a sufficient number of compatible mates are available to allow outcrossing and the production of viable achenes.	Cherokee, AL, McNairy, TN, Madison, TN	γes	no	γes	yes	omni- directional buffer of distance 57 feet

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
3412	Dakota Skipper (Hesperia dacotae)	PCE includes: wet-mesic tallgrass or mixed grass prairie containing 5- 25% tree/shrub cover; native grasses (inc. prairie dropseed or little bluestem) to provide food, and native forbs (inc. purple coneflower, bluebell bellflower, white prairie clover, upright prairie coneflower, etc.) to provide nectar and water during periods of flight; perennial grassland habitat for dispersal with limited or no barriers to dispersal (including <25% tree cover and no row crops).	Clay, MN, Polk, MN, Pope, MN	no	no	yes	yes	omni- directional buffer of distance 57 feet

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
4910	Salt Creek Tiger beetle (Cicindela nevadica lincolniana)	PCE includes: exposed mudflats associated with saline wetlands or the exposed banks and islands of streams and seeps to support egg- laying and foraging requirements (specifically includes Salmo and Saltillo soil types); vegetated wetlands adjacent to core habitats that provide shade for subspecies thermoregula tion, support a source of prey for adult and larval forms of the species, and protect core habitats.	Lancaster, NE, Saunders, NE	no	no	yes	yes	omni- directional buffer of distance 57 feet
7167	Kentucky glade cress (Leavenworth ia exigua laciniata)	PCE includes: cedar glades and gladelike areas within the species' range that include full or nearly full sunlight and an	Bullitt, KY, Jefferson, KY	yes	no	yes	yes	omni- directional buffer of distance 57 feet

Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
		undisturbed soil seed bank; vegetated land around glades and gladelike areas that extends up and down slope and ends at natural or manmade breaks.						
1014 7	Poweshiek skipperling (Oarisma poweshiek)	PCE includes: wet-mesic tallgrass or mixed grass prairie containing a predominanc e of native grasses and flowering forbs and 5- 25% tree/shrub cover; prairie fen habitats containing a predominanc e of native grasses and flowering forbs - native grass species are to provide food and cover (species include prairie dropseed, little bluestem,	Clay, MN, Polk, MN	no	no	yes	yes	omni- directional buffer of distance 57 feet

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Entity ID	Species Name	Notes on Relevant Primary Constituent Elements (PCE)	Counties	Non- monocot plant?	PCEs include Ag fields?	PCE's include Non- monocot plants	Mitigation required for "no modification"	Mitigation
		etc), and						
		native forbs						
		are to						
		provide						
		nectar and						
		water during						
		periods of						
		flight (inc.						
		purple						
		coneflower,						
		black-eyed						
		Susall,						
		shibbin 0x-						
		tickseed.						
		etc.):						
		perennial						
		grassland						
		habitat for						
		dispersal with						
		limited or no						
		barriers to						
		dispersal						
		(including						
		<25% tree						
		cover and no						
		row crops).						

Appendix F. Incidents

As noted previously numerous incidents of damage to soybean and other crop and non-crop species were reported to EPA by States in 2017 and 2018. While very few formal submissions of the nature of the incidents have been provided to the Agency, virtually all reports associated the damage to plants to the dicamba GMO use. EPA has tabulated reported numbers of incidents by state for 2017 and 2018. In general, the greatest cluster of incidents are associated with soybean use in AR, MO, IL, MN (2017), and IN (2018) with far fewer reported in the deep south, upper Midwest, and eastern portions of the soybean and cotton growing areas. **Figure F.1** below presents a map that overlays the numbers of incidents by state for 2018 relative to the location of field trials conducted in 2017 and 2018 (yellow hash marks) discussed in this assessment. Overall it appears that most incidents appear to correlate with the states clustered along the middle Mississippi River valley. In addition, there is a correlation between where the field trials were being conducted and where the incidents are occurring, though the correlation is not strong.

There are several uncertainties with this analysis. The number of incidents may not accurately represent the extent of dicamba-related damage; incidents may be under- or over-reported. See discussion on "Incidents Alleging Crop Damage from Off-Target Movement of Dicamba" in the EPA's 2018 Over-the-Top Dicamba Products for Genetically Modified Cotton and Soybeans: Benefits and Impacts. It is also unclear how other factors such as variation in climate, topography (*e.g.*, inversion potential), water chemistry (e.g. water pH), and agricultural practices (e.g. water softening for hard water) influence these occurrences. However, the mapping of incidents is suggestive of a tendency for greater numbers of damaged acres of non-GMO soybean in the middle portion of the registered use area.



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Figure F.1. Locations of 2018 Incident Data and Field Studies

Appendix G. Meeting Minutes for EPA Discussion with Dr. Norsworthy (10/4/2018)

On Thursday, Oct 4th, EPA members participated in a conference call with Dr. Norsworthy regarding the 2018 study to get clarification on the potentially confounding issues:

• Issue One: Acetochlor tank mix and potential to adversely affect soybeans during the trials

With regards to the effects of the use of Warrant, Dr. Norsworthy indicated it was the registrant and grower, not Dr. Norsworthy, who prepared the tank mix to include Warrant. With regards to damage resulting from acetochlor, Dr. Norsworthy indicated that Warrant can be used as postemergent application on soybeans and that there was no acetochlor damage to the Xtend soybeans, planted on the treated field, or the Roundup Ready soybeans, planted surrounding the treated field. Additionally, Dr. Norsworthy indicated that the damage resulting from acetochlor exposure is fundamentally different from that produced by dicamba and that the majority of weed scientists can differentiate between these types of damage. While dicamba damage results in a cupping of the leaves, acetochlor damage results in a crinkling of the leaf and a wavy appearance.

• Issue Two: Acetochlor tank mixture could alter the volatile potential of dicamba in the study, negating Xtendimax with Vapor Grip performance

Dr. Norsworthy has investigated the effect of tank mixture partners and tank holding time as it relates to tank content pH. This was done to address any concern that conditions of the tank mixture could have altered the pH of the spray tank contents such that the buffering capacity of Xtendimax would be nullified and promote low pH shift, inducing enhanced dicamba volatility. Preliminary data show no effect on tank pH with Warrant as a tank mix partner, including tank mix holding time.

Dr. Norsworthy indicated that he has also conducted trials under hoop tunnels investigating volatility of Xtendimax with (1) Roundup Powermax II and Warrant and (2) Roundup Powermax II and Warrant that had been sitting in a tank for 4 days (approximating the tank holding time encountered in the field study). Preliminary data indicates that there was no increase in volatility based on tank holding time.

Dr. Norsworthy has committed to sharing these data with EPA.

Issue Three: Plant damage scoring is alleged to be atypical compared to other field studies

Dr. Norsworthy referred EPA to the two types of visual signs of injury methods used to score observations of injury during the field study. Both methods were employed side by side during the evaluation of transect. Both methods are in close agreement with respect to visual damage extent at each point along the transects.

Issue Four: Tarped plants were insufficient to prevent spray drift damage, thereby overestimating the role of vapor drift in the study

Dr. Norsworthy emphasized that the use of the tarps was at the behest of the registrant sponsor and are not inconsistent with the method used in other field studies, including those conducted by the registrant.

Issue Five: The use of bucketed plants along transects to segregate damage from primary drift from secondary vapor drift was inappropriate due to the potential for cross contamination with adjacent un-bucketed plants.

Dr. Norsworthy indicated that plants within 6 inches of the outside of the buckets were removed in order to prevent cross contamination of the bucketed plants from plants impacted by primary and secondary drift.

Issue Six: The use of bucketed plants along transects to segregate damage from primary drift from secondary vapor drift unduly stressed the plants and resulted in questionable results attributed to vapor exposure.

Dr. Norsworthy indicated that buckets were in-place only for the duration of spray and for up to 30 minutes post application. He did state that visible plant stress occurred as a result of covering the plants with tarps and buckets. However, the plant damage from tarp/bucket effects was easily distinguishable from the damage resulting from dicamba exposure and the damage from tarps/buckets was no longer apparent 21 days after treatment. His presentation of visual signs of damage for bucketed plants was based on the extent of visual signs of damage consistent to the scoring of the types of damage attributable to dicamba exposure. Dr. Norsworthy also reiterated the similarity of the extent of damage with distance between bucketed plants, suggesting a common level of exposure.

Issue 7: Irrigation confounds the transect data because the irrigation water can be transporting herbicide to the off-treatment field soybeans.

Dr. Norsworthy confirmed for EPA that no irrigation water originating from the treatment area was transported to the transect areas for the west, east and south transects of the field study. The only transect receiving irrigation water originating from the treated field was to the north. Visual plant damage along the North transect extended much further than the other transects; 40% visual damage extended to approximately 750 ft for the North transect, whereas for the South, East, and West transects, 40% visual injury was limited to 150 ft. Flood irrigation was employed at the site and irrigation water was applied approximately 7-10 days after the dicamba application. (Note for this reason, EPA has confined its evaluation of the field study to the west, east and south transects.) Discussions with Dr. Norsworthy indicated that off-site damage was most pronounced for soybean plants that had received runoff from the treated field and that the visual injury to plants Northeast and Northwest of the field, that did not receive runoff from irrigation water, was much lower than those that had received runoff water. As such, Dr. Norsworthy concluded that the visual injury along the North transect was the result of dicamba in the runoff from the irrigated field. Dr. Norsworthy also indicated that data from another site, where irrigation was not performed, but a significant rainfall event occurred within three days of application, produced similar off-field plant effects as seen in the north transect of Proctor, Arkansas field study.

• Future availability of yield data

EPA asked if yield data would be available soon for use in the analysis. Dr. Norsworthy indicated that the fields would not be harvested until the 3rd or 4th week of October.

• Potential hypotheses to explain differences in the Arkansas data and other field trials from other areas

EPA inquired of Dr. Norsworthy his thoughts as to why the results from his trials were different than those observed in other areas of the country. Dr. Norsworthy indicated that he wasn't sure. Dr. Norsworthy indicated there could be issues relating to the proximity of the region to Crowley's Ridge and the frequency of inversions in the area, and that soil pHs were low in region relative to other areas of the country. In the end, Dr. Norsworthy indicated that there were a lot of complicating factors and that temperature, while it plays a major role in volatilization, was not the only factor.

Referring back to the discussion of irrigation, Dr. Norsworthy also discussed the potential for irrigation to play a role. He opined that Midwest soils may have sufficient moisture and fertility characteristics as opposed to the South-central soils which are thinner in depth of topsoil and often require irrigation to maintain adequate soil moisture. He also opined that the presence of irrigation has the potential to enhance visual damage extent as the plants are actively growing, but may also limit the extent of damage to yield because the plants have resources to affect recovery from damage.

Appendix H. Discussion of additional factors influencing off-site vapor drift

H.1 Temperature

Temperature influences the vaporization rate of a pesticide mainly through its effect on the vapor pressure of the pesticide. Vapor pressures of pesticides typically follow a reciprocal-temperature relationship given by the Antoine equation⁴

$$logVP = A - \frac{B}{T+C}$$

where VP is the vapor pressure, T is the temperature, and A, B, and C are constants specific to the chemical. From the equation, as the temperature increases, the value B/(T+C) decreases, and vapor pressure increases. As such, as the air temperature and soil temperature increase, so does the vapor pressure of dicamba and subsequently the vaporization rate. This is not to say that other environmental factors, such as wind speed, soil moisture, precipitation, and sorption to soil particles and plant surfaces, may not also play a role in enhancing or retarding vaporization, only that temperature is considered an important factor in evaluating the evaporation of dicamba. **Figure H.1** depicts the effect of temperature on the vapor pressure of dicamba⁵. Based on this curve, the volatility of dicamba begins to move away from a flat line and begins to increase at approximately 90°F. Current label language instructs users on practices to minimize spray drift by accounting for the effect of temperature on droplet size⁶. This current restriction is not intended to address volatile emissions of dicamba.

⁴ Spencer, W. and Cliath, M. 1974. Vaporization of Chemicals. Environmental Dynamics of Pesticides, Rizwanul Haque and VH Freed, editors.

⁵ Recreated from Abraham, W. Date Unknown. The Chemistry Behind Low-Volatility Dicamba.

https://blog.americanchemistry.com/wp-content/uploads/2018/06/Dicamba_TheOtherDicambaStory.pdf ⁶ Current label language for Xtendimax states "when making applications in low relative humidity or temperatures above 91⁰ F set up equipment to larger droplets to compensate for evaporation."



Figure H.1. Temperature Effects on the Vapor Pressure of Pure Dicamba

H.2 The role of pH and vapor drift

Considering the chemistry of dicamba and the VaporGrip technology, it is clear that pH also plays a role in the volatilization of dicamba from a treated field. Dicamba has a pKa of 1.87 and is governed by the typical acid-base equilibrium of a weak carboxylic acid. As the pH of a formulation shifts away from the pKa of dicamba and towards higher pH levels, more of dicamba is dissociated and only a very small fraction of dicamba is in the free acid form, which is the volatile form of dicamba. For a pH of 5.0, only 0.1% of the dicamba is in the free acid form. Most dicamba products are formulated as dicamba salts of organic amines. These salts when dissolved in water dissociate into dicamba anion and counterion which is invariably an organic ammonium cation. The dicamba anion can combine with any available proton (H+) in solution to form the volatile dicamba acid.²

The ability to maintain the pH above levels where dicamba acid forms is critical in controlling dicamba volatility potential from that formulation and any other additives added to the spray solution to be applied. The VaporGrip Technology (used in the Xtendimax formulation) uses a buffering agent to help maintain the pH of a solution to reduce the vapor pressure of dicamba and prevent the movement of dicamba from treated fields. **Figure H.2** provides a comparison of the vapor pressures of pure dicamba and that of dicamba in Xtendimax.²

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Figure H.2. Comparison of Vapor Pressures for Pure Dicamba and Xtendimax

However, several studies (discussed below) have been submitted to the Agency to indicate that the addition of glyphosate to dicamba products may be lowering the pH and increasing the volatility of dicamba.

H.2.2 Dupont Trials

Dupont conducted a number of trials in 2016 and 2017 evaluating the effects to volatility of adding glyphosate FeXapan (DuPont's dicamba product). In a set of humidome trials, different formulations of dicamba, applied alone, with different formulations of glyphosate, and with combinations of glyphosate plus other herbicides, were dispersed in water. Dicamba was applied at a rate of 1120 g ae/ha (1 lb ae/A), using different product formulations along with different formulations of glyphosate applied at 2240 g ae/ha (2 lb ae/A). The resulting water solutions were sprayed through a flat fan nozzle in a laboratory sprayer at a water spray volume of 93.5 L/ha onto soil spread evenly, 1-cm deep, in a 26 cm by 52 cm plastic tray. Trays containing herbicide-treated soil were immediately covered with plastic domes that contained an exit portal suitable for a glass tube filled with a polyurethane foam filter. Covered trays, containing herbicide-treated soil and glass tubes, were incubated in a growth chamber set at 35°C (95 °F) and 40% relative humidity with a 14-hr light cycle of 150 µmol/m2 of light for 24 hours. During the 24-hr incubation, air was pulled over the treated soil and through the polyurethane foam filter at a rate of 2 L/min. Dicamba was then extracted from the foam filters

and was quantified via liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) analysis. Results of the trials are provided in **Table H.1**. Volatility appears to decrease from Banvel to Clarity to FeXapan, but then increases with the addition of different forms of glyphosate. Flux rates were estimated by the reviewer by dividing the mass in the filter by the area of the tray (26 cm by 52 cm) and the duration of the trial (24 hours). The 24-hour average flux rates for FeXapan with glyphosate are comparable to those estimated for the field volatility studies provided in **Figure 1** in **Section 4** above.

Herbicide products applied	Mass per filter (µg)	24-hour Average Flux (μg/m ² -s)	Number of samples
Banvel	23.8 ± 4.2	2.04E-03	9
Clarity	0.42 ± 0.25	3.60E-05	18
FeXapan	0.04 ± 0.02	3.42E-06	18
FeXapan+Durango (DMA salt of glyphosate)	6.77 ± 1.67	5.80E-04	9
FeXapan+Honcho (IPA salt of glyphosate)	7.4 ± 2.36	6.33E-04	9
FeXapan+RoundUp Powermax (K salt of glyphosate)	4.28 ± 1.03	3.66E-04	18
M-1768 (premix dicamba+glyphosate+Vaporgrip)	0.19 ± 1.11	1.63E-05	9

Table H.1. Comparison of the Volatility of Various Dicamba Products, V	Nith and V	Nithout
Glyphosate		

In a second set of humidome trials, the volatility of XtendiMax with VaporGrip (Dicamba DGA) and tank mixtures with Round Up PowerMax (potassium salt glyphosate), Durango DMA (dimethylamine salt glyphosate), Intact Xtra, K₂PO₄, and ammonium sulfate (AMS) were evaluated. Applications of dicamba were made at 560 g ae/ha (0.5 lb ae/A). Volatility chamber experiments (0.9 cm thick acrylic with outside dimensions of 51 x 26 x 39 cm in length, width and height, respectively) were used, where the temperature and relative humidity were controlled for up to 96 h. Air sampling tubes were connected to 0.64 cm diameter tubing placed through the volatility chamber cover. A centralized source supplied a vacuum calibrated to 1 L/min with air flow valves. Sampling tubes were changed out at 24, 48, 72 and 96 h after herbicide application and the acid of dicamba were quantified via LC/MS/MS. **Figure H.3** presents some of the results. More dicamba is released as the pH decreases. It also appears that when Intact is used, some of the impact of glyphosate on reducing pH is suppressed. Also, as discussed earlier, as the pH drops below 5, the amount of dicamba that is released increases significantly (3-10x). It should be noted that the addition of AMS to Xtendimax (the second bar from the left in **Figure H.3**) in a tank mix is prohibited on the label.



Figure H.3. Comparison of Volatility and pH for Various Xtendimax Mixtures

H.2.3 Norsworthy Trials

In the summer of 2018, Dr. Norsworthy from the University of Arkansas conducted low tunnel tests to assess the relative volatility of dicamba products in the field. Soil placed in trays was treated with various dicamba products at 2 lbs ae/A (4x the maximum label rate), with and without glyphosate added to the tank mix. Treated soil trays were then inserted into a tunnel which enclosed two rows of non-dicamba tolerant soybean plants. Soybean plants were in the V2 to V6 growth stage. After 48 hours, the tunnels and treated soil trays were removed and the soybean plants were monitored for visual injury 26 days after application. **Figure H.4** depicts the results. Visual injury increases for Engenia when glyphosate (Roundup Powermax) is added to the product mixture. A similar analysis for how the visual injury changes for Xtendimax with and without glyphosate was done in September 2018, but the results are not available. Additionally, as part of the study the pH of the solutions was also tested before and after application. The results are provided in **Figure H.5**. From the figure, the pH of Xtendimax alone is roughly 5.5 before and after application. But with the addition of glyphosate, the pH drops to around 5, allowing for more of the dicamba free acid to form.

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Figure H.4. Visual Injury of Soybeans to Various Dicamba Mixtures



Figure H.5. Impact of Roundup Addition to Xtendimax on pH

Lastly, referring to **Figure 5** (Section 4.1.1), the total emissions from a field treated with Xtendimax (the top two bars in the figure) are lower than all of those where glyphosate (Roundup) is added to the tank mix.

