Memorandum Supporting Decision to Approve Registration for the Uses of Dicamba on Dicamba Tolerant Cotton and Soybean

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I. Summary

This memorandum presents the rationale to support the decisions of the U.S. Environmental Protection Agency (referred hereafter as EPA or the Agency) to register[1] under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), three end use dicamba products for use on dicamba tolerant (DT) cotton and soybeans. Bayer and BASF submitted registration applications on July 2, 2020 for new registrations of XtendiMax and Engenia for use on DT cotton and DT soybeans. Syngenta submitted an application for a label amendment on August 12, 2020 that proposed extending the upcoming December 20, 2020 expiration date for Tavium.[2] This document does not approve any particular product for sale and distribution. Products are individually approved through a separate Registration Notice that is the license that permits the sale and distribution of the pesticide product.

EPA has evaluated extensive information and data from registrants, academics, weed scientists and field experts, information from the open literature and even though EPA did not hold a public comment opportunity for these registration actions, the Agency received and considered information from other stakeholders. EPA conducted robust evaluations of the risks to human health and the environment, including risks to non-target plants from potential spray drift and volatile emissions, as well as the benefits and impacts to users of the products and non-users. EPA conducted species-specific evaluations to make effect determinations for federally listed endangered and threatened species (listed species), and where necessary consulted with the Fish and Wildlife Service[3] under section 7(a)(2) of the Endangered Species Act (ESA). A recent decision of 9th Circuit Court of Appeals noted certain deficiencies in EPA's 2018 registration decision for certain dicamba products for use on DT crops. While conducting its evaluations for this new dicamba decision, EPA considered the issues raised by the Court. As explained below, EPA believes this decision meets the FIFRA standard for registration and is supported by substantial evidence.

Based on these robust assessments, which took into account the control measures required by the labeling, EPA determined that the applications meet the standard for registration under FIFRA section 3(c)(5). The labeling requirements and restrictions associated with these registration actions include a suite of mandatory control measures that address the potential for spray drift, volatile emissions and runoff. These include a national application cut-off date of June 30 and July 30 for soybeans and cotton, respectively, the mandatory use of approved volatility reduction adjuvants[4] (VRAs), and a larger infield downwind buffer. Additionally, the registrations restrict use to certified applicators (and not by persons under their supervision) and require dicamba-specific training on the risks associated with dicamba, required control measures, and resistance management measures necessary to prevent unreasonable adverse effects. The registration also includes requirements for enhanced incident and resistance reporting by the registrants to ensure

[1] One of the products described in this rationale (EPA Registration Number 100-1623; A21472 Plus VaporGrip Technology (Alternate Brand Name: Tavium)) is still registered, but the registration is set to expire in December 2020. In the case of that product, EPA has presented the rationale for the decision to extend the registration.
[2] Since Tavium is currently registered for use on DT cotton and DT soybeans, none of these registrations are considered to include any new uses.
[3] There were no listed species within the jurisdiction of the National Marine Fisheries Service that required consultation for this action.
[4] Also called volatility reduction agents (VRA) or pH buffering adjuvants.

EPA has appropriate information to continue monitoring these registrations. EPA is also requiring enhanced record-keeping from applicators to ensure compliance with control measures. EPA is requiring as a term of registration the assurances from the registrants that the VRAs/pH Buffering Adjuvants is available in amounts necessary for use with the dicamba products for use on DT crops.

The control measures included in these registrations are quite different from those that were approved in the actions taken in 2018. Table 1 summarizes the major 2020 control measures compared to those in the 2018 registrations.

Table 1. