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

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

DATE: November 1, 2018

SUBJECT: Transmittal of "Over-the-Top Dicamba Products for Genetically Modified Cotton and Soybeans: Benefits and Impacts"

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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

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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.

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 (MOA[1]). 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.

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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 Xtendimax™ and Fexapan™ expiring on November 9, 2018 and Engenia™ 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 registrants on 2,622 alleged incidents involving dicamba.

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 off-field (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 110-foot 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).

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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,

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) herbicides[4] 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;

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[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 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.

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

Active Ingredient	WSSA Group No.	Documented Resistance[1]	Total Area Treated (acres)[2]	Chemical Cost ($/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	-

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, cloransulam-methyl, 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

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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 pre-selecting 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 stand-alone 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.

<u>Uncertainties</u>

- 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

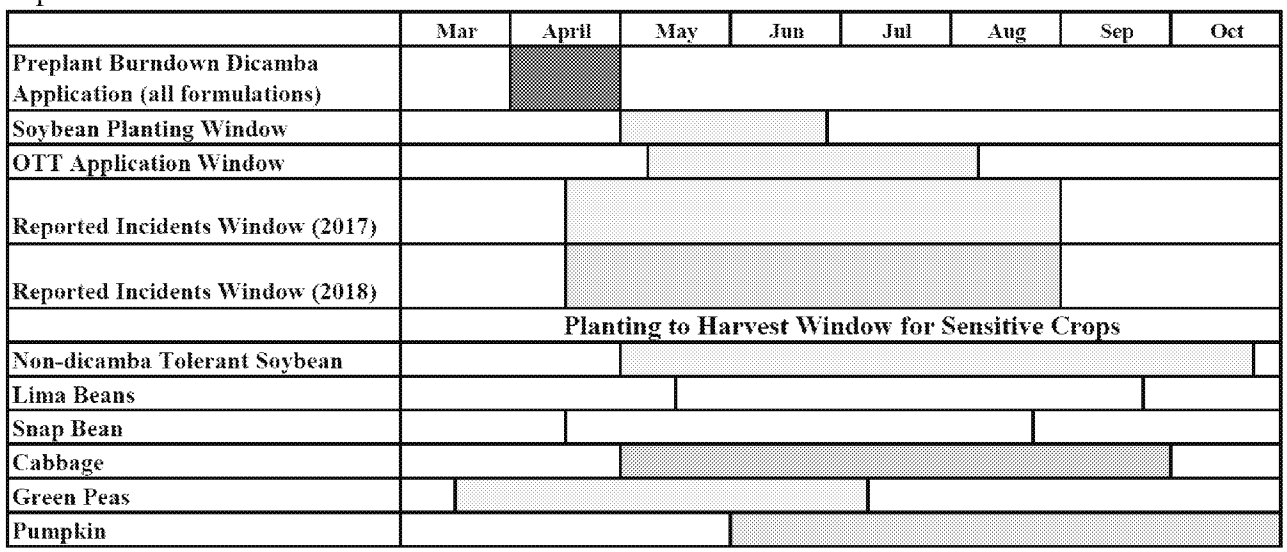
In 2017 and 2018, there have been many incidents alleging potential damage from off-target dicamba movement reported to the Agency by the registrants under FIFRA Section 6(a)2, by individual growers, and by State regulatory partners. Many other reports have been published in the extension reports, agricultural 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).

Impacts to growers of other dicamba sensitive crops. 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 Incidents[1] in 2017 and 2018



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

Impacts to the landscape. 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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