H.3 Summary and Data Needs (Temperature and pH)

In summary, volatility is an exposure component of most field study plant responses, as seen in the large and small field trials. Temperature, in theory, influences the vapor pressure of dicamba and therefore volatility. Additionally, data evaluating the role of temperature while controlling other variables could inform potential mitigation practices. The pH of the tank mix solution has the potential to alter the extent of volatility as well, with decreasing pH resulting in increasing volatility. As a result, given the same environmental conditions, if the pH of the tank mixture drops below 5, increased volatility is likely to occur and plant responses to dicamba secondary drift are likely to extend over longer distances. Additional data examining the approved tank mix partners and how they impact the pH of the product would allow EPA to evaluate if this is occurring. Testing tank mix partners and including a series of waters designed to mimic the variety of water pH throughout the country, particularly in areas with the largest number of incidents, would inform this uncertainty.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

DATE:	November 1,	2018
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SUBJECT:Transmittal of "Over-the-Top Dicamba Products for Genetically ModifiedCotton and Soybeans: Benefits and Impacts"

FROM:Wynne Miller, DirectorBiological and Economic Analysis Division (7503P)Office of Pesticide Programs (OPP)

TO: Michael Goodis, Director Registration Division (7504P) Office of Pesticide Programs (OPP)

As finalized on October 31, 2018, please find attached the final document entitled, "Over-the-Top Dicamba Products for Genetically Modified Cotton and Soybeans: Benefits and Impacts."

Attachment

OVER-THE-TOP DICAMBA PRODUCTS FOR GENETICALLY MODIFIED COTTON AND SOYBEANS: BENEFITS AND IMPACTS

October 31, 2018

Prepared by

OFFICE OF PESTICIDE PROGRAMS

U.S. Environmental Protection Agency 1200 Pennsylvania Ave., NW Washington, DC 20460

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EXECUTIVE SUMMARY

The Agency is considering extending the registrations of three over-the-top (OTT) dicamba products for use on dicamba-tolerant (DT) cotton and soybean. In this document, the Agency reviewed the potential benefits of these products to growers and the potential impacts to non-users from this regulatory action. For this benefits analysis, the baseline is the pre-2016 status of dicamba (i.e., when OTT uses were not registered for DT soybean and cotton). When comparing the baseline against an amended registration in which OTT uses are available for DT cotton and soybean, the Agency finds the following overall benefits for OTT dicamba:

- It provides growers with an additional postemergence active ingredient to manage difficult to control broadleaf weeds during the crop growing season, particularly for those situations where herbicide-resistant biotypes such as glyphosate-Palmer amaranth may occur (and relatively few alternatives are available).
- It provides a long-term benefit as a tool to delay the evolution of resistance of other herbicides when used as part of a season-long weed management program that includes preemergence (residual) and postemergence (foliar) herbicides (along with rotations between different mechanisms of action).

Additionally, as in the case of other genetically modified herbicide resistant varieties (i.e., glyphosate, glufosinate, and 2,4-D), the use of the OTT herbicide partner may reduce the management complexity associated with pre-selecting an effective postemergence herbicide with little to no risk of damage to the treated crop. However, repeated uses to control Palmer amaranth, or herbicide-resistant weeds, may increase selection pressure for the evolution of dicamba-resistant weeds.

In 2017 and 2018, there have been a record number of complaints alleging damage from off-target dicamba movement reported to the Agency by the registrants under FIFRA Section 6(a)2, by individual growers, and by State regulatory partners. Other reports have been published in the extension reports, agricultural news media, and the scientific literature. By using these reports, the potential impacts to non-users from the 2018 extension of the registration of the OTT dicamba products can be described, as informed by anecdotal evidence. The OTT dicamba labels mention hundreds of crops that are susceptible or sensitive to low levels of dicamba. These plants include non-DT soybeans and cotton, all fruiting vegetables, all fruit trees, all cucurbits, grapes, beans, flowers and ornamentals, peas, potatoes, sunflower, tobacco, and other broadleaf plants. The labels also list about 250 weeds – annual and perennial broadleaf plants and trees – that are controlled by dicamba, some of which are desirable in non-crop settings. These plants could potentially be impacted by off-target drift of dicamba. Damage for these sensitive plants could range from superficial visual symptomology to yield loss and/or plant death.

The Agency has considered label language changes, clarifying use instructions, and revised terms of registration for OTT dicamba products for 2019 and 2020, which are intended to continue to further minimize the potential for off-target movement.

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INTRODUCTION

Purpose

To inform the regulatory decision, this document examines the potential benefits to growers and impacts to non-dicamba users of the extension of the registration of dicamba products for Over-the-Top (OTT) use on dicamba-tolerant (DT) cotton and soybean. The baseline for the analysis of the benefits and impacts is the pre-2016 status of dicamba. In other words, it is the scenario where OTT dicamba is not registered. The Agency's analysis of benefits primarily evaluated the benefit claims made by the registrants. Finally, potential impacts to non-users are described based on stakeholder letters, reports from State regulatory partners, and/or published literature.

BACKGROUND

Dicamba is a widely used herbicide on agricultural crops, fallow land, pastures, turfgrass, and rangeland. Dicamba is a benzoic acid that acts similarly to an endogenous auxin (indole acetic acid) (WSSA, 2014) by affecting cell wall plasticity and nucleic acid metabolism. It is classified by the Weed Science Society of America (WSSA) as a Group 4 Mechanism of Action (MOA¹). At high concentrations it inhibits cell division, growth in meristematic regions (areas where cells are dividing) and stimulates ethylene biosynthesis. Dicamba is used for control of emerged broadleaf weeds and provides some residual control of germinating weeds (WSSA, 2014).

Regulatory History

Dicamba (Banvel, dimethylamine salt) was first registered in the U.S. in 1967. Subsequently, different salts of dicamba have been registered that have lower volatility than the first dicamba product. These lower volatility salts include Banvel II (sodium salt) in 1981 and Clarity (diglycolamine salt) in 1990 (Hartzler, 2017).

Historically, most dicamba applications occurred in late winter or early spring for preplant or fallow removal of broadleaf vegetation prior to planting crops. Prior to the registration of OTT dicamba on soybeans and cotton, about 35 million acres of agricultural land were treated annually with 6 million pounds of dicamba (5-yr average; MRD 2012-2016). Field corn and winter and spring wheat were the agricultural use sites with the largest number of acres treated with dicamba with an average of 19.8 million total acres treated [TAT] per year (MRD, 2012-2016). Other use sites with substantial use from 2012-2016 include cotton, fallow land, pasture land, sorghum, and soybeans (preplant only).

The United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) regulates the planting, importation, or transportation of GM plants pursuant to its authority under the Plant Protection Act (PPA). By regulation, APHIS classifies most GM plants as plant pests or potential plant pests and as "regulated articles." Under the PPA, a regulated article

¹ MOA is the mechanism in the plant that the herbicide detrimentally affects so that the plant succumbs to the herbicide; e.g., inhibition of an enzyme that is vital to plant growth or the inability of a plant to metabolize the herbicide before it has done damage (Vencill et.al., 2012). Repeated and intensive use of herbicides with the same mechanisms of action can lead to the selection of herbicide resistant weeds.

must receive prior approval from APHIS before it is introduced. The USDA announced the deregulation of dicamba-tolerant (DT) soybean and cotton seed (USDA, 2015) prior to the registration of the OTT herbicide partner. The DT cotton and soybean seed was immediately marketed, and about 1.7 million acres of DT soybeans (~2 percent of total soybean acres) and less than 50,000 acres of DT cotton (less than 1 percent of total cotton acres) were planted in 2016 (MRD, 2016). During the 2016 growing season, there were no registered dicamba products for OTT application to these crops, as review of the GM crop and associated pesticide are regulated by separate agencies under two different laws and timeframes (PPA and FIFRA).

In late 2016 and early 2017, the Agency registered the three new, lower volatility OTT dicamba products (EPA, 2016a; 2016b; 2017a) for use on genetically modified (GM) DT cotton and soybean plants. The three OTT dicamba products included Xtendimax® with VaporGrip® Technology (diglycolamine salt; Monsanto, now Bayer), Fexapan® with VaporGrip® Technology (diglycolamine salt; DuPont, now Corteva) and Engenia® (bis aminopropyl methylamine or BAPMA salt; BASF). All three registrations are time-limited and will automatically expire after two years unless they are extended – with XtendimaxTM and FexapanTM expiring on November 9, 2018 and EngeniaTM expiring on December 20, 2018. In 2016, the Agency found that the main benefit of postemergence OTT dicamba applications was that it provided DT soybean and cotton growers with another active ingredient to manage difficult to control broadleaf weeds during the crop growing season, especially glyphosate-resistant weeds (Yourman and Chism, 2016).

The average annual amount of dicamba applied to cotton and soybeans from 2012-2016 was 231,000 pounds acid equivalent (a.e.) and 537,000 pounds a.e., respectively. In 2017, following the registration of OTT dicamba products, the total amount (including preemergence and postemergence use) applied to cotton and soybean increased by approximately 6-fold to nearly 2 million pounds a.e. in cotton and to nearly 8 million pounds in soybean (MRD, 2016; USDA, 2017a). Data for the 2018 use season are not yet available, but it is expected that significantly more dicamba was used.

In 2017, EPA worked with state lead agencies, USDA, and pesticide registrants to implement label changes for the 2018 use season that would address some of the postulated causes for off-target dicamba movement. The registrants voluntarily agreed to label changes that imposed additional requirements for the OTT use of these products in 2018, including:

- Classifying these products as restricted use;
- Requiring dicamba-specific training for all certified applicators;
- Requiring growers to maintain specific records regarding the use of these products to improve compliance with label restrictions;
- Limiting applications to when maximum wind speeds are not greater than 10 mph (from 15 mph) to reduce potential spray drift;
- Reducing the times during the day when applications can occur (sunrise to sunset);
- Including tank clean-out language (directions) to prevent cross contamination; and

• Enhancing susceptible crop language and record keeping with sensitive crop (any plant that can be damaged by low levels of dicamba) registries to increase awareness of risk to especially sensitive crops nearby.

The current regulatory action being considered by the Agency is the extension of OTT dicamba product registrations for two years.

Broadleaf Weed Control in Cotton and Soybeans

There are two basic weed control systems for broadleaf weed control in soybeans and cotton. The first system involves conventional varieties of soybean and cotton that have not been genetically modified to survive applications of broad-spectrum herbicides. In conventional systems, broadleaf weeds are controlled with preemergence herbicides that can be applied either before or after the crop emerges to prevent weeds from emerging. Additionally, growers control emerged broadleaf weeds with postemergence herbicides applied OTT or are applied with directed- or hooded-sprayers because the herbicide cannot be applied OTT of the crops. The second system, which represents 94 percent of the acreage in cotton and soybean (USDA, 2018a), involves the use of soybean and cotton varieties that are genetically modified (GM) to tolerate broad-spectrum herbicide applications for weed control OTT of the actively growing crop. The OTT herbicide applications target emerged weeds; however, pre- and postemergence herbicides used on conventional varieties can be used in GM systems.

Incidents Alleging Crop Damage from Off-Target Movement of Dicamba

EPA defines a pesticide incident as any exposure or effect from a pesticide's use that is not expected or intended (EPA, 2017b). Incident reports may include only an allegation of damage resulting from a particular active ingredient or product. Under FIFRA §26, states have primary enforcement responsibilities for pesticide use violations. FIFRA allows states wide latitude to apply their own authorities to regulate pesticides. States also have the authority to investigate pesticide incidents, including potential misuse, drift, and off-target impacts. Alleged dicamba damage may be confirmed by state agencies through visual investigations, examination of spray records, and/or laboratory analysis. EPA does not have complete information on, out of the number of alleged incidents, the number that have been confirmed to involve dicamba as many investigations are ongoing or inconclusive. However, in some states, such as Iowa and Indiana, a high percentage of alleged incidents have been confirmed.

Uncertainties

The data provided by the Association of American Pesticide Control Officials (AAPCO, 2018) did not specify which states performed on-site investigations of the complaints, how many of those incidents were investigated, the conclusions of those investigations, the acreage of the crops actually damaged by off-target movement, or ultimate impact to crop yield. The number of confirmed incidents may not accurately represent the extent of OTT dicamba-related damage to non-target plants. Incidents may be under- or over-reported. For example, the number of alleged damage due to OTT dicamba might be over-reported because there may be a propensity to attribute any crop damage to OTT dicamba when, in fact, the damage to plants was not from OTT dicamba (Monsanto, 2018a). Specifically, other potential sources of off-target dicamba movement – such as corn, small grains, and pasture – are also located near the crops where the incidents alleging damage from dicamba occurred. Because this type of symptomology could have been occurring for years without being widely recognized or understood until recently, the AAPCO data on alleged incidents could represent an over-reporting of actual damage by OTT dicamba on soybeans and cotton.

Conversely, members of AAPCO and others have indicated that the number of incidents of alleged dicamba-related damage are lower than the actual incidents observed (Smith, 2018; Baldwin, undated; AAPCO and EPA Recurring Call, 2018). The reasons for this include: damage from drift is not covered by crop insurance; maintaining good relationships with neighbors; fear that the crop will be considered adulterated and cannot be sold; fear that the grower will lose their organic certification; and grower perception that no action will be taken.

Another limitation is that incidents do not indicate the total number of acres impacted. Accordingly, even if there were a relatively high amount of incident reports, some have alleged that a relatively small number of acres could have been impacted. (Monsanto, 2018a).

Reports of visual crop damage may not equate to crop yield loss. Therefore, because this information is not collected, EPA is not able to ascertain the true impact of these incident reports to actual crop yield loss.

Additional Uncertainties Include:

- Most laboratories are not able to differentiate between the formulations of dicamba whether older formulations or the newer OTT formulations with current residue methods. However, investigators can determine the product used by examining spray records.
- The mechanisms of off-target movement of dicamba are sometimes not determinable. For example, the Office of the Indiana State Chemist concluded that the mechanism of off-target movement was undeterminable in 74 percent of the incidents (Office of the Indiana State Chemist, 2018b).
- While dicamba damage can easily be determined by the investigator because of the unique symptomology to sensitive, non-target plants, in many incidents state investigators are not able to determine the precise source causing the dicamba damage.
- Visual symptomology from dicamba, regardless of formulation, is distinctly identifiable (cupping on newly emerged leaves) in sensitive plants and it takes 5-10 days to appear (Cornell, undated). Thus, there is a lag between the application date and date the incident is reported and investigated by the state lead agency. Furthermore, there is also a lag time between the date when the state agency receives the information and the date the information was reported.

Number of Incidents Alleging Damage from Off-Target Movement of Dicamba

From 2010 to 2015, the Agency received no more than 40 dicamba incident reports in a single year under the Adverse Effects Reporting in Section 6(a)(2) of FIFRA, which requires registrants to submit information about adverse effects. In 2016, the Agency received information from registrants on 118 alleged incidents involving dicamba. In 2017, the Agency received information from from registrants on 2,622 alleged incidents involving dicamba.

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In 2017 and 2018, state lead agencies reported a substantial increase in the number of alleged incidents of crop damage from off-target movement of dicamba (AAPCO, 2018; Missouri Department of Agriculture, 2018; Office of the Indiana State Chemist, 2017, 2018; Iowa Department of Agriculture and Land Stewardship, 2017). In 2017, state lead agencies conducted about 2,700 investigations of incidents alleging crop damage from off-target movement of dicamba (Bradley, 2017). In 2018, state lead agencies continued to receive reports and investigate incidents of alleged crop damage, which were fewer in number than 2017. Approximately 1,400 OTT dicamba-related incidents were reported to AAPCO as of September 6, 2018 (AAPCO, 2018). The sensitive crops identified in these alleged incidents include fruit trees, pecans, tomatoes, private gardens, non-dicamba tolerant soybeans, berries, grapes, potatoes, cucumbers, cypress trees, tobacco, and damage to vegetation involved in honey production.

Potential Causes of Alleged Incidents

There is a lack of consensus regarding the specific causes of off-target movement of dicamba, which formulation of dicamba is potentially moving off-target, and its potential damage to sensitive crops or plants. State lead agencies indicate that incidents may be due to misuse (e.g., not following the label or use of an older more volatile formulation)², particle drift from adjacent crops or sites, temperature inversions, tank contamination (e.g., dicamba was not completely removed from the spray equipment and is sprayed on the next field at a lower concentration), or volatility (the dicamba was applied and then moved off the treated area after the application process was completed).³ It is important to note that the older, registered formulations of dicamba:

- Can be used on dozens of use sites, including corn, small grains, and pasture land;
- Have increased in usage in recent years (Monsanto, 2018a);
- Are not restricted use pesticides and can be applied by anyone;
- Have no requirements for training to teach applicators how to minimize off-target movement;
- Are generally higher in volatility and drift potential;
- Can be tank mixed with any compatible product, which may further increase volatility and drift potential;
- Need not be used with a drift reduction agent, although one is recommended;
- Can be applied without any buffer to minimize downwind off-target movement;
- Can be applied using many nozzle-types rather than being restricted only to nozzle types that minimize drift potential;
- Can be applied between sunset and sunrise, when temperature inversions are more likely to occur;

² Older formulations of dicamba are not registered for use on DT cotton or soybean crops for post-emergence (OTT) use on DT cotton or soybean crops and is inconsistent with the pesticide's labeling and a violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

³ For example, in a study conducted in Michigan, one academic researcher found that "[s]ome of these instances occurred because applicators took some of the label restrictions too lightly and did not follow the label when making applications. Some of these violations included not using the correct nozzles, spraying in too high of winds or during temperature inversions, not following the buffer requirements or tank mixture restrictions, and spraying when the wind was blowing toward susceptible crops. Improper sprayer and tank cleanout also lead to damage of susceptible crops. Other instances included dicamba movement in runoff waters following heavy rains and in some instances off-target movement could not easily be explained, leading some to believe dicamba volatility was occurring." (Sprague, 2017a)

- Can be applied aerially during high wind events; and
- Are not subject to any reporting or recordkeeping requirements.

Volatility is the tendency of a substance to vaporize, or change from a liquid to a gas or vapor. Because the older formulations of dicamba are more likely to volatilize and move off-target, older products of dicamba are not labeled for OTT use and OTT applications are not allowed. In general, environmental conditions during the hours or days after application, such as high temperatures, can increase the likelihood of volatilization (Dow AgroSciences, 2014) and subsequent movement offfield (Iowa State University, 2017); therefore; volatility and subsequent off-target movement can occur even when a volatile chemical is applied in accordance with the label. Newer formulations of dicamba are designed to be less volatile.

Every OTT dicamba product has been implicated in a couple of the states' investigations as having caused off-target damage. Specifically, confirmed dicamba investigations in Indiana found that in 2017, Engenia was identified in 45 percent of the incidents, Xtendimax in 40 percent, FeXapan in 7 percent, and some other dicamba products in 8 percent (Office of the Indiana State Chemist [OISC], 2018). In Indiana in 2018, Engenia was identified in 66 percent of incidents, Xtendimax in 19 percent, FeXapan in 3 percent, and other dicamba products in 11 percent (Office of the Indiana State Chemist, 2018). For 2017, the Indiana State Chemist made the following findings about the cause of off-target movement or damage: 4 percent was attributable to tank contamination; 23 percent was related to direct particle drift; and 74 percent was not attributable to a specific mechanism of movement. In the vast majority of 2017 investigations, the Indiana State Chemist determined that there were label violations. The Indiana State Chemist found that 95 percent of the incidents involved documented label violations (the total percentages of all violations exceed 95 percent because many incidents included more than one violation. It is important to note that a documented label violation does not necessarily indicate the specific reason for off-target movement. In 2017, OISC indicates the following proportions of incidents with label violations: 46 percent for wind blowing toward adjacent sensitive crops; 2 percent for failure to maintain a 110foot buffer; 8 percent for applying with a wind speed less than 3 mph; 4 percent for applying with a wind speed (or gusts) greater than 15 mph; 1 percent applied when rain was forecasted within 24 hours; 7 percent did not have a site survey; 71 percent did not visit the appropriate websites; and 1 percent exceeded boom height.

Similarly, in 2017, the Iowa Department of Agriculture and Land Stewardship (2017) received 131 complaints of alleged damage from growth regulator herbicides (e.g. dicamba, 2,4-D) to off-target, sensitive crops. Dicamba applications were verified in 117 investigations (89 percent). Of the 117 investigations with confirmed dicamba applications, 88 investigations included OTT applications of dicamba to soybean (Iowa Department of Agriculture and Land Stewardship, 2018). Therefore, 67 percent of alleged damage complaints from auxin herbicides were confirmed to be from OTT dicamba and all OTT formulations were identified as having been used in these incidents (Iowa Department of Agriculture and Land Stewardship, 2018).

Timing of Incidents

In 2017, EPA received the first incident reports alleging crop damage from off-target movement of dicamba in May and June (EPA, 2017c). In 2018, the first incidents alleging crop damage from off-target movement of dicamba were reported in Tennessee and Iowa during the week of May 21, 2018 (AAPCO, 2018). The number of incidents alleging dicamba damage continued to rise steadily throughout June and July, with most incidents reported in late-June, July, and August (AAPCO, 2018).

POTENTIAL LABEL LANGUAGE FOR THE 2019 USE SEASON

FIFRA Label Content

The Agency has considered label language changes and revised terms of registration for OTT dicamba products beginning in 2019, which are intended to address the recent incidents alleging off-target movement and to clarify the use instructions. See EPA's 2018 Amended Registration Decision for dicamba for a more extensive list and discussion. The primary changes to the use pattern include the following:

- Use would be limited to only commercial and private certified applicators and labels would not allow individuals under their supervision to use these products.
- For cotton, the maximum number of OTT applications would decrease from four to two applications and the last application must be made not later than 60 days after planting cotton.
- In soybeans, two applications would be allowed and the last OTT application must be made not later than 45 days after planting soybeans.
- To avoid times of day when temperature inversions are most likely to occur and dicamba can be carried off-target, applications would be required to be made only from 1 hour after sunrise until 2 hours before sunset.

Endangered Species Act Label Content

In addition to the FIFRA label changes noted earlier and to make a no-effects finding under the Endangered Species Act (ESA), the EPA plans to establish buffers to protect endangered species that may be near an application site, and, therefore, susceptible to off-target movement of dicamba. As noted in the EPA's 2018 "Registration Decision for the Continuation of Uses of Dicamba on Dicamba Tolerant Cotton and Soybean," EPA concluded that new information supported the need for an additional in-field 57-foot omnidirectional buffer in areas where listed dicot plant species are present to support the previous No Effect calls. For the new OTT dicamba labels, EPA will add an omnidirectional buffer of 57 feet in addition to the downwind buffer in counties where endangered species are present. The previously approved label contains a 110-foot downwind buffer will be retained.

BENEFITS

This section presents information on the benefits and usage of dicamba as a postemergence or 'over the top' application (OTT dicamba) to cotton and soybean. It discusses the benefits of an additional herbicide for growers of DT soybean and cotton. Conceptually, the benefits of the use by the grower of OTT dicamba to control broadleaf weeds, specifically those with glyphosate-resistance, can be described as improvements in yields and/or decreases in costs of production in comparison to alternative measures to control weeds after the crops have emerged. Costs are considered broadly. In addition to direct monetary benefits, use of OTT dicamba could result in less tangible savings, such as a reduction in management effort, or savings over time, such as decreasing the potential for resistance developing to other herbicides.

The unit of analysis for this assessment is an acre of cotton or soybean treated with OTT dicamba. This is an appropriate unit of analysis since it reflects the benefits to an individual grower. It is similar in scale to the risk assessments EPA conducts, for example, the risks to an individual treating a field with OTT dicamba or the risks to non-target organisms in areas adjacent to a field treated with OTT dicamba. EPA first identifies the primary pest or pests that growers target with OTT dicamba and then identifies alternative control measures, in this case, measures used prior to the registration of OTT dicamba. EPA then discusses the benefits that may accrue to a grower using OTT dicamba. This discussion is largely qualitative; given the recent registration, data on yield effects and costs of using OTT dicamba are preliminary or not yet available.

To the extent that quantitative estimates of benefits can be made per acre, EPA could extrapolate those estimates to the national level by multiplying the per-acre benefits by the estimated acres treated with OTT dicamba. If there are substantial changes in total output of cotton or soybean as a result of increased yields and/or cheaper production, there could be a decrease in the price of a commodity. If that were to happen, consumers of cotton and soybean products would benefit while benefits accruing to producers, as a whole, could decrease.

Potential Benefits Identified in the 2016 Registration Decision

In 2016, the Agency reviewed the benefits of the registration of OTT dicamba products for genetically modified DT cotton and soybean. The registration of new OTT dicamba products would provide postemergence (foliar) control of a wide range of annual and perennial broadleaf weeds. In particular, OTT dicamba would benefit growers targeting glyphosate-resistant broadleaf weeds, including Palmer amaranth, for which there are few available herbicides. Older dicamba products could be used prior to emergence of cotton and soybeans but could not be broadcast over the top of the crops while they were actively growing. With the addition of the dicamba resistance trait to cotton and soybeans, the new products could be applied OTT of the crop when the crop and weeds are actively growing.

2016 Registrant Claims

In 2016, Monsanto described the potential benefits of a postemergence dicamba product for use on dicamba-tolerant (DT) cotton and soybean (Monsanto, 2015). Monsanto (now Bayer) made the following claims of benefits: (1) A postemergence application of dicamba on DT crops during the growing season would help to control glyphosate-resistant weeds (14 species in the U.S.) by adding another mechanism of action (MOA) to reduce the chance that further herbicide-resistant weeds will survive and reproduce; (2) New formulations of dicamba would be a useful tool for resistance management, because dicamba has been used for over 50 years on numerous crops, with both preemergence and postemergence applications to grass crops, with little weed resistance; (3) The product label would indicate a type of nozzle that will limit drift onto non-target crops. The proposed labels included additional restrictions to reduce drift, including wind speed and direction,

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spray volume, equipment ground speed and boom height, and temperature inversions; and (4) The use of dicamba would "provide environmental and economic benefits by enabling the continued use of reduced tillage agronomic practices and reducing the input required for farmers to produce a successful crop." (Monsanto, 2015)

2016 EPA Analysis

Because this was a new use registration, the Agency's 2016 benefits assessment reviewed the potential benefits as described by Monsanto because they were the primary source of current information to describe the value of this new product. In 2016, the Agency found that the main benefit of postemergence OTT dicamba applications was that it provided DT soybean and cotton growers with another active ingredient to manage difficult to control broadleaf weeds during the crop growing season, especially glyphosate-resistant weeds (Yourman and Chism, 2016). Prior to this registration, dicamba could only be used as a preplant broadcast treatment to control emerged weeds in cotton or soybean. As for the remaining three benefits claims, the Agency concluded that there was some weed resistance to dicamba as there were two dicamba-resistant biotypes in the U.S., Kochia and prickly lettuce across millions of acres of soybean and cotton. Monsanto did not provide data for the claim that OTT dicamba alone would allow "continued use of reduced tillage". The Agency considers this practice to be dependent on crop varieties, specific agricultural equipment, and herbicide programs (using multiple active ingredients).

The 2016 EPA benefits assessment also discussed potential impacts. The assessment (Yourman and Chism, 2016) noted that "an increased number of applications of dicamba to large acreage may increase the likelihood of off-target damage to surrounding sensitive plants through drift and/or volatility.... Mitigation through label restrictions of wind speed, droplet size, buffers, etc. should reduce the chance of off-[target] damage."

Benefits of Registration of OTT Dicamba Products for Use in 2019 and 2020

Stakeholder Letters

EPA received a variety of comments from the public concerning the registered uses for dicamba OTT of DT cotton and soybeans. The feedback EPA received included comments both in favor of and opposed to the continued registration of dicamba OTT uses on DT cotton and soybeans is addressed in the registration decision document.

One specific comment indicated that the alternative, glufosinate, has limitations. According to the Cotton Foundation, glufosinate "is not as effective nor as reliable as the labeled auxin herbicides [2,4-D and dicamba]. Under cool temperatures at planting in some areas, the product does not provide effective control. Additionally, the larger the pigweed plants become the control provided by glufosinate decreases and becomes more erratic" (Cotton Foundation, 2018). The Cotton Foundation also stated that pigweed could not be controlled without the auxin products and that additional applications of alternative herbicides "would not provide effective control and would put extreme selection for resistant weeds."
The Agency found research suggesting that control of Palmer amaranth (a type of pigweed) with glufosinate provides similar weed control compared to dicamba (Peterson et al., 2017); other research suggests that glufosinate does not control large Palmer amaranth or provide acceptable control in cool, cloudy conditions (Ohio State University, 2017). Additionally, there are reports that dicamba does not provide adequate control (less than 60 percent control) of protoporphyrinogen oxidase (PPO)/glyphosate-resistant Palmer amaranth (Steckel, 2017). Because there are conflicting data, the Agency assumes there are situations where dicamba may perform better than glufosinate and vice versa; however, the Agency does not have information about which scenario is the most common. Based on published research the Agency expects that 2,4-D, as another auxin herbicide, would have similar performance as dicamba (Miller and Norsworthy, 2016).

Potential Benefits According to the Registrant

The Agency received descriptions of benefits of OTT dicamba applications from Bayer (2018) and BASF (2018) that were similar to those in 2016. The registrants' stated benefits are: (1) there is a need for diversified weed management in cotton and soybean because there are few alternatives and some herbicides may cause crop injury; (2) OTT dicamba controls herbicide resistant weeds and will be useful for preventing or delaying resistance; (3) dicamba is a crucial to maintaining conservation tillage programs that reduce erosion, nutrient, and pesticide runoff; and (4) dicamba provides economic benefits of reducing growers losses due to weeds.

EPA Review of Registrant-Stated Potential Benefits in Cotton and Soybean

(1) Potential benefit of providing another herbicide for weed control. The Agency finds that the registration of OTT dicamba will provide growers of DT soybean and cotton with an additional active ingredient (a.i.) to manage difficult to control broadleaf weeds during the crop growing season. In cases where there are herbicide-resistant weeds, the Agency finds there are few herbicides available for users (see Alternatives for Season Long Control).

Alternatives for Season Long Control

For GM herbicide-resistant soybeans and cotton, there are four herbicides that can be used OTT without negatively affecting the crop. These are dicamba and 2,4-D (which control broadleaf weeds), and glyphosate and glufosinate which are non-selective, i.e., they control broadleaf and grass weeds. In all cases, the grower must use seed that is genetically modified to be resistant to one or more of the OTT herbicides. Therefore, there are other herbicide-resistant varieties (2,4-D, glufosinate and glyphosate) that are similar to DT varieties. The majority of soybean and cotton acres grown (94 percent of acres of both crops in 2018) use herbicide-resistant GM varieties (USDA, 2018a).

Palmer amaranth was selected as a case study because it has several characteristics that have led to Palmer amaranth being one of the most difficult weeds to control in the U.S. (Van Wychen, 2016a) and is a primary target weed by dicamba (MRD, 2012-2016). For instance, it has developed resistance to 6 different MOA groups (Heap, 2018). Not only does it have a high reproductive potential, with the ability to produce over 460,000 seeds per plant (Sosnoskie, et.al., 2014), it also has high water use-efficiency, a long germination window (March through September), and a rapid growth rate (more than 2 to 3 inches per day under optimum growth conditions) (Crow et al., 2016).

In addition, Palmer amaranth must be controlled all season long because it can compete with crops for nutrients, sunlight and water, and interfere with harvesting the crop. Rowland et al. (1999) showed that season long competition of Palmer amaranth in a meter of row of cotton can reduce yield by an average of 9 percent (range 6-11.5 percent) per weed until the density of weeds exceeds 8 plants per meter of row, at which point intraspecific competition occurred and cotton yield losses were less pronounced when compared to cotton with no Palmer amaranth. A 2013 survey estimates that glyphosate resistant Palmer amaranth has cost soybean producers millions of dollars in the midsouth because of increased production costs such as hand weeding, which costs approximately \$24/acre (Riar et al., 2013).

OTT dicamba product labels list preemergence and postemergence control of weeds such as Palmer amaranth. The Agency recognizes that preemergence (residual soil activity) and postemergence (foliar activity) herbicides⁴ are an important component of a season-long weed management program. Preemergence herbicides (to the weed) prevent the emergence of Palmer amaranth, and if there are no emerged Palmer amaranth plants, there is no need for postemergence (to the weed) applications. However, there are circumstances where postemergence herbicides are important. For example, postemergence herbicides (to the crop and weed) may be needed if preemergence herbicides are not effective (e.g., insufficient moisture to activate, too much rainfall which moves herbicide away from weed seeds, and resistant biotypes) or if there are Palmer amaranth plants that escaped earlier control measures and need to be controlled.

Pesticide usage data indicate 9 postemergence herbicides (to the crop and weed, including directed sprays or applications with hooded sprayers) were used in 2012-2016 in cotton and 14 herbicides in soybean (MRD, 2012-2016) targeting all broadleaf weeds. Of these postemergence herbicides, 4 and 13 active ingredients were applied OTT without injuring the cotton and soybean, respectively (Table 1). Of the 13 OTT soybean herbicides, 3 are not recommended by extension publications; one was recommended as a tank mix partner only (University of Arkansas, 2018, Steckel, 2018; Sprague, 2017b; Flessner et al., 2016; Jhala, 2014), effectively leaving 9 OTT herbicides for soybean weed control.

Over-the-top alternatives are further reduced if a grower has herbicide-resistant biotypes such as Palmer amaranth. Based on pesticide usage data from 2012 to 2016, glufosinate was an herbicide that was commonly applied, but there were other options (acifluorfen, cloransulam-methyl, imazamox, and fluthiacet-methyl) recommended in at least one of the extension weed control guides reviewed for control of Palmer amaranth (University of Arkansas, 2018, Steckel, 2018;

⁴ The Agency identified 30 and 36 preemergence and postemergence active ingredients (including dicamba) (12 and 10 MOA) that are used to control Palmer amaranth in cotton and soybean, respectively, using pesticide usage data (MRD, 2012-2016), many of which are confirmed by university extension recommendations (University of Arkansas, 2018; Steckel, 2018; Flessner et al., 2016; Sprague, 2017b; Jhala, 2014; Mississippi State University, 2017; Marshall, 2017; McGinty, 2016). Preemergence herbicides (to the crop and/or weed) are critical and recommended components of a season-long Palmer amaranth control program (Marshall 2017, McGinty, 2016; EPA Reg. Nos. 524-617 [Xtendimax]; 524-617 [Engenia]; and 352-913 [Fexapan]) and numerous other broadleaf weeds as some provide residual control for up to four to eight weeks.

Sprague, 2017b). For both soybean and cotton, there is one other herbicide, 2,4-D, that provides similar control as dicamba when using a 2,4-D-resistant variety.

	WSSA	Documented	Total Area	Chemical Cost		
Active Ingredient	Group No.	Resistance ¹	Treated (acres) ²	(\$/acre)		
Cotton						
Pyrithiobac	2	Yes	376,000	15		
$2,4-D^3$	4	-	not labeled ⁴	14 ⁵		
dicamba ³	4	-	not labeled ⁴	12-13 ⁵		
glyphosate ³	9	Yes	1,511,000	5		
glufosinate ³	10	-	1,009,000	16		
MSMA ⁶	28	-	307,000	6		
other ⁷	-	-	231,000	-		
Soybean						
2,4-D ³	4	-	not labeled ⁴	14 ⁵		
dicamba ³	4	-	not labeled ⁴	12-13 ⁵		
glyphosate ³	9	Yes	1,190,00	5		
glufosinate ³	10	-	810,000	16		
fomesafen	14	Yes	1,510,000	6		
other ⁸	_	-	549,000	-		

Table 1. Postemergence Over-the-Top Herbicides Used for Palmer Amaranth Control in Cotton and Soybean, 2012-2016 (Annual Average).

Source: WSSA, 2018; MRD, 2012-2016; Kansas State University, 2018.

1 Heap 2018. Dash "-" indicates there were no cases of Palmer amaranth resistance reported in the U.S.

2 Total acres treated accounts for multiple applications to the same acre.

3 These active ingredients can only be applied to varieties that are resistant to these active ingredients. Varieties are specific to glyphosate, glufosinate, 2,4-D and dicamba, meaning that dicamba can only be applied to DT varieties, 2,4-D can only be applied to 2,4-D resistant varieties; the trait conferring resistance to dicamba is combined with glufosinate resistance in cotton, thus glufosinate can be applied to DT and glufosinate resistant varieties of cotton. Glufosinate cannot be applied to DT soybeans.

4 Dicamba and 2,4-D not labeled for postemergence applications until 2017.

5 Price estimates are from Kansas State University (2018). All other price estimates are from MRD (2012-2016).

6 Can be applied over the top (OTT) or with directed/hooded sprayers. Crop injury will occur when applied OTT. 7 Other OTT applications being used include. Cotton: carfentrazone-ethyl, dimethenamid-p, pyraflufen ethyl, trifloxysulfuron.

8 Other OTT applications being used include: Soybean: 2,4-DB, acifluorfen. bentazone, chlorimuron, cloransulammethyl, fluthiacet-methyl, imazamox, lactofen, paraquat, thifensulfuron.

Based on market research data (MRD, 2012-2016), preemergence applications of 2,4-D and dicamba are relatively inexpensive, averaging around \$3.00 and \$4.00 per acre, respectively, in both cotton and soybean. Postemergence applications, however, appear to be more expensive at around \$12 to \$13 per acre (Kansas State University, 2018). This suggests that they are similar in cost to glufosinate, which averaged \$16 per acre, according to market research data (2012-2016). Comparison of chemical costs do not capture the full extent of the farmer's decision, however, as each chemical is associated with a particular seed trait conferring tolerance to the herbicide. Thus, the cost of the entire package of technologies, trait and herbicide, must be considered as well as any incentives offered by seed and herbicide suppliers. Further, there may be other traits associated with the available herbicide-tolerant varieties that affect yields under different circumstances. It

may be that seed selection is heavily influenced by yield potential under specific agronomic conditions, even specific field conditions, and subsequent herbicide choices are largely dictated by the associated herbicide tolerance. That is, the benefits of the herbicide program (that includes OTT dicamba) and its ability to control weeds cannot be isolated completely from the value of the entire package of technologies (seed, herbicides, and price incentives).

In comparison to conventional systems producing non-GM varieties, a benefit of cultivating varieties adapted to OTT dicamba may be the reduced management complexity associated with preselecting an effective postemergence herbicide with little to no risk of crop damage.

Non-chemical control options: Herbicides are the primary means of weed control but there are other strategies that a grower can utilize to aid in weed control (Pennsylvania State University, 2013). Practices that aid in achieving canopy closure as quickly as possible, like selecting a hybrid that has good early season vigor and pest resistance, adopting good planting practices that make the crop more competitive (row spacing, seed density, and planting depth), and providing adequate water and nutrients, reduce germination of new weeds. Crop rotations and cover crops can also assist with weed control. Once weeds are present, tillage and/or mechanical removal, i.e., hoeing, are non-chemical weed control options (Pennsylvania State University, 2013). Many acres of cotton and soybeans are grown using reduced tillage systems to reduce soil erosion, nutrient and moisture loss. In those fields, tillage may not be an appropriate method for weed control. Other non-chemical weed control methods include directly destroying weed seeds after harvest by using a Harrington Seed Destructor (which grinds the weed seeds) or by windrowing the chaff so that it can be burned and destroy the weed seeds.

(2) Potential benefit for resistance management. The Agency recognizes the use of dicamba, when used as part of a season-long weed management program that includes preemergence (residual) and postemergence (foliar) herbicides, provides a long-term benefit as a tool to delay resistance of other herbicides. Fifty years of dicamba use, in rotation with other herbicides, has resulted in only two confirmed resistant weed species in the United States, Kochia and prickly lettuce (Heap, 2018). However, with the development of DT crops, the widespread use and multiple in-season applications will increase selection pressure on weeds to evolve resistance to dicamba.

The registrants provided a map to demonstrate how widespread herbicide-resistant weeds are in the U.S. and stated that dicamba would be beneficial for controlling resistant weeds. According to BASF (no date), 5.5 percent of agricultural land has weeds resistant to multiple herbicides (PPOs and glyphosate). The Agency does not have data to verify the location or the percent of cotton and soybean acreage with these resistant weeds. However, dicamba used on DT crops is not a standalone herbicide program even though the label states it has preemergence (soil residual) and postemergence (foliar) activity; other herbicides, especially preemergence herbicides, should be used as registrants and university researchers recommend (University of Arkansas, 2018; Steckel, 2018; Flessner et al., 2016; Sprague, 2017b; Jhala, 2014, Mississippi State University, 2017; Marshall, 2017; McGinty, 2016; EPA Reg. Nos. 524-617 [Xtendimax]; 524-617 [Engenia]; and 352-913 [Fexapan]). For example, various registered preemergence herbicide treatments can

provide weed control for up to four to eight weeks (e.g., Bradley et al., 2008; University of Maryland, 2017, Stalcup, 2015). In addition, depending on the location and weed pressure, other herbicide MOAs will be needed to manage weeds where dicamba is not effective, such as for dicamba-resistant Kochia in soybean or ryegrass in cotton fields.

Because of the complexities involved with controlling multiple weeds (Xtendimax has over 250 weeds labeled for control), the Agency considered one of the more difficult-to-control weeds in cotton and soybean, Palmer amaranth (Van Wychen, 2016a and 2016b). Palmer amaranth is native to the U.S. and occurs in 28 states (Hensleigh and Pokorny, 2017), and there are over 50 Palmer amaranth biotypes with resistance to at least one herbicide within 6 MOA groups in the U.S. (Heap, 2018). Additionally, more than 15 of the biotypes exhibit multiple herbicide resistance with up to three different herbicides within three different MOA (Heap, 2018). The Agency assumes that Palmer amaranth serves as surrogate for other difficult to control broadleaf weeds.

The registrants have indicated that for best performance dicamba should be applied when weeds are less than 4 inches tall, and labels also recommend targeting small weeds as part of a resistance management plan (EPA Reg. Nos. 352-913 [Fexapan], 524-617 [Xtendimax], 524-617 [Engenia]). Two labels indicate that the registrant "does not warrant product performance of an [postemergence, in-crop] application for weeds greater than 4 inches in height" (EPA Reg. Nos. 352-913 [Fexapan], 524-617 [Xtendimax]). Because Palmer amaranth can grow 2 to 3 inches per day (Sosnoskie et al, 2014), there is a narrow window when effective applications of dicamba can be made. Additionally, extension specialists have reported less than 60 percent control of glyphosate/PPO (Protoporphyrinogen oxidase, WSSA Group 14) resistant Palmer amaranth with dicamba. (Steckel, 2017). Excellent weed control is considered to be 90 or better percent control (Marshall, 2017).

(3) Potential benefit for conservation tillage programs. Although the registrants state that dicamba is a crucial part of maintaining a conservation tillage program, they did not provide data that directly supports their assertion. Therefore, the Agency is not able to verify this benefit.

(4) Potential benefit for reducing yield losses due to weeds. The registrants state that dicamba provides economic benefits of reducing growers' losses due to weeds. The Agency finds that dicamba can control weeds that might lead to yield loss but did not find sufficient information to show it was more effective than other weed control programs in reducing yield loss due to weeds. The information presented by Bayer (2018) could not be interpreted because there was no description of the broadleaf species or their density present in the studies and because dicamba was applied twice as often as the alternative postemergence herbicide. Work from other researchers (see discussion in sections on Alternatives for Season Long Control and Yield Under Moderate to Severe Weed Infestations) shows that alternative weed control programs can also provide effective Palmer amaranth control.

Yield Under Moderate to Severe Weed Infestations

Because the Agency regulates pesticides, it evaluates the impact on crop yield when the pest is controlled versus when the pest is not controlled and not the yield potential inherent in a seed trait. After reviewing the data currently available (data on soybean and cotton yields are not available for

2018) (USDA, 2018b), the Agency is not able to conclude that OTT dicamba use increases yields through the control of target weeds compared to alternative weed control programs in cotton and soybean. Crop yields are influenced by the complex interaction between the genetics of the plant, external factors such as weather, geography, soil characteristics and the effects of other biological organisms (e.g., weeds, insects). Irwin (2017) examined the yield effects of changing crop management practices (e.g., row width, planting depth, crop rotation). He concluded that while improvement in genetics and in changing management practices contributed, the biggest factor explaining recent high soybean yields is exceptionally good growing season weather. Because these factors operate at the field-, or subfield-level, using aggregated state-level data to investigate one individual factor (such as yield effects from low levels of dicamba exposure) is not informative and cannot be used to establish causation.

Comparison to Baseline:

For this benefits analysis, the baseline is the pre-2016 status of dicamba (i.e., when OTT uses were not registered for DT soybean and cotton). When comparing the baseline against an amended registration in which OTT uses are available for DT cotton and soybean, the Agency finds the following overall benefits for OTT dicamba:

- It provides growers with an additional postemergence active ingredient to manage difficult to control broadleaf weeds during the crop growing season, particularly for those situations where herbicide-resistant biotypes, such as glyphosate-resistant Palmer amaranth, may occur (and few alternatives are available).
- It provides a long-term benefit as a tool to delay resistance of other herbicides when used as part of a season-long weed management program that includes preemergence (residual) and postemergence (foliar) herbicides (along with rotations between different MOA).

Additionally, as in the case of other genetically modified herbicide resistant varieties (i.e., glyphosate, glufosinate, and 2,4-D), the use of the OTT herbicide partner may reduce the management complexity associated with pre-selecting an effective postemergence herbicide with little to no risk of damage to the treated crop.

Uncertainties

- The Agency does not have product specific usage data for dicamba during the 2017 and 2018 growing seasons to assess the use specific to postemergence OTT dicamba.
- EPA recognizes that there are difficult-to-control weeds other than Palmer amaranth but assumes this scenario reflects similar challenging weed control situations.
- The registrant provided estimates at the state level on the distribution of herbicide resistant weeds which are included in the assessment (see above). The Agency, however, does not have additional information on the distribution or the severity of herbicide resistant weeds throughout the U.S. to estimate the number of impacted acres.
- The Agency assumes that growers will use preemergence herbicides and rotate with the remaining efficacious OTT products to prevent/delay development/spread of resistance.
- The Agency considers the impact of an herbicide to control weeds and therefore reduce yield impacts. Data presented above are not conclusive on this point.

POTENTIAL IMPACTS OF REGISTRATION OF OTT DICAMBA TO NON-USERS

In 2017 and 2018, there have been many incidents alleging potential damage from off-target dicamba movement reported to the Agency by the registrants under FIFRA Section 6(a)2, by individual growers, and by State regulatory partners. Many other reports have been published in the extension reports, agricultural news media, and the scientific literature. By using these reports, the potential impacts to non-users from the 2018 registration of OTT dicamba products can be described. The Agency has considered label language changes and revised terms of registration for OTT dicamba products beginning in the 2019 use season, intended to continue to minimize the potential for off-target injuries.

Impacts to non-DT soybean growers. Monsanto predicted that 40 million acres of DT soybeans would be planted in 2018 (Monsanto, 2018b). USDA (2018c) reported that 89.6 million acres of soybeans were expected to be planted in 2018. This implies that 49.6 million acres (55 percent) of the 2018 U.S. soybean crop is non-DT and can be damaged by very low levels of off-target dicamba. Exposure results in damage levels that range from superficial visual symptomology to possible yield loss to plant death. In general, exposure during the reproductive growth stages could result in reductions in yield (Barber et al., 2017), but the Agency does not have information to quantify this claim. USDA reports crop progress for soybeans weekly during the growing season. Crop progress is given as percent of the crop in the state at a given crop growth stage (USDA, 2018b). These data show that application window of OTT dicamba overlaps with the bloom period of soybeans (reproductive growth stage R1).

<u>Impacts to growers of other dicamba sensitive crops.</u> Many other plants are sensitive to low levels of dicamba and are listed on the dicamba labels. The OTT dicamba labels mention several hundred susceptible (e.g., sensitive) crops /crop groups such as non-DT soybeans and cotton, all fruiting vegetables, all fruit trees, all cucurbits, grapes, beans, flowers and ornamentals, peas, potatoes, sunflower, tobacco and other broadleaf plants. Labels also list about 250 weeds – annual and perennial broadleaf plants and trees – that are controlled, some of which are desirable in non-crop settings. The application window of OTT dicamba products overlaps with the presence of other sensitive crops (Figure 1).

Acres reported in Table 2 are not comprehensive and should not be considered an estimate of acres impacted nationally. Many states do not collect information on the number of affected acres when investigating incidents. undated

Figure 1. Estimated Planting and Harvest Dates for Soybeans and Other Sensitive Crops in Illinois, Estimated Application Window for Preplant and OTT Dicamba Applications, and Comparison of Reported Dicamba-related Incidents¹ in 2017 and 2018

	Mar	April	May	Jun	Jul	Aug	Sep	Oct
Preplant Burndown Dicamba								
Application (all formulations)								
Soybean Planting Window								
OTT Application Window								
Reported Incidents Window (2017)								
Reported Incidents Window (2018)								
	Planting to Harvest Window for Sensitive Crops							
Non-dicamba Tolerant Soybean								
Lima Beans								
Snap Bean								
Cabbage								
Green Peas								
Pumpkin								

¹Majority of incidents in Illinois were to non-dicamba tolerant soybean. Sources: USDA 2018b (5-yr average); AAPCO, 2018; USDA, 2010; USDA, 2007.

<u>Impacts to the landscape</u>. In 2017 and 2018, state lead agencies received reports from growers about alleged incidents claiming damage to trees and other non-crop plants (Bradley, 2017, 2018; AAPCO 2018). Potential impacts could result in damage to shelterbelts and windbreaks, as well as plants in public parks and spaces.

Uncertainties

- The Agency does not know the extent of the damage to sensitive crops, as investigations do not follow the damaged crop to yield. Damage could range from superficial visual symptomology to yield loss and/or plant death.
- The number of incidents may not accurately represent the extent of dicamba-related damage; incidents may be under- or over-reported. See section on "Incidents Alleging Crop Damage from Off-Target Movement of Dicamba" for discussion on uncertainties regarding incidents.

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Message

From:	Baris.Reuben@epa.gov [Baris.Reuben@epa.gov]
Sent:	10/31/2018 1:59:17 AM
То:	MARVIN, THOMAS [AG/1920] [thomas.marvin@bayer.com]
Subject:	Re: Revised RE: terms and conditions - with labeling

They are ready to share if you want to see them. But really no substantial change from 2016.

Sent from my iPhone

On Oct 30, 2018, at 9:24 PM, MARVIN, THOMAS [AG/1920] <<u>thomas.marvin@bayer.com</u>> wrote:

Thanks, we are reviewing. When do you expect to send revised Appendices?

Tom Marvin Director, Federal Regulatory Affairs 1300 I Street, NW Washington, DC 20005 Cell: 202-676-7846 Desk: 202-383-2851

From: Baris, Reuben [mailto:Baris.Reuben@epa.gov]
Sent: Tuesday, October 30, 2018 9:18 PM
To: MARVIN, THOMAS [AG/1920] <<u>thomas.marvin@bayer.com</u>>
Cc: Kenny, Daniel <<u>Kenny.Dan@epa.gov</u>>; Goodis, Michael <<u>Goodis.Michael@epa.gov</u>>
Subject: Revised RE: terms and conditions - with labeling

Hi Tom,

Apologies. Revisde Data requirements appended below. For transparency #20 was removed since the concept was incorporated into #17. Thank you. Reuben

REUBEN BARIS | PRODUCT MANAGER, TEAM 25 | HERBICIDE BRANCH U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS | (703) 305-7356

From: Baris, Reuben
Sent: Tuesday, October 30, 2018 8:06 PM
To: 'MARVIN, THOMAS [AG/1920]' <<u>thomas.marvin@bayer.com</u>>
Cc: Kenny, Daniel <<u>Kenny.Dan@epa.gov</u>>; Goodis, Michael <<u>Goodis.Michael@epa.gov</u>>
Subject: terms and conditions - with labeling

Hi Tom,

I've copied the revised terms and conditions below per your conversation with Mike. Let us know if you have any questions. A written response acknowledging the receipt of the terms and acceptance said terms is preferable by noon tomorrow (10/31/2018). Note the referenced appendices will be more or less the same as the 2016 New Use registration with exception to consistency with updates to the terms and conditions. Thank you Reuben

EPA is extending the expiration of these uses until December 20, 2020. The following terms are separated into five categories: General Terms, Labeling/Relabeling, Tank Mixing and Spray Drift Requirements, Enhanced Reporting, and Data Requirements.

General Terms

- 1. You must submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
- 2. You are required to comply with the data requirements described in the DCIs identified below:
 - a. Dicamba GDCI-029801-1659 (DuPont)
 - b. Dicamba GDCI-029801-1721 (Bayer/Monsanto & BASF)

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

3. This registration will automatically expire on December 20, 2020.

Labeling/Relabeling

The previously approved labeling contains an expiration date of MM DD, 2018 and cannot be used beyond that date. New labeling is required for use of the product beyond this date. Beginning MM DD, 2018, before using any product with expired labeling, users must first access [Insert Registrant]'s website located at [URL] to review directions for use and obtain a copy of the current final printed label, and must have that label in their possession at the time of use.

- 4. Final Printed Label. You must submit one copy of the final printed labeling that is consistent with the new accepted label to EPA before any existing product already in the channels of trade is relabeled with that label, or before you release any new product for shipment featuring that label. Any changes to the final printed labeling must be submitted to EPA before being used in future production.
- 5. Posting Updated Information for Users. From MM DD, 2018 through December 20, 2020, you must maintain a website at [URL] and publish the following material and statements in a clear and easily accessible manner:
 - a. A copy of the most current final printed label submitted to EPA per paragraph 4;
 - b. "[Insert Product Name] is a Restricted Use Pesticide.";
 - c. "The label affixed to the container in your possession may contain incomplete or outdated directions for use. Use of this product is prohibited unless the user has received and is in possession of the labeling linked on this website featuring an expiration date of December 20, 2020 at the time of use.";
 - d. "Users must comply in all respects with labeling featuring an expiration date of December 20, 2020, regardless of any contrary language on the label physically affixed to any individual container."; and
 - e. "If you have any questions about the use of this product, please contact [Registrant assistance telephone number]."

When relabeling or labeling as set forth below, the new final printed label (approved on [MM/DD/2018]) must be affixed to *each individual container* (inner and outer) of [Insert Product name] (EPA Reg. No. XXX) that is intended for end use, sale or distribution.

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- 6. Relabeling Product Already in Trade. All product currently in the channels of trade, in retail inventories, in the distribution chain (packaged and released for shipment), and product that was manufactured before MM DD, 2018 must be relabeled with a sticker and the final printed label (per paragraph number 4 above) on the container. [Insert Registrant] agrees to the following:
 - a. <!--[if !supportLists]--><!--[endif]-->All relabeling will be conducted in an EPAregistered establishment, and production must be reported per FIFRA Section 7.
 - b. <!--[if !supportLists]--><!--[endif]-->The sticker will contain the following information:
 - i. <!--[if !supportLists]--><!--[endif]-->"Restricted Use Pesticide";
 - ii. <!--[if !supportLists]--><!--[endif]-->"The label affixed to this container contains incomplete or outdated directions for use. Use of this product is prohibited unless the user has received and is in possession of the current labeling listing an expiration date of December 20, 2020 at the time of use."; and
 - iii. <!--[if !supportLists]--><!--[endif]-->"User must comply in all respects with new label(ing) listing an expiration date of 12/20/2020, regardless of any contrary language on existing label physically affixed to any individual container."
 - c. <!--[if !supportLists]--><!--[endif]-->Copies of the final printed labels must be provided to distributors and must accompany each stickered container at all times.
 - d. <!--[if !supportLists]--><!--[endif]-->Communicate efficiently with [Insert Registrant]'s entire distribution chain. Specifically:
 - i. <!--[if !supportLists]--><!--[endif]-->By MM DD, 2018, [Insert Registrant] submits to EPA a list of known distributors and retailers that may have received product with previously-accepted labels.
 - ii. <!--[if !supportLists]--><!--[endif]-->By MM DD, 2018, [Insert Registrant] must inform all distributors and retailers on that list of the need, as it is represented in this letter, to relabel and Sticker, of the legal liability that would result from their sale or distribution of product with previously-accepted labels after MM DD, 2018, and that relabeling and Stickering are production activities under FIFRA and no retailer or distributor may begin any production activities until their establishment is registered with EPA.
 - iii. <!--[if !supportLists]--><!--[endif]-->For those distributors and retailers that are able to relabel and Sticker in an EPA-registered establishment, [Insert Registrant] must instruct them how to affix the Sticker and the new printed label to each product container, and must supply the new final printed labels and Stickers in order for them to do so.
 - iv. <!--[if !supportLists]--><!--[endif]-->For those distributors and retailers that are interested in registering an establishment for pesticide production, [Insert Registrant] must advise them on how to register and remind them of FIFRA's production reporting requirements.
 - v. <!--[if !supportLists]--><!--[endif]-->For those distributors and retailers who do not intend to relabel themselves, [Insert Registrant] must instruct them to contact [Insert Registrant's specific contact or email] immediately, so that [Insert Registrant] can reclaim the inventory. If [Insert Registrant] performs the relabeling, it must be done at an EPA-registered establishment, and all production must be reported per FIFRA section 7.
 - e. <!--[if !supportLists]--><!--[endif]-->[Insert Registrant] must provide EPA a copy of each communication required above within 30 days of each communication.
- 7. New Production. [Insert Registrant] is responsible for ensuring all product produced, packaged, and released for shipment on MM DD, 2018 and thereafter bears the new final printed labeling

submitted to EPA per paragraph number 4 above. [Insert Registrant] must ensure all production activities take place in an EPA-registered establishment and that all production is reported pursuant to FIFRA section 7.

You are advised that if you wish to add/retain a reference to the company's website on your label, then the website becomes "labeling" under FIFRA. If the website content is false or misleading, all products referencing the website would be misbranded and it would be unlawful to sell or distribute them under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Should the Agency find, or if it is brought to our attention, that a website contains false or misleading statements or claims substantially differing from the EPA-accepted registration, the matter will be referred to the EPA's Office of Enforcement and Compliance.

Tank Mixing and Spray Drift Requirements

- 8. You must maintain a website at [Insert Relevant Website]. That website will include a list of products that have been tested pursuant to Appendix A and found, based upon such testing, not to adversely affect the spray drift properties of [Insert Product Name]. The website will identify a testing protocol, consistent with Appendix A, that is appropriate for determining whether the tested product will adversely affect the drift properties of [Insert Product Name]. The website must state that any person seeking to have a product added to the list must perform a study either pursuant to the testing protocol identified on the website or another protocol that has been approved for the particular purpose by EPA, and must submit the test data and results, along with a certification that the studies were performed either pursuant to the testing protocols identified on the website or pursuant to another protocol(s) approved by EPA and that the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of [Insert Product Name], to EPA. EPA will notify you when the Agency determines that a product has been certified to be appropriately added to the list, and you will add appropriately certified products to the list no more than 90 days after you receive such notice from EPA. Testing of Tank-Mix Products must be conducted in compliance with procedures as stated forth in Appendix A.
- 9. All test data relating to the impact of tank-mixing any product with [Insert Product Name] on drift properties of [Insert Product Name] generated by you or somebody working for you must be submitted to EPA, along with a certification indicating whether the study was performed either pursuant to the testing protocols identified on the website or pursuant to other protocols approved by EPA and whether the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of [Insert Product Name], at the following address: [TBD]
- 10. The prohibition of using products in a tank-mix with [Insert Product Name] unless the product used is contained on the list at [Insert Relevant Company Website], and the identification of the website address, shall be included in educational and information materials developed for [Insert Product Name], including the materials identified in Appendix D, Section B(I).
- 11. You must maintain, update and follow an Herbicide Resistance Management Plan (HRM) as laid out in Appendix D regarding grower agreements, field detection and remediation, education, evaluation, reporting, and best management practices (BMPs).

Enhanced Reporting

If [insert registrant] or any of its consultants, attorneys, or agents, acquires any of the information identified below, that information must be reported to EPA under section 6(a)(2), or under 40 CFR 159.195 unless you have previously submitted that information to EPA's Office of Pesticide Programs.

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- 12. All information received by telephone or in writing 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 (intentional or accidental). All information should be forwarded to EPA 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. Data should be organized by product and state and should include available information regarding acreage involved, plant species involved, severity of damage, and similar information received. This information must be submitted with cumulative totals and be submitted monthly, beginning March 1, 2019.
- 13. All information received by telephone or in writing regarding reports of dicamba-resistant weeds, and cases of weed control failure. All information should be forwarded to EPA regardless of which dicamba product may have been used and/or whether or not the alleged resistance occurred after an application made according to label directions.
- 14. A summary of all studies being conducted (or planned to be conducted), sponsored by [insert registrant] (or planned to be sponsored by), or any study being conducted known by any of its consultants, attorneys, or agents that a study investigating pertaining to adverse off-target movement of dicamba (e.g., volatility, physical drift, runoff) must be provided to the EPA.
- 15. Any information or analysis suggesting foods/commodities contain or may contain dicamba residues that are not covered by a tolerance or exceed established tolerance levels.

Given the high number of alleged dicamba-related adverse incidents reported to EPA in 2017 and 2018 by state lead agencies (SLAs) as well as registrants under FIFRA section 6(a)(2), it is an Agency priority to work with registrants to better understand potential risks and impacts from the use of dicamba on dicamba-tolerant soybean and dicamba-tolerant cotton. The following information is being required to be submitted to the Agency to assist the Agency in making future regulatory decisions regarding these uses.

- 16. Seed sales information for dicamba tolerant soybean seed and dicamba tolerant cotton seed. This information should include all sales of such seed for planting or planted in the 2017 though 2020 growing seasons and should be categorized by state.
- 17. Sales reports categorized by state of [Insert Product Name] since it was originally registered by the EPA for the over-the-top uses on soybeans and cotton.
- 18. Number and type of containers, including volume of material, [Insert Product Name] that carry labeling approved October 12, 2017 that were relabeled in 2018 with the amended labeling approved by the Agency on October 31, 2018. This information should be categorized by state.

Additional Data Requirements

The following additional studies are required as a condition of this amended registration. Since these are non-guideline studies, prior to developing a protocol and initiating any study, [Insert Registrant] must meet with EPA staff to engage in a data quality objective discussion regarding environmental conditions, sampling, and species evaluated. Protocols must be submitted before December 31, 2018 for the Agency to review. Field studies must be conducted during the 2019 growing season. Final reports must be submitted to the Agency in connection with the January 15, 2020 required reporting submission outlined in Appendix D, Section D.

17. Field studies examining off-site movement of dicamba. Specifically, the study design needs to evaluate impacts on plant height and yield from primary and secondary drift off-target, with transects in all four cardinal directions. These studies should represent varied geographic areas and include locations where high numbers of complaints have been logged and ranges of environmental conditions (e.g., temperature and humidity). Additionally, a module of the study

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needs to evaluate the effects of dicamba-containing agricultural irrigation water on non-target plants. Data evaluating the response of non-DT soybean or other non-target plants exposed to irrigation water contaminated with dicamba is focus of this module. A consistent protocol is required for all field locations.

- 18. Studies to investigate temperature effects on volatility of dicamba. The use of humidome studies would allow EPA to evaluate the effects of temperature in a controlled environment for a multitude of temperature, relative humidity, and tank mix pH conditions.
- 19. Ecological effects data on non-target plants, related to survival, growth and reproduction for select sensitive tree/shrub/woody perennial species. The study design could involve an extended period for consideration of perennial species.
- 20. Studies examining the effect of lower pH on secondary movement both in terms of the spray tank mixture. An analysis to examine variability introduced by tank mix partners on the pH of the finished solution. The study should be broad enough to test a series of waters which will mimic the variety of water pH throughout the country, particularly in areas with the largest number of incidents. These tests would examine variability of tank mixture combinations relative to the pH of the applied solution.

This system contains confidential and copyrighted information. Access to the system is limited to users only and only for approved business purposes. Anyone obtaining access to and using this system acknowledges that all information on this system including but not limited to electronic mail, word processing, directories and files, constitutes private property belonging to the Company.

Anyone using or viewing this system is further advised that the use of this system may be recorded and the information contained herein maybe monitored, retrieved and reviewed if, in the company's sole discretion, there is a business reason to do so.

If improper activity or use is suspected, all available information may be used by the Company for possible disciplinary action, prosecution, civil claim or any remedy or lawful purpose.

General Terms

- You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
- 2. You are required to comply with the data requirements described in the DCIs identified below:
 - a. Dicamba GDCI-029801-1659 (DuPont)
 - b. Dicamba GDCI-029801-1721 (Bayer/Monsanto & BASF)

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

3. This registration will automatically expire on December 20, 2020.

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- 4. Final Printed Label. You must submit one copy of the final printed labeling that is consistent with the new accepted label to EPA before any existing product already in the channels of trade is relabeled with that label, or before you release any new product for shipment featuring that label. Any changes to the final printed labeling must be submitted to EPA before being used in future production.
- 5. Posting Updated Information for Users. From MM DD, 2018 through December 20, 2020, you must maintain a website at [URL] and publish the following material and statements in a clear and easily accessible manner:
 - a. A copy of the most current final printed label submitted to EPA per paragraph 4;
 - b. "[Insert Product Name] is a Restricted Use Pesticide.";
 - c. "The label affixed to the container in your possession may contain incomplete or outdated directions for use. Use of this product is prohibited unless the user has received and is in possession of the labeling linked on this website featuring an expiration date of December 20, 2020 at the time of use.";
 - "Users must comply in all respects with labeling featuring an expiration date of December 20, 2020, regardless of any contrary language on the label physically affixed to any individual container."; and
 - e. "If you have any questions about the use of this product, please contact [Registrant assistance telephone number]."

When relabeling or labeling as set forth below, <u>either the sticker or</u> the new final printed label (approved on [MM/DD/2018]) must be affixed to *each individual container* (inner and outer) of [Insert Product name] (EPA Reg. No. XXX) that is intended for end use, sale or distribution.

6. Relabeling Product Already in Trade. All product currently in the channels of trade, in retail inventories, in the distribution chain (packaged and released for shipment), and product that

Commented [A1]: Bayer's assertion: Registrant cannot control individual use of product.

Commented [A2R1]: Response: must be retained. This is a statement of fact not a term.

Commented [A3]: New labeling is required <u>on the</u> <u>product</u> beyond this date

Commented [A4R3]: EPA response: "Reasonable effort" is insufficient. See preference below.

Commented [A5R3]: If registrant cannot accept this language. An alternative solution is to use the previously accepted labeling from the 2017 amendments. Copied here.

Immediately, for product currently in retail inventories, in the distribution chain (packaged and released for shipment), and product that will be manufactured before new glossy label booklets are available will be relabeled with a Sticker and a New Label. was manufactured before MM DD, 2018 must be relabeled with a sticker on the container with an approved label (dated MM DD, 2018) accompanying the container, or and the final orintedapproved label (per paragraph number 4 above) on the container, if stickering is used then a sufficient number of copies of the current labeling (approved MM DD, 2018) jisting an expiration date of December 20, 2020 will be placed in the carton to accompany the number of individual containers in the carton. [Insert Registrant] agrees to the following:

- a. All relabeling will be conducted in an EPA-registered establishment, and production must be reported per FIFRA Section 7.
- b. **Handling State** is the sticker will contain the following information:
 - "Restricted Use Pesticide";
 - "The label affixed to this container contains incomplete or outdated directions for use. Use of this product is prohibited unless the user has received and is in possession of the current labeling listing an expiration date of December 20, 2020 at the time of use."; and
 - "User must comply in all respects with new label(ing) listing an expiration date of 12/20/2020, regardless of any contrary language on existing label physically affixed to any individual container."
- c. Copies of the final printed approved labels must be provided to distributors and must accompany each stickered container at all times.
- d. Communicate efficiently with [Insert Registrant]'s entire distribution chain. Specifically:
 - i. By MM DD, 2018, [Insert Registrant] submits to EPA a list of known distributors and retailers that may have received product with previously-accepted labels. Such list shall be treated by EPA as confidential business information.
 - ii. By MM DD, 2018, [Insert Registrant] must inform all distributors and retailers on that list of the need, as it is represented in this letter, to relabel and Sticker, of the legal liability that would result from their sale or distribution of product with previously-accepted labels after MM DD, 2018, and that relabeling and Stickering are production activities under FIFRA and no retailer or distributor may begin any production activities until their establishment is registered with EPA.
 - iii. For those distributors and retailers that are able to relabel and Sticker in an EPA-registered establishment, [Insert Registrant] must instruct them how to affix the Sticker and <u>sticker</u> the new printed label to each product container, and must supply the new <u>final printed approved</u> labels (<u>dated mm DD, 2018</u>) and <u>stickers in order for them to do so.</u>
 - iv. For those distributors and retailers that are interested in registering an establishment for pesticide production, [Insert Registrant] must <u>advice refer</u> them to <u>EPA reconstruct</u> on how to register <u>with EPA as a</u> <u>registered establishment</u> and remind them of FIFRA's production reporting requirements.
 - v. For those distributors and retailers who do not intend to relabel themselves, [Insert Registrant] must instruct them to contact [Insert Registrant's specific contact or email] immediately, so that [Insert Registrant] can reclaim the inventory. If [Insert Registrant] performs the relabeling, it must be done at an EPA-registered establishment, and all production must be reported per FIFRA section 7.
- e. [Insert Registrant] must provide EPA a copy of each communication required above within 30 days of each communication.

Commented [A6]: If registrant cannot accept the language above then will have to use the "immediately" term from 2017. An alternative solution is to use the previously accepted labeling from the 2017 amendments. Copied here.

Immediately, for product currently in retail inventories, in the distribution chain (packaged and released for shipment), and product that will be manufactured before new glossy label booklets are available will be relabeled with a Sticker and a New Label.

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Commented [A7]: This is implied. These terms are only for stickering. If registrant chooses, it is an option to only relabel and remove the stickering procedures. 7. New Production. [Insert Registrant] is responsible for ensuring all product produced, packaged, and released for shipment <u>beginning on MM DD</u>, 2018 and thereafter bears the new final printed labeling submitted to EPA per paragraph number 4 above. [Insert Registrant] must ensure all production activities take place in an EPA-registered establishment and that all production is reported pursuant to FIFRA section 7.

You are advised that if you wish to add/retain a reference to the company's website on your label, then the website becomes "labeling" under FIFRA. If the website content is false or misleading, all products referencing the website would be misbranded and it would be unlawful to sell or distribute them under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Should the Agency find, or if it is brought to our attention, that a website contains false or misleading statements or claims substantially differing from the EPA-accepted registration, the matter will be referred to the EPA's Office of Enforcement and Compliance.

Tank Mixing and Spray Drift Requirements

- 8. You must maintain a website at [Insert Relevant Website]. That website will include a list of products that have been tested pursuant to Appendix A and found, based upon such testing, not to adversely affect the spray drift properties of [Insert Product Name]. The website will identify a testing protocol, consistent with Appendix A, that is appropriate for determining whether the tested product will adversely affect the drift properties of [Insert Product Name]. The website must state that any person seeking to have a product added to the list must perform a study either pursuant to the testing protocol identified on the website or another protocol that has been approved for the particular purpose by EPA, and must submit the test data and results, along with a certification that the studies were performed either pursuant to the testing protocols identified on the website or pursuant to another protocol(s) approved by EPA and that the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of [Insert Product Name], to EPA. EPA will notify you when the Agency determines that a product has been certified to be appropriately added to the list, and you will add appropriately certified products to the list no more than 90 days after you receive such notice from EPA. Testing of Tank-Mix Products must be conducted in compliance with procedures as stated forth in Appendix A.
- 9. All test data relating to the impact of tank-mixing any product with [Insert Product Name] on drift properties of [Insert Product Name] generated by you or somebody working for you must be submitted to EPA, along with a certification indicating whether the study was performed either pursuant to the testing protocols identified on the website or pursuant to other protocols approved by EPA and whether the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of [Insert Product Name], at the following address: [TBD]
- 10. The prohibition of using products in a tank-mix with [Insert Product Name] unless the product used is contained on the list at [Insert Relevant Company Website], and the identification of the website address, shall be included in educational and information materials developed for [Insert Product Name], including the materials identified in Appendix D, Section B(I).

Commented [A8]: This is a placeholder for relevant expiration date for xtendimax, fexapan and engenia (since they are different).

11. You must maintain, update and follow an Herbicide Resistance Management Plan (HRM) as laid out in Appendix D regarding grower agreements, field detection and remediation, education, evaluation, reporting, and best management practices (BMPs).

Enhanced Reporting

If [insert registrant] or any of its consultants, attorneys, or agents, acquires any of the information identified below, that information must be reported to EPA's <u>Office of Pesticide Programs</u> under section 6(a)(2), or under 40 CFR 159.195 unless you have previously submitted that information to EPA's <u>Office</u> of Pesticide Programs.

- 12. All information received by telephone or in writing 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 (intentional or accidental). All information should be forwarded to EPA 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. Data should be organized by product and state and should include available information regarding acreage involved, plant species involved, severity of damage, and similar information received. This information must be submitted with cumulative totals and be submitted monthly, beginning March 1, 2019.
- 13. All information received by telephone or in writing regarding reports of dicamba-resistant weeds, and cases of weed control failure and/or suspected resistance. All information should be forwarded to EPA regardless of which dicamba product may have been used and/or whether or not the alleged resistance occurred after an application made according to label directions.
- 14. A summary of all studies being conducted (or planned to be conducted) of proposed by [insert registrant] (or planned to be sponsored by), or any study being conducted known by any of its consultants, attorneys, or agents that a study investigating pertaining to adverse off-target movement of dicamba (e.g., volatility, physical drift, runoff) must be provided to the EPA.
- 15. Any information or analysis finding that foods/commodities contain dicamba residues that are not covered by a tolerance or exceed established tolerance levels.

Given the high number of alleged dicamba-related adverse incidents reported to EPA in 2017 and 2018 by state lead agencies (SLAs) as well as registrants under FIFRA section 6(a)(2), it is an Agency priority to work with registrants to better understand potential risks and impacts from the use of dicamba on dicamba-tolerant soybean and dicamba-tolerant cotton. The following information, which shall be treated by EPA as confidential business information, is being required to be submitted to the Agency to assist the Agency in making future regulatory decisions regarding these uses.

- 16. Seed sales information for dicamba tolerant soybean seed and dicamba tolerant cotton seed. This information should include all sales of such seed for planting or planted in the 2017 though 2020 growing seasons and should be categorized by state.
- 17. Sales reports categorized by state of [Insert Product Name] since it was originally registered by the EPA for the over-the-top uses on soybeans and cotton.
- 18. Number and type of containers, including volume of material, [Insert Product Name] <u>including approved</u> October 12, 2017 that were relabeled in 2018 with the amended labeling approved by the Agency on October 31, 2018. This information should be categorized by state.

Commented [A9]: Retaining citation

Commented [A10]: EPA agrees with Bayer's addition of suspected resistance. Retain "weed control failure" Commented [A11]: No agreement on Bayer's proposed deletion.

Commented [A12]: Need to retain this term. See modifications

Commented [A13]: Objective of this term is to understand the potential for misuse in 2019. Objective is to know what % of product is relabeled. Is there a better way to achieve this based on information that registrants do know?

Commented [A14R13]: Registrant(s) need to respond.

Additional Data Requirements

The following additional <u>confirmatory</u> studies are required as a condition of this amended registration. Since these are non-guideline studies, prior to developing a protocol and initiating any study, [Insert Registrant] must meet with EPA staff by <u>November 12, 2018</u> to present and engage in a data quality objective discussion regarding environmental conditions, sampling, and species evaluated. Protocols must be submitted before December 31, 2018 for the Agency's to review consideration. This work to ascree on final protocols will be undertaken on a schedule that recognizes the timing for conducting research during 2019 Field studies must be conducted during the 2019 growing season, and #final reports must be submitted to the Agency in connection with the January 15, 2020 required reporting submission outlined in Appendix D, Section D.

- 19. Efield studies examining off-site movement of dicamba. Specifically, the study design needs to evaluate impacts on plant height and yield from primary and secondary drift off-target, with transects in all four cardinal directions. These studies should represent varied geographic areas and include locations where high numbers of complaints have been logged and ranges of environmental conditions (e.g., temperature and humidity). Additionally, a module of the study needs to evaluate the effects of dicamba-containing agricultural irrigation water on non-target plants. Data evaluating the response of non-DT soybean or other non-target plants exposed to irrigation water contaminated with dicamba is focus of this module. A consistent protocol is required for all field locations.
- 20. Studies to investigate temperature effects on volatility of dicamba. The use of humidome studies would allow EPA to evaluate the effects of temperature in a controlled environment for a multitude of temperature, relative humidity, and tank mix pH conditions.
- Ecological effects data on non-target plants, related to survival, growth and reproduction for select sensitive tree/shrub/woody perennial species. The study design could involve an extended period for consideration of perennial species.
- 22. Study which evaluates the effect of pH on secondary movement of dicamba. The analysis should examine variability introduced by tank mix partners and different water conditions on the pH of the mixed material. The study should reflect a variety of water pH throughout the country, particularly in areas with the largest technology adoption and incidents. These tests should examine the pH of the applied solution.

Commented [A15]: All three are responsible.

Commented [A16]: Alternative language to meet by Nov. 12 for registrant to present proposed data quality objectives.

Commented [A17]: Edits back. There's sufficient flexibility in the term to complete and accept a protocol before December 31.

Commented [A18]: Alternative language to ensure all parties agree on protocols with sufficient time to initiate studies in the 2019 season.

Commented [A19]: Component is important as there is evidence showing irrigation water containing concentrations of dicamba have impacted non-DT crops.

Commented [A20]: Bayer Rebuttal: Current label already contains a number of restrictions relative to this topic, which resulted from EPA's prior assessment. Not clear what purpose of this study would be if existing restrictions remain in place. See, for example, these label restrictions currently in effect:

Section 3.2 Environmental Hazards Ground and Surface Water Protection

Point source contamination - To prevent point source contamination, do not mix or load this pesticide product within 50 feet of wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. Do not apply pesticide product within 50 feet of wells. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas as described below.

Mixing, loading, rinsing, or washing operations performed within 50 feet of a well are allowed only when conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be on or move across the pad. The pad must be selfcontained to prevent surface water flow over or from the pad. The pad capacity must be maintained at 110% that of the largest pesticide container or application

Commented [A21]: Such data would be irrelevant to EPA's risk assessment as EPA has already identified soybean as the most sensitive species to dicamba. Further, unlike soybean, trees/shrubs/wood perennial species have significantly longer growth cycles that

Commented [A22R21]: This is still required. Special sensitivity has been shown in the field. Sensitive enough to question whether soybeans are sensitive enough. No data currently exists for perennial crops. Highlighting 6(a)2 requirements as field information is evidentiary [...]

Commented [A23R21]: Maybe put in context of

Commented [A24]: Modified. No change in requirement. Just tweaked language.

Case: 19-70115, 08/13/2019, ID: 11396549, DktEntry: 36-2, Page 241 of 271



Richard P. Keigwin Director, Office of Pesticide Programs US Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Via email: keigwin.richard@epa.gov

Submitted via E-Mail and USPS on September 6, 2018

Rueben Baris Office of Pesticide Programs, Herbicide Branch United States Environmental Protection Agency Washington, DC 20460 Via email: baris.reuben@epa.gov

Andrew Wheeler, Acting EPA Administrator US EPA Headquarters William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W. Mail Code: 1101A Washington, DC 20460 Via email: Wheeler.andrew@Epa.gov

Re: Re-registration of Dicamba New Use on Herbicide-Tolerant Soybeans and Cotton

Mr. Keigwin, Mr. Baris, and Mr. Wheeler:

Please accept the enclosed documents on behalf of the Center for Food Safety for the Environmental Protection Agency's consideration in determining its next action(s) on the new use of dicamba on genetically engineered herbicide-tolerant soy and cotton, including the formulation Xtendimax, EPA Reg. No. 524-617, the registration of which ends on November 9, 2018. These materials are submitted via electronic mail (zip file) and through USPS, the enclosed thumb drive.

Sincerely,

Amy van Saun Staff Attorney Center for Food Safety 917 SW Oak St. Suite 300 Portland, OR 97205 (971) 271-7372 avansaun@centerforfoodsafety.org

NATIONAL HEADQUARTERS

660 Pennsylvania Avenue, SE Suite 402 303 Sacramento Street, 2nd Floor Washingoton, D.C. 20003 T: 202-547-9359 F: 202-547-9429 T: 415-826-2770 F: 415-826-0507 T: 971-271-7372 F: 971-271-7374

CALIFORNIA OFFICE San Francisco, CA 94111

PACIFIC NORTHWEST OFFICE

917 SW Oak Street, Suite 300 Portland, OR 97205

office@centerforfoodsafet

Center for Biological Diversity - Earth's New Ways - Illinois Environmental Council Illinois Stewardship Alliance - Iroquois Valley Farmland REIT, PBC Prairie Rivers Network - The Land Connection

August 10, 2018

Andrew Wheeler, Acting EPA Administrator

US EPA Headquarters William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W. Mail Code: 1101A Washington, DC 20460

Via email: Wheeler.andrew@Epa.gov

Re: Comments regarding the renewal of the registration of dicamba for over-the-top use on herbicide tolerant soybean and cotton.

Dear Mr. Wheeler:

Please accept the following comments on behalf of the Center for Biological Diversity, Earth's New Ways, the Illinois Environmental Council, the Illinois Stewardship Alliance, Iroquois Valley Farmland REIT, PBC, Prairie Rivers Network, and The Land Connection, regarding the renewal of the registration for the growth regulator herbicide dicamba (3,6-Dichloro-2-methoxybenzoic acid) on herbicide tolerant soybean and cotton.

We are writing to request that the USEPA **decline** the renewal of the registration of dicamba, with label names Engenia, FeXapan, and Xtendimax.

The unstable nature of the new formulations of this chemical pose serious threats to the future of farms growing non-GMO and/or specialty crops, orchards and vineyards, as well as to the native flora and fauna in these regions. There were an estimated 40 million acres of dicamba resistant soybeans planted throughout the United States in 2018. This greatly increased the wide-scale use of the new formulations of dicamba, and therefore increased exposure to off-target plants, as well as increased pollution to air and water resources. There are numerous reasons why registration for these products should not be renewed.

1. Physical drift and volatilization

We acknowledge the environmental protection efforts made by strengthening the application and label restrictions. These increased restrictions were designed to reduce physical drift during application and particle drift during inversions. However, these efforts are still inadequate. With the limitations now set for application (wind speed between 3 and 10 mph, no rain event predicted for 24 hours, no application during a temperature inversion, no application upwind of a sensitive crop, and application only during daylight hours), the window for application is extremely limited. A study performed by researchers at Purdue University revealed applicators had very few hours in which to apply registered dicamba products legally

and according to label instructions.¹ This increases the likelihood that the product will be used off-label, and therefore increases risks posed to non-GMO and specialty crops and native flora and fauna.

Despite the tightening of the application and label restrictions, the fact remains that this is a chemical that does not obey boundaries. These restrictions do nothing to address the chemical's volatility. Even with the updated label changes there were over 600 complaints of dicamba damage on an estimated 1.1 million acres so far this year - numbers that are sure to rise.² It is widely acknowledged that, post-application, dicamba volatilizes and disperses, often moving up to several miles. Recent studies from state extension researchers have found little difference in volatility between older and newer formulations. Research out of the Universities of Arkansas and Missouri show that newer dicamba formulations not only result in volatility, but can do so at levels similar to older formulations, which are known to be highly volatile.³ The issues of off-label use and volatility are causing extensive impacts to specialty crops, organic farms, and farms growing non-GMO crops. Farmers across the U.S. are reporting damage to their specialty crops, non-GMO soybeans, vineyards, and even declines in honey production surrounding crop fields treated with dicamba.⁴

2. Rights and freedoms of farmers and growers

Farmers in the United States should have the right and freedom to grow what they want and not fear losing their business due to chemical damage. Farms that choose not to grow GMO crops, that grow specialty crops, organic crops, or are smaller in size and highly diverse are under intense pressure due to dicamba volatilization, drift, and the risk of contamination.

3. Injuries to native flora, fauna, and aquatic systems

Throughout the Midwest, people have been witnessing and documenting off-target damage to native habitats including woodlands and prairies. Across the U.S., incidences of damage to trees and plants on both public and private lands are widespread. In Illinois alone, damage to native forested tracts on public and private lands, as well as landscaping trees, has been significant in the past two years. Natural areas that are now the only refuge for wildlife and biodiversity are experiencing injuries from volatile growth regulator herbicides.

Many species of trees are susceptible to growth regulator herbicide drift (photos attached). Some of the most sensitive species include: redbud, red oak, post oak, black oak, box elder,

¹ Ikley, J. and Johnson, B. (2018) Update on Wind Speeds and the New Dicamba Label. Pest and Crop Newsletter, Entomology Extension Newsletter, Purdue University, July 20, 2018. Issue 2018.16 Available here: <u>https://extension.entm.purdue.edu/newsletters/pestandcrop/article/update-on-wind-speeds-and-the-new-dicamba-labels/</u>

² Bradley, K. July 15 Dicamba injury update. Different Year, same questions. July 19, 2018. Available here: https://ipm.missouri.edu/ipcm/2018/7/July-15-Dicamba-injury-update-different-year-same-questions/.

³ Norsworthy, J.K, Barber, T, Scott, B. Presentation to the Arkansas Dicamba Task Force. "Dicamba: What do we know?" Sept. 21, 2017. Appendix B. Available here:

http://www.aad.arkansas.gov/Websites/aad/files/Content/6126295/Dicamba Task Force Report, sept 21 2017.pdf; and Bradley, K. Presentation to the Dicamba Injury Forum. Dicamba Update July 6, 2017. Available here: https://weedscience.missouri.edu/2017%20Dicamba%20Injury%20Forum.pdf.

⁴ Chow, L. (2018) Dicamba roars back for third season in a row. EcoWatch, June 22, 2018. Available here: <u>https://www.ecowatch.com/dicamba-crop-damage-2580306844.html</u>; Hettinger, J. (2017) Complaints surge about weed killer dicamba's damage to oak trees. Available here: <u>http://investigatemidwest.org/2017/10/09/complaints-surge-about-weed-killer-dicambas-damage-to-oak-trees/</u>; University of Missouri. "Dicamba injury is back in 2018". *Successful Farming.* June 21, 2018. <u>https://www.agriculture.com/crops/soybeans/dicamba-injury-is-back-in-2018</u>.

and sycamore. These trees are critical to environmental health. They stabilize soil and sequester carbon, provide vital early spring nectar and pollen resources for bees and pollinators. Many tree species have complex relationships with pollinators such as lepidopterans (moths and butterflies) and coleopterans (beetles) which serve as food for our protected migratory birds and many fish. Additionally, their fruits, nuts, and seeds provide food for many game species, supporting hunting and fishing revenue streams for many states.

All flora and fauna are under intense pressure resulting from habitat loss, climate change, invasive species, hydrologic changes, and pollution. States throughout the Nation are spending millions of dollars to restore and protect wildlife habitat. Additionally, many farmers provide wildlife and pollinator habitat on their farms through federally-funded conservation programs. Agrichemicals like dicamba can potentially negate, at varying degrees and intensities, the benefits gained through the conservation efforts of hundreds of thousands of people and billions of dollars.

Flowering plants exposed to dicamba (approximately 1% of the field application rate via simulated particle drift) showed a reduction in flower expression and delayed onset of flowering. These flowers were also less likely to be visited by pollinators.⁵ Research has shown that the active ingredient in dicamba is lethal to lady beetles, a commercially important beneficial predatory insect.⁶ It is also known that even low levels of dicamba can have indirect effects on caterpillars; studies have shown that butterfly caterpillars that fed on broadleaf plants exposed to dicamba were much smaller and had a lower pupal mass than those feeding on healthy plants, which can influence their survival and reproductive capacity as adults.⁷

Very little peer-reviewed research has been performed on the new formulations of dicamba and little to no research has been performed on the "inert" or "inactive" ingredients of these formulations. Additionally, farmers and applicators state they frequently mix more than one chemical in a tank during application. We have little to no information about the synergistic effects of the myriad of chemical combinations, the interactions of their inert ingredients, or the toxicity of the frequency and rate of exposure to invertebrates, birds, mammals, fish, reptiles, amphibians, and bacteria and fungi.

Additionally, it is uncertain how much damage from acute and chronic exposure to herbicides is visible to the trained eye. It is unclear if there are sub-optical, though problematic physiologic changes occurring in flowering plants and trees that are not visible or quantifiable.

Dicamba enters waterbodies through foliar and surface runoff.⁸ These water bodies are habitat for fish and wildlife, drinking water resources, areas of recreation, and are used for utilitarian purposes such as irrigation and industrial use. The levels of dicamba in surface water since the massive increase in its use is unknown. Research has indicated that dicamba should be

⁵ Bohnenblust, E., Vaudo, A. Egan, J., Mortensen, D., Tooker, J. (2016) *Effects of the herbicide dicamba on nontarget plants and pollinator visitation. Environmental Toxicology and Chemistry* 35, 144.

⁶ Freydier, L., Lundgren, J. (2016) Unintended effects of the herbicides 2,4-D and dicamba on lady beetles. *Ecotoxicology.* 25, 1270.

⁷ Bohnenblust E, Egan J.F, Mortensen D, Tooker J (2013). *Direct and indirect effects of the synthetic-auxin herbicide dicamba on two lepidopteran species. Environmental Entomology*, 42(3): 586-94.

⁸ Grover, R. et al., (1997) *Magnitude and persistence of herbicide residues in farm dugouts and ponds in the Canadian prairies. Environmental Toxicology and Chemistry*. 16, 638; Nishimura, J., Gazzo, K., Budd, R. (2015) *Environmental Fate and Toxicology of Dicamba*. Department of Pesticide Regulation, California Environmental Protection Agency. Report available here: <u>https://www.cdpr.ca.gov/docs/emon/pubs/fatememo/dicamba.pdf</u>.

considered a possible endocrine disruptor in some species of fish.⁹ With such widespread and increased use of new formulations that contain new inert ingredients, more research is needed to understand the acute and chronic effects of exposure to aquatic and terrestrial organisms.

4. Ineffective or non-existent mechanisms for injury reporting, misuse enforcement, and feedback processes for label reviews.

There is no good feedback mechanism to prompt product label reviews by the state and federal agencies. The main feedback is whether products work for their intended uses, and whether they lose their efficacies or competitiveness in the marketplace. Unlike with pharmaceuticals where patients and doctors can continue to test efficacies and potential side effects, the environment has no voice for feedback.

It is widely accepted that cases of damage are grossly under-reported. There are numerous reasons landowners, managers, and farmers do not file complaints with the Department of Agriculture. These include: lack of trust in the reporting process, lack of confidence in achieving redress of grievances and compensation for damage, fear of losing their organic certification or being delayed in the process of achieving organic status, no-application error was witnessed, fear of social backlash within local farming community, mis-interpreting cause of symptoms as something other than herbicide damage, lack of appropriate reporting process for injuries received, etc... This under-reporting is a significant issue across the U.S. and grossly underrepresents the extent of off-target herbicide drift, volatilization and damage.

There is no accountability for damage to crops, farms, or personal property due to volatilization. In Illinois and many other states across the U.S. the pesticide misuse complaint process is not structured to handle cases where volatilization is the cause of injury. Additionally, many state agencies lack qualified staff to assist in the documentation of injuries. Therefore, many cases of damage are simply not reported and are not documented in any location.

5. Biomonitoring needs

Primary and secondary effects can be silently expressed for decades with no monitoring protocols in place. There is no federal or state funded biomonitoring program that is dedicated to monitoring the environmental and biological impacts of such broadscale use of an herbicide. Products such as dicamba that resulted in fewer harms when products were first registered, now when combined with greatly expanded monoculture acreages and the greatly increased capacities of application technologies, may pose much greater risks to the environment and human health. Environmental risks are magnified in diminished and fragmented habitats that are subjected to other, multiple threats.

There is a significant lack in understanding of this issue with the general public and the majority of landowners do not understand that they have herbicide injury on their property, which further contributes to the harm posed by underreporting injury and damage. There are countless cases of people asking why their trees look so sick this year, not even knowing that nearby agrichemicals can move off-site after application.

⁹ Zhu, L; Li, W; Zha, J; Wang, Z (2015). Dicamba affects sex steroid hormone level and mRNA expression of related genes in adult rare minnow (Gobiocypris rarus) at environmentally relevant concentrations. Environmental toxicology. 30 (6): 693–703.

Closing remarks

Farmers have the right, but are losing the freedom, to grow what they want because of chemical damage. More and more farmers are choosing not to grow GMO crops in favor of specialty crops and organic crops, and many choose to run smaller, highly diversified farms. These farmers are under intense pressure due to dicamba volatilization, drift, and the risk of contamination. They should not have to fear losing their crops, customers, certification, or their ability to produce the crops that their family has grown for generations.

The 2018 growing season is still underway. In many parts of the country, reports of off-target damage are just beginning to become evident. Injuries from off-target exposure to dicamba that are being witnessed in our native ecosystems are avoidable. These ecosystems do not need another stressor, in addition to the existing pressures of habitat loss, climate change, pollution, pesticides, hydrologic changes, and invasive species. For the reasons outlined above, we respectfully request you **decline** the renewal of dicamba on genetically engineered soybeans and cotton.

Sincerely,

Vie Ent them

Kim Erndt-Pitcher Habitat and Agriculture Programs Specialist Prairie Rivers Network

Notto Day

Nathan Donley, Ph.D Senior Scientist Center for Biological Diversity

finstuk

Liz Moran Stelk Executive Director Illinois Stewardship Alliance

July make

Jen Walling Executive Director Illinois Environmental Council

John Steven Branner

John Steven Bianucci Earth's New Ways, LLC Co-founder

John Steven Biannici

John Steven Bianucci Director of Impact Iroquois Valley Farmland REIT, PBC

Mallorking

Mallory Krieger Farmer Training Manager The Land Connection

cc: Charlotte Bertrand, Acting Principal Deputy Assistant Administrator in the Office of Chemical Safety and Pollution Prevention (OCSPP) - US EPA Bertrand.charlotte@Epa.gov

Rick P. Keigwin, Jr., Director of Office of Pesticide Programs - US EPA Keigwin.richard@Epa.gov

From:	Keigwin, Richard
To:	Davis, Donna; Rosenblatt, Daniel; Baris, Reuben; Rowland, Grant
Cc:	Goodis, Michael
Subject:	FW: Arkansas Honeybees and Dicamba
Date:	Friday, June 22, 2018 10:43:43 AM

Here's another one. Reuben-- I think you may have tried to reached out to Mr. Coy already. If you could follow-up with him, I'd appreciate it. He also referenced a Penn State study (he said he'd send me the citation) that documents pollinator declines associated with dicamba use.

-----Original Message-----From: Richard Coy Sent: Thursday, June 21, 2018 9:53 PM To: Keigwin, Richard <Keigwin.Richard@epa.gov> Subject: Arkansas Honeybees and Dicamba

Mr Keigwin,

I would like to make you aware of the Dicamba issues in Arkansas. I am a 3rd generation Beekeeper currently producing my 27th honey crop. 2017 had many challenges with Dicamba which resulted in 50 percent reduction in honey production. 2018 is looking like a repeat. I would like to talk with you about this situation. My number is Thank you for your time.

Richard Coy Coy's Honey Farm, Inc.

Sent from my iPhone

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Message

From:	Baris.Reuben@epa.gov [Baris.Reuben@epa.gov]
Sent:	10/30/2018 3:32:44 AM
То:	MARVIN, THOMAS [AG/1920] [thomas.marvin@bayer.com]
CC:	Kenny, Daniel [Kenny.Dan@epa.gov]
Subject:	Re: Terms of Registration

Not substantially. Only to make them relevant to this registration.

Sent from my iPhone

On Oct 29, 2018, at 8:27 PM, MARVIN, THOMAS [AG/1920] <<u>thomas.marvin@bayer.com</u>> wrote:

Thanks Reuben. Do you anticipate any changes to the Appendices referenced below?

Tom Marvin Director, Federal Regulatory Affairs 1300 I Street, NW Washington, DC 20005 Cell: 202-676-7846 Desk: 202-383-2851

From: Baris, Reuben [mailto:Baris.Reuben@epa.gov]
Sent: Monday, October 29, 2018 6:03 PM
To: MARVIN, THOMAS [AG/1920] <<u>thomas.marvin@bayer.com</u>>
Cc: Kenny, Daniel <<u>Kenny.Dan@epa.gov</u>>
Subject: Terms of Registration

Tom,

In response to Dan's email sent last Friday, we are transmitting the draft proposed terms and conditions for your registration. These terms are listed below. In order to properly effectuate an amendment to the existing registration and label, EPA will need your acknowledgement and concurrence on these items. Thank you,

Reuben

REUBEN BARIS | PRODUCT MANAGER, TEAM 25 | HERBICIDE BRANCH U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS | (703) 305-7356

EPA is extending the expiration of these uses until December 20, 2020. The following terms are separated into five categories: General Terms, Labeling/Relabeling, Tank Mixing and Spray Drift Requirements, Enhanced Reporting, and Data Requirements.

General Terms

- 1. You must submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
- 2. You are required to comply with the data requirements described in the DCIs identified below:
 - a. Dicamba GDCI-XXXXXX-XXXX

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You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

3. This registration will automatically expire on December 20, 2020.

Labeling/Relabeling

Specific regulatory text will be shared later.

Tank Mixing and Spray Drift Requirements

- 4. You must maintain a website at [Insert Relevant Website]. That website will include a list of products that have been tested pursuant to Appendix A and found, based upon such testing, not to adversely affect the spray drift properties of [Insert Product Name]. The website will identify a testing protocol, consistent with Appendix A, that is appropriate for determining whether the tested product will adversely affect the drift properties of [Insert Product Name]. The website must state that any person seeking to have a product added to the list must perform a study either pursuant to the testing protocol identified on the website or another protocol that has been approved for the particular purpose by EPA, and must submit the test data and results, along with a certification that the studies were performed either pursuant to the testing protocols identified on the website or pursuant to another protocol(s) approved by EPA and that the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of [Insert Product Name], to EPA. EPA will notify you when the Agency determines that a product has been certified to be appropriately added to the list, and you will add appropriately certified products to the list no more than 90 days after you receive such notice from EPA. Testing of Tank-Mix Products must be conducted in compliance with procedures as stated forth in Appendix A.
- 5. All test data relating to the impact of tank-mixing any product with [Insert Product Name] on drift properties of [Insert Product Name] generated by you or somebody working for you must be submitted to EPA, along with a certification indicating whether the study was performed either pursuant to the testing protocols identified on the website or pursuant to other protocols approved by EPA and whether the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of [Insert Product Name], at the following address: [TBD]
- 6. The prohibition of using products in a tank-mix with [Insert Product Name] unless the product used is contained on the list at [Insert Relevant Company Website], and the identification of the website address, shall be included in educational and information materials developed for [Insert Product Name], including the materials identified in Appendix D, Section B(1).
- 7. You must maintain, update and follow an Herbicide Resistance Management Plan (HRM) as laid out in Appendix D regarding grower agreements, field detection and remediation, education, evaluation, reporting, and best management practices (BMPs).

Enhanced Reporting

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If [insert registrant] or any of its consultants, attorneys, or agents, acquires any of the information identified below, that information must be reported to EPA under section 6(a)(2) unless you have previously submitted that information to EPA's Office of Pesticide Programs.

- 8. All information received by telephone or in writing regarding potential damage to nontarget vegetation from use of dicamba during the 2019 and 2020 growing seasons regardless of any determination that the incident resulted from misuse (intentional or accidental). All information should be forwarded to EPA 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. Data should be organized by product and state and should include available information regarding acreage involved, plant species involved, severity of damage, and similar information received. This information must be submitted with cumulative totals and be submitted monthly, beginning March 1, 2019.
- 9. All information received by telephone or in writing regarding reports of dicambaresistant weeds, and cases of weed control failure. All information should be forwarded to EPA regardless of which dicamba product may have been used and/or whether or not the alleged resistance occurred after an application made according to label directions.
- 10. A summary of all studies being conducted (or planned to be conducted), sponsored by [insert registrant] (or planned to be sponsored by), or any study being conducted known by any of its consultants, attorneys, or agents that a study investigating pertaining to adverse off-target movement of dicamba (e.g., volatility, physical drift, runoff) must be provided to the EPA.
- 11. Any information or analysis suggesting foods/commodities contain or may contain dicamba residues that are not covered by a tolerance or exceed established tolerance levels.

Given the high number of alleged dicamba-related adverse incidents reported to EPA in 2017 and 2018 by SLAs as well as registrants under FIFRA section 6(a)(2), it is an Agency priority to work with registrants to better understand potential risks and impacts from the use of dicamba on dicamba-tolerant soybean and dicamba-tolerant cotton. The following information is being required to be submitted to the Agency to provide contextual information that would assist the Agency in making any further regulatory decisions regarding these uses.

- 12. Seed sales information for dicamba tolerant soybean seed and dicamba tolerant cotton seed. This information should include all sales of such seed for planting or planted in the 2017 though 2020 growing seasons and should be categorized by state.**
- **Note this term is only applicable to Bayer/Monsanto and its licensees.
- 13. Sales reports categorized by state of [Insert Product Name] since it was originally registered by the EPA for the over-the-top uses on soybeans and cotton.
- 14. Number and type of containers, including volume of material, [Insert Product Name] that carry labeling approved [MM, DD, YYYY] that were relabeled in 2018 with the amended labeling approved by the Agency on [MM, DD, YYYY]. This information should be categorized by state.

Additional Data Requirements

The following additional studies are required as a condition of this amended registration. Since these are non-guideline studies, prior to developing a protocol and initiating any study, [Insert Registrant] must meet with EPA staff to engage in a data quality objective discussion regarding

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environmental conditions, sampling, and species evaluated. Protocols must be submitted before December 31, 2018 for the Agency to review. Field studies must be conducted during the 2019 growing season. Final reports must be submitted to the Agency in connection with the January 15, 2020 required reporting submission outlined in Appendix D, Section D.

- 17. Field studies examining impacts on plant height and yield from primary and secondary drift off-target, with transects in all four cardinal directions. These studies should represent varied geographic areas and include locations where high numbers of complaints have been logged and ranges of environmental conditions (e.g., temperature and humidity).
- 18. Studies to investigate temperature effects on volatility of dicamba. The use of humidome studies would allow EPA to evaluate the effects of temperature in a controlled environment for a multitude of temperature, relative humidity, and tank mix pH conditions.
- 19. Ecological effects data on non-target plants, related to survival, growth and reproduction for select sensitive tree/shrub/woody perennial species. The study design could involve an extended period for consideration of perennial species.
- 20. Studies examining the effects of dicamba-containing runoff water on non-target plants, including runoff to agricultural irrigation water. Data evaluating the response of non-DT soybean or other non-target plants exposed to irrigation water contaminated with dicamba is focus of this study.
- 21. Studies examining the effect of lower pH on secondary movement of dicamba. The analysis should examine variability introduced by tank mix partners on the pH of the finished solution. The study should be broad enough to test a series of waters which will mimic the variety of water pH throughout the country, particularly in areas with the largest number of incidents. These tests would examine variability of tank mixture combinations relative to the pH of the applied solution.

From: Kenny, Daniel
Sent: Friday, October 26, 2018 7:44 PM
To: Goodis, Michael <<u>Goodis.Michael@epa.gov</u>>
Cc: Rosenblatt, Daniel <<u>Rosenblatt.Dan@epa.gov</u>>; Baris, Reuben <<u>Baris.Reuben@epa.gov</u>>; Hathaway, Margaret <<u>Hathaway.Margaret@epa.gov</u>>; Schmid, Emily <<u>Schmid.Emily@epa.gov</u>>
Subject: FW: Dicamba

FYI – This head's up went out to the registrants to alert them of our need for a speedy agreement on the terms and conditions.

From: Kenny, Daniel Sent: Friday, October 26, 2018 7:26 PM To: Max Safarpour <<u>maximilian.safarpour@basf.com</u>>; Houtman, Bruce (BA) <<u>bahoutman@dow.com</u>>; 'MARVIN, THOMAS [AG/1920]' <<u>thomas.marvin@bayer.com</u>> Subject: Dicamba

Dear Registrant -

As you know, the office is working toward finalizing a regulatory decision on the OTT uses for dicamba. And as has been discussed, the procedures of FIFRA require that you acknowledge and affirmatively seek the various labeling changes and regulatory conditions that would be applicable to these uses going forward. This specifically refers to the parameters such as the negotiated label, the methods and schedule for accomplishing the label transition with retailers and the user community, the

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commitments for developing additional data to support the uses going forward and several other key areas.

OCSPP has been developing a suite of assessments and regulatory documents which will support this decision. We are looking ahead to next week and in order to position this so that a timely decision can be executed, I am writing to ask that you prepare for an email message from EPA on Monday, October 29, in which we will transmit to you (and the other impacted registrants) the draft proposed terms and conditions. And in order to properly effectuate an amendment to the existing registration and label, EPA will need your acknowledgement and concurrence on these items.

Therefore, I would ask for your company to anticipate this and to work towards developing a timely response on the information EPA will be sharing with you.

Thank you,

Dan Kenny

Daniel Kenny, Chief Herbicide Branch Registration Division Office of Pesticide Programs U.S. Environmental Protection Agency

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Message

From:	MARVIN, THOMAS [AG/1920] [thomas.marvin@bayer.com]
Sent:	10/18/2018 3:49:05 PM
То:	Baris, Reuben [Baris.Reuben@epa.gov]; tina.bhakta@bayer.com
Subject:	RE: EPA label edits for Xtendimax 524-617
Attachments:	MASTER LABEL 524-617_10182018.pdf

Reuben,

Please find attached a further revision in response to EPA's comments.

Tom

Tom Marvin Director, Federal Regulatory Affairs 1300 I Street, NW Washington, DC 20005 Cell: 202-676-7846 Desk: 202-383-2851

From: Baris, Reuben [mailto:Baris.Reuben@epa.gov]
Sent: Thursday, October 11, 2018 6:47 PM
To: MARVIN, THOMAS [AG/1920] <thomas.marvin@bayer.com>; tina.bhakta@bayer.com
Subject: EPA label edits for Xtendimax 524-617

Tom and Tina,

Attached are the latest round of comments from me and my team. Happy to walk you all through them if anything is unclear.

I think we're still making progress, but with all of the uncertainty on the Endangered Species side, there is still a lot of work left.

Thanks.

Reuben

REUBEN BARIS | PRODUCT MANAGER, TEAM 25 | HERBICIDE BRANCH U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS | (703) 305-7356

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Message

From:	Scott, David E [scottde@purdue.edu]
Sent:	10/11/2018 11:05:11 AM
То:	Baris, Reuben [Baris.Reuben@epa.gov]
CC:	Reed, Leo A [reedla@purdue.edu]; George Saxton [saxtong@purdue.edu]
Subject:	Dicamba Registration

Reuben,

I hope all is going well. I know you are currently very busy, so I will get right to the point. Any idea as to when the Agency will make the registration decision on dicamba? Indiana needs to assemble a work group to determine how we will react to the decision and prepare for the 2019 use season. Starting those deliberations without a clear idea of where the Agency is headed is extremely difficult.

Because of the tight timeline, it appears unlikely that SLAs are going to have an opportunity to comment constructively and meaningfully on the decision or the label language that might result prior to public release. Therefore, in developing a 2019 label for these products, it is strongly recommended that the Agency:

- 1. assign a specific distance to the application restriction on downwind adjacent and neighboring sensitive crops/sites;
- 2. clarify specifically all of the adjacent and neighboring sites that require buffers;
- 3. clarify that wind speed restrictions greater than 10 mph include gusts;
- 4. specify required procedural and record keeping to provide evidence that an inversion condition did not exist in the field during the time period of application;
- 5. clarify specifically that off-target movement from volatility after the application either is or is not considered to be a non-compliant act that the applicator will be held responsible for.

Although SLAs have learned that it is very challenging to collect evidence to confirm most of the above, including environmental evidence to support drift, versus application into inversion, versus volatility, we should at least have a common and consistent set of well-understood drift management design standards on the label to guide our compliance investigations. That seems like the least that the Agency could do, in light of the fact that the registrants continue to insist that the product can be used as directed without unreasonable adverse effects and that all of the 2017 and 2018 incidents are the sole responsibility of non-compliant applicators. Currently with the scientific uncertainty surrounding the source or cause of off-target movement, the registrants can continue to place blame on the applicator with the knowledge that state responders probably cannot piece together what actually occurred during application.

Thanks for your consideration. We realize that this is a difficult decision.

Dave Scott Pesticide Administrator Office of Indiana State Chemist scottde@purdue.edu 765-494-1593

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Update on Dicamba Evaluation

As of Wednesday, October 3rd, EFED's position on enlarging the action area for evaluation of endangered species was to incorporate an omni-directional, 60-m "buffer" around the soybean and cotton crop data layers and determine where the enlarged action area overlapped with the species range/critical habitat at 1% or greater. The 60-m "buffer" was based on a weight-of-evidence evaluation of available data for visual injury versus yield at the reproductive stage, which indicated that at 10% visual injury, a 5% reduction in yield would be expected.

The 60-m "buffer" was presented as preliminary and contingent on the results of further evaluation of the 2018 Norsworthy Proctor Arkansas field study. Early evaluation of the visual signs of injury curves for transects in Norsworthy were evaluated against a registrant-suggested 20% visual signs of injury threshold to approximate the threshold for effects on height and yield. Subsequent EFED evaluation of all available visual signs of injury measurements compared with height and yield effects measurements indicated a reasonable and protective threshold for visual signs would be 10%. The Norsworthy study when evaluated with a 10% visual signs of injury threshold suggested that a larger buffer (135 m) would be appropriate. However, some potentially confounding issues regarding this study were presented by the registrant as suggestive that the study was not reliable.

On Thursday, Oct 4th, EPA members of EFED and RD participated in a conference call with Dr. Norsworthy regarding the 2018 study to get clarification on the potentially confounding issues:

• Issue One: Acetochlor tank mix and potential to adversely affect soybeans during the trials

With regards to the effects of the use of Warrant, Dr. Norsworthy indicated it was the registrant and grower, not Dr. Norsworthy, who prepared the tank mix to include Warrant and that after the delay Dr. Norsworthy suggested that a new tank mixture be prepared, but that the registrant and grower recommended using the prepared tank mix. With regards to damage resulting from acetochlor, Dr. Norsworthy indicated that Warrant can be used as post-emergent application on soybeans and that there was no acetochlor damage to the Xtend soybeans, planted on the treated field, or the Roundup Ready soybeans, planted surrounding the treated field. Additionally, Dr. Norsworthy indicated that the damage resulting from acetochlor exposure is fundamentally different from that produced by dicamba and that the majority of weed scientists can differentiate between these types of damage. While dicamba damage results in a cupping of the leaves, acetochlor damage results in a crinkling of the leaf and a wavy appearance.

• Issue Two: Acetochlor tank mixture could alter the volatile potential of dicamba in the study, negating Xtendimax with Vapor Grip performance

Dr. Norsworthy has investigated the effect of tank mixture partners and tank holding time as it relates to tank content pH. This was done to address any concern that conditions of the tank mixture could have altered the pH of the spray tank contents such that the buffering capacity of Xtendimax would be nullified and promote low pH shift, inducing enhanced dicamba volatility. Preliminary data show no effect on tank pH with the tank mix partners, including microencapsulated acetochlor (Warrant), with and without tank mix holding time

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Dr. Norsworthy indicated that he has also conducted trials under hoop tunnels investigating volatility of Xtendimax with (1) Roundup Powermax and Warrant and (2) Roundup Powermax and Warrant that had been sitting in a tank for 4 days (approximating the tank holding time encountered in the field study). Preliminary data indicates that there was no increase in volatility based on tank holding time.

Dr. Norsworthy has committed to sharing these data with EPA.

Issue Three: Plant damage scoring is alleged to be atypical compared to other field studies

Dr. Norsworthy referred EFED to the two types of visual signs of injury methods used to score observations of injury during the field study. Both methods were employed side by side during the evaluation of transect. Both methods are in close agreement with respect to visual damage extent at each point along the transects.

Issue Four: Tarped plants were insufficient to prevent spray drift damage, thereby overestimating the role of vapor drift in the study

Dr. Norsworthy emphasized that the use of the tarps was at the behest of the registrant sponsor and are not inconsistent with the method used in other field studies.

Issue Five: The use of bucketed plants along transects to segregate damage from primary drift from secondary vapor drift was inappropriate due to the potential for cross contamination with adjacent un-bucketed plants.

Dr. Norsworthy indicated that plants within 6 inches of the outside of the buckets were removed in order to prevent cross contamination of the bucketed plants from plants impacted by primary and secondary drift.

Issue Six: The use of bucketed plants along transects to segregate damage from primary drift from secondary vapor drift unduly stressed the plants and resulted in questionable results attributed to vapor exposure.

Dr. Norsworthy indicated that buckets were in-place only for the duration of spray and for up to 30 minutes post application. He did state that visible plant stress occurred as a result of covering the plants with tarps and buckets. However, the plant damage from tarp/bucket effects was easily distinguishable from the damage resulting from dicamba exposure and the damage from tarps/buckets was no longer apparent 14 days after treatment. His presentation of visual signs of damage for bucketed plants was based on the extent of visual signs of damage consistent to the scoring of the types of damage attributable to dicamba exposure. Dr. Norsworthy also reiterated the similarity of the extent of damage with distance between bucketed plants, suggesting a common level of exposure.

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Issue 7: Irrigation confounds the transect data because the irrigation water can be transporting herbicide to the off-treatment field soybeans.

Dr. Norsworthy confirmed for EFED that no irrigation water originating from the treatment area was transported to the transect areas for the west, east and south transects of the field study. The only transect receiving irrigation water originating from the treated field was to the north. (Note for this reason, EFED has confined its evaluation of the field study to the west, east and south transects.) Dr. Norsworthy also indicated that data from another site, where irrigation was not performed, but a significant rainfall event occurred within three days of application, produced similar off-field plant effects as seen in the north transect of Proctor, Arkansas field study.

Future availability of yield data

EPA asked if yield data would be available soon for use in the analysis. Dr. Norsworthy indicated that the fields would not be harvested until the 3rd or 4th week of October.

• Potential hypotheses to explain differences in the Arkansas data and other field trials from other areas

EPA inquired of Dr. Norsworthy his thoughts as to why the results from his trials were different than those observed in other areas of the country. Dr. Norsworthy indicated that he wasn't sure. Dr. Norsworthy indicated there could be issues relating to the proximity of the region to Crowley's Ridge and the frequency of inversions in the area, and that soil pHs were low in region relative to other areas of the country. In the end, Dr. Norsworthy indicated that there were a lot of complicating factors and that temperature, while it plays a major role in volatilization, was not the only factor.

Referring back to the discussion of irrigation, Dr. Norsworthy also discussed the potential for irrigation to play a role. He opined that Midwest soils may have sufficient moisture and fertility characteristics as opposed to the South-central soils which are thinner in depth of topsoil and often require irrigation to maintain adequate soil moisture. He also opined that the presence of irrigation has the potential to enhance visual damage extent as the plants are actively growing, but may also limit the extent of damage to yield because the plants have resources to affect recovery from damage.

EFED conclusions:

Based on this discussion, EFED cannot preclude the use of the Norsworthy data in the expansion of the dicamba action area. Acceptance of the Norsworthy data as valid results in the recommendation of a 135-m "buffer" around the soybean and cotton crop data layers for the purposes of establishing a protective and technically defensible limit to the action area for the proposed regulatory action.

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Message

From:	Corbin, Mark [Corbin.Mark@epa.gov]
Sent:	10/5/2018 5:31:04 PM
To:	Jason Keith Norsworthy [jnorswor@uark.edu]
CC:	Odenkirchen, Edward [Odenkirchen.Edward@epa.gov]; Anderson, Brian [Anderson.Brian@epa.gov]; Peck, Charles
	[Peck.Charles@epa.gov]; Farruggia, Frank [Farruggia.Frank@epa.gov]
Subject:	Phone Call
Attachments:	one pager update norsworthy 100518.docx

Dr Norsworthy

Thank you for taking the time out yesterday to walk us through your data and answer all of the questions we need to address. To that end we have drafted a one-pager for our management to summarize the points we discussed and the responses. We would like to run that by you to ensure that it accurately reflects your take on what we discussed and the points that were made.

I realize you are busy but if you have time please take a look at the attached summary and provide and any feedback you can it would be much appreciated. And of course if you have any questions please let me know. We are off Monday for Columbus day but I will be around Tuesday.

Thank you again

Mark Corbin Branch Chief, Environmental Risk Branch 6 Environmental Fate and Effects Division (7507P) Office of Pesticide Programs U.S. Environmental Protection Agency Washington DC 20460 703-605-0033

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Message

From:	Beck, Nancy [Beck.Nancy@epa.gov]
Sent:	10/1/2018 10:46:27 PM
То:	Steve Smith [ssmith@REDGOLD.com]; Bennett, Tate [Bennett.Tate@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov];
	Bolen, Derrick [bolen.derrick@epa.gov]
CC:	Keigwin, Richard [Keigwin.Richard@epa.gov]; Kenny, Daniel [Kenny.Dan@epa.gov]; Baris, Reuben
	[Baris.Reuben@epa.gov]; Keller, Kaitlin [keller.kaitlin@epa.gov]
Subject:	RE: Thank you

Steve,

Thank you for coming in to meet with us and for providing this follow-up information. We greatly appreciate your taking the time to engage with the Agency on this important matter.

The EPA values your input as it will help inform our regulatory decision on whether to continue to allow the over-the-top uses of dicamba products.

Many thanks, Nancy

Nancy B. Beck, Ph.D., DABT Deputy Assistant Administrator, OCSPP P: 202-564-1273 M: 202-731-9910 beck.nancy@epa.gov

From: Steve Smith [mailto:ssmith@REDGOLD.com]
Sent: Sunday, September 30, 2018 3:41 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>; Bennett, Tate <Bennett.Tate@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>;
Bolen, Derrick <bolen.derrick@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>; Kenny, Daniel <Kenny.Dan@epa.gov>; Baris, Reuben
<Baris.Reuben@epa.gov>
Subject: Thank you

Ms. Beck, Ms. Bennett, Mr. Baptist and Mr. Bolen,

First I want to thank you for your commitment of time to meet with me on Friday. The chance to tell the story of what I see is a real threat to all of agriculture, not just specialty crops, was really appreciated. I had mentioned my Congressional testimony from 2010 so I have attached that to this note. In it you'll see some bolded statements concerning the risk to specialty crops, that the widespread use of dicamba is incompatible with Midwestern agriculture and that the increased usage of dicamba is poor public policy. It is my hope that you can see that the these statements are not only true, but unfortunately a reality that has harmed all segments. The public will become more aware of what is happening and all of agriculture will suffer a "black-eye" when everyone figures out the source of the damages to sensitive landscapes and trees in addition to non-tolerant crops.

One of the items you questioned me about was the coordination of concerns among many different stakeholder groups. Specifically, United Fresh was mentioned and I casually made the comment that several years ago I did approach them about the issue but they had never really taken ahold of the concern. One reason for this is that much of their major production takes place in regions where dicamba will not be extensively used and the other reason is that much of the fresh produce they deal with is imported and not even raised in the US. Their limited membership that would be affected has just not been vocal enough to spur them into the advocacy role this product really does demand

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for specialty crops. And also, as indicated, from a political standpoint, most anything that the processing industry would deem beneficial, United Fresh is in general opposition. That is disappointing to me but is in fact the reality and I wanted to explain that situation a little further.

Other segments of Midwestern agriculture are beginning to take serious note of the threat of dicamba use. Recently Beck's Seeds (the largest independent seed producer) and Stine Seed authored a letter to EPA explaining their concerns about grower choices. But even deeper in their concerns has been the issue of seed germination problems from off-target dicamba movement. When dicamba hits soybean seed, the germination is greatly reduced so their entire seed crop is at risk and many acres will be unacceptable to be used as seed for 2019. AAPCO has expressed their concerns about what this issue is doing to the regulatory departments in all the affected states and Indiana specifically commented in a letter concurring with the AAPCO note. At a recent meeting of the Indiana Pesticide Review Board, the State Chemist described their department not as the investigative and regulatory agency they were designed to be but as the "Dicamba Response Team," a description that emphasizes how their department has been inundated and fully absorbed into the problems dicamba has caused. I made a brief mention that my own home was hit and I just received the damage estimate from a professional landscaper with damage in excess of \$9000.00. The odds of me getting any settlement is probably low as an individual, but this is an example of what will be happening to the general public and they will not stand for it in the long run.

Any registration of dicamba that even remotely resembles the status quo will harm all of agriculture. As I suggested in our meeting, I recommend that **no post-planting applications should be approved**. It will not completely eliminate all potential damages but would go a long way to reduce problems by a major percentage.

Thank you again for your time, I do realize the amazing strain this technology has caused all regulatory agencies in the country and you are at the focal point of trying to do the right thing for the future. The clamoring voices of the manufacturers and special interest groups demanding reregistration should not drown out the voices of those who understand the risks involved. Those risks are both predictable and preventable.

Sincerely,

Steve Smith Chairman, Save Our Crops Coalition

Steve Smith | Director of Agriculture | Red Gold 1500 Tomato Country Way | P.O. Box 83 | Elwood, IN 46036 Tel 765.557.5500 x1419 | Personal Matters / Ex. 6 Fax 765.557.3624 ssmith@redgold.com | www.RedGoldFoods.com



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		2017	2018
STATE	October 15, 2	2017	15-Oct-18
Alabama		7	5
Alaska	Not in Survey		NR
Arizona	Not in Survey		0
Arkansas		986	200
California	Not in Survey		NR
Colorado	Not in Survey		0
Connecticu	Not in Survey		NR
Delaware	Not in Survey		0
Florida	Not in Survey		0
Georgia		0	No Response
Hawaii	Not in Survey		NR
Idaho	Not in Survey		NR
Illinois		245	330
Indiana		128	143
lowa		107	147
Kansas		125	No Response
Kentucky		18	No Response
Louisiana		2	35
Maine	Not in Survey		NR
Maryland	Not in Survey		0
Massachus	Not in Survey		NR
Michigan		2	8
Minnesota		250	29
Mississippi		78	69
Missouri		310	217
Montana	Not in Survey		NR
Nebraska		93	105
Nevada	Not in Survey		NR
New Hamp	Not in Survey		NR
New Jersey	Not in Survey		0
New Mexic	Not in Survey		0
New York	Not in Survey		0
North Carc		15	10
North Dake		40	47
Ohio		28	52
Oragon	Not in Current	19	25
Dependence	Not in Survey	0	
Pennsylvar Rhodo Jolov	Not in Survey	0	U
South Care	Not in Survey	3	No Response
South Dak		114	46
Tennessee		132	52
		- 52	52

2017	Kevin Bradley Survey
2018	AAPCO survey of states
NR	Not Registered
No Response	Registered but state hasn't provic

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Texas	Not in Survey		5
Utah	Not in Survey		NR
Vermont	Not in Survey		NR
Virginia	C)	0
Washingto	Not in Survey		NR
West Virgi	2	2	1
Wisconsin	4	Ļ	No Response
Wyoming	Not in Survey		No Response

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led information

Message	
Message From: Sent: To:	Wozniak, Chris [wozniak.chris@epa.gov] 9/28/2018 1:03:47 PM Dyer, Brian [Dyer.Brian@epa.gov]; Wozniak, Chris [wozniak.chris@epa.gov]; Cerrelli, Susanne [Cerrelli.Susanne@epa.gov]; Kough, John [Kough.John@epa.gov]; Gagliardi, Joel [Gagliardi.Joel@epa.gov]; Martinez, Jeannette [Martinez.Jeannette@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Borges, Shannon [Borges.Shannon@epa.gov]; Reynolds, Alan [Reynolds.Alan@epa.gov]; Huskey, Angela [Huskey.Angela@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]; Kausch, Jeannine [Kausch.Jeannine@epa.gov]; Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]; Facey, Judy [Facey.Judy@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov]; Leahy, John [Leahy.John@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]; Striegel, Wiebke [Striegel.Wiebke@epa.gov]; Eiden, Catherine
CC: Subject:	[Eiden.Catherine@epa.gov]; Hathaway, Margaret [Hathaway.Margaret@epa.gov]; Bilardo, Elyse [Bilardo.Elyse@epa.gov]; Zuber, Mohammed [Zuber.Mohammed@epa.gov]; Butler, Sarah [butler.sarah@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Welch, Kara [welch.kara@epa.gov]; Murasaki, Seiichi [Murasaki.Seiichi@epa.gov]; Perry, Mark [Perry.Mark@epa.gov]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Pierce, Amanda [pierce.amanda@epa.gov]; Osterweil, Elyse [Osterweil.Elyse@epa.gov]; Ridley, Caroline [Ridley.Caroline@epa.gov]; Ellis, Frank [Ellis.Frank@epa.gov]; Kelly, Stephanie [kelly.stephanie@epa.gov] Becker, Jonathan [Becker.Jonathan@epa.gov]; Chism, William [Chism.Bill@epa.gov]; Jones, Arnet [Jones.Arnet@epa.gov]; Cournoyer, Patrick [patrick.cournoyer@fda.hhs.gov] Drifting Weedkiller Puts Prized Trees At Risk

FYI

https://www.npr.org/sections/thesalt/2018/09/27/651262491/a-drifting-weedkiller-puts-prized-trees-at-risk

A Drifting Weedkiller Puts Prized Trees At Risk

A Drifting Weedkiller Puts Prized Trees At Risk

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September 27, 20184:09 PM ET

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Heard on All Things Considered



Dan Charles

Twitter



Enlarge this image

Cypress trees line Reelfoot Lake, in northwestern Tennessee. Some of them show signs of damage from an herbicide that farmers sprayed on nearby soybean fields. **Dan Charles/NPR hide caption**

toggle caption

Dan Charles/NPR

Cypress trees line Reelfoot Lake, in northwestern Tennessee. Some of them show signs of damage from an herbicide that farmers sprayed on nearby soybean fields.

Dan Charles/NPR

Mike Hayes and I are sitting on the patio of <u>Blue Bank Resort</u>, the business he owns on Reelfoot Lake, in Tennessee. The sun is going down. It's beautiful.

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What really catches your eye here is the cypress trees. They line the lake, and thousands of them are standing right in the water. Hayes tells me that they are more than 200 years old.

They were here in **1812**, when the lake was formed: A cataclysmic earthquake shook this area, the land dropped, and water from the Mississippi River rushed in and covered **15**,000 acres of cypress forest. Yet these trees survived and became a home for fish and birds.

"The fishing's around the tree; the eagles nest in the tree, the egrets. So much wildlife all out in the trees," he says. "The trees define Reelfoot Lake."



Enlarge this image

Mike Hayes owns Blue Bank Resort. His great-grandfather began taking visitors on tours of the lake in the **1880**s. **Dan Charles/NPR hide caption**

toggle caption Dan Charles/NPR

Mike Hayes owns Blue Bank Resort. His great-grandfather began taking visitors on tours of the lake in the 1880s.

Dan Charles/NPR

Last year, though, Hayes noticed that the trees didn't look right. Their needles were turning brown. Some were curling. "Something was going on that never happened before," he says.

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Neighbors were talking about it. Everybody had a theory: disease; drought; insects. "They thought of other things, but when it came down to it, it was a drifting chemical," Hayes says.

Article continues after sponsorship

The chemical is called dicamba. It's a weedkiller, and it blew in from nearby soybean and cotton fields.



<u>The Salt</u>

<u>These Citizen-Regulators In Arkansas Defied Monsanto. Now They're Under</u> <u>Attack</u>

Similar things have happened across the Midwest and Mid-South over the past two years. From Mississippi to Illinois, people have noticed trees or other kinds of wild vegetation that show signs of damage from dicamba. The Environmental Protection Agency now has to decide whether farmers should be allowed to keep using this chemical in quite the same way. The agency's previous approval expires at the end of the year.

Many farmers have come to rely on dicamba. In the area around Reelfoot Lake, the vast majority of farmers use the chemical, says Jason Hamlin, a consultant who works with farmers in west Tennessee and southeastern Missouri.

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Enlarge this image

The edges of this sycamore leaf are turned upward into a cuplike shape, the typical sign of exposure to dicamba. **Dan Charles/NPR hide caption**

toggle caption

Dan Charles/NPR

The edges of this sycamore leaf are turned upward into a cuplike shape, the typical sign of exposure to dicamba.

Dan Charles/NPR

Farmers have turned to dicamba because it still works; many other herbicides don't anymore, because weeds have become resistant to them. Dicamba is a new option for farmers growing soybeans and cotton because the big seed company Monsanto, which is now owned by Bayer, created new genetically modified versions of these crops that can tolerate dicamba. This means that farmers can spray this chemical and the weeds die, but the crops are fine. Farmers got permission to spray dicamba on their new, tolerant crops two years ago.

"Nobody wants it to get on their neighbor's crop, the tree line, the lake, the state park, whatever; nobody wants that. But they have to have a tool to control their weeds or they can't farm, you know?" says Hamlin.

Dicamba has long been known as a chemical that's hard to control. It can evaporate from the soil or plants where it was sprayed, and that vapor can drift for miles. But both Monsanto and the chemical company BASF developed new "low volatility" formulations to solve this problem.

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The problem resurfaced, though. In each of the past two years, drifting dicamba has been blamed for damaging more than 1 million acres of neighboring crops, mostly soybeans. It has provoked fights between farmers and set off a huge controversy.



Enlarge this image

Prematurely brown needles on this cypress tree show evidence of exposure to dicamba. Dan Charles/NPR hide caption

toggle caption Dan Charles/NPR

Prematurely brown needles on this cypress tree show evidence of exposure to dicamba.

Dan Charles/NPR

Receiving less attention, so far, is the damage to wild plants. Few people were watching them quite so closely.

"I've never really paid attention to trees," says Tom Burnham, a farmer in Mississippi County, Ark. "But in the last two or three years I've actually started looking at trees in people's yards and everything, and you know it's amazing, once you start looking, what you see."

So I started looking. Greg Allen, an agricultural extension agent with the University of Tennessee, took me on a little drive down a country road a few miles from Reelfoot Lake. We passed a big field of soybeans on our right. On our left was woodland.

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I didn't really know what to look for. I asked Allen what caught his eye. He rolled down his window and gestured toward a nearby tree. "Well, one thing that would've caught my eye is that sycamore, and them itty-bitty leaves," he says.

Normal sycamore leave are big and flat; these are curved into the shape of small cups, a sign of exposure to dicamba. "And you can see it goes all the way to the top," he says. "That's a 30- or 40-foot tree."

I realize that the leaves of almost every sycamore tree nearby show similar symptoms. Other trees, though, do not. Dicamba affects various plant species very differently. Based on what scientists have observed this past year, the tree species that seem most sensitive to dicamba include sycamore, cypress, Bradford pear, and white oak.



<u>The Salt</u>

West Texas Vineyards Blasted By Herbicide Drift From Nearby Cotton Fields

The amount of damage also changes from place to place. In Iowa, forestry experts haven't seen many signs of exposure to dicamba. In Arkansas, though, a scientist that state officials hired to conduct a survey saw dicambadamaged trees in every town that he visited across the northeastern part of the state.

It's now up to the EPA to decide just how much protection these trees need, balancing that against the desire of many farmers to keep using dicamba.

There are billions of dollars at stake. Monsanto is arguing that the government can't take this tool away from farmers. If used properly, the company says, dicamba doesn't hurt anything but weeds.

Back at Reelfoot Lake, Hayes says his prematurely brown cypress trees are evidence that this isn't true. He thinks state politicians are ignoring the problem — in part because they're scared of Monsanto.

"The problem with dicamba is, there's so much money behind it," he says with a deep sigh. "I've never seen so many people run from a problem so bad in my life. It really hurts to lose what we're about to lose."

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Dicamba hasn't killed the trees in the lake, but Hayes is convinced that the chemical has weakened them. And new cypress trees can't sprout and grow in the water. The trees that make Reelfoot Lake what it is — if they die, they're gone forever, he says.

Do not believe everything you read on the internet, especially quotes from famous people. Abraham Lincoln (probably)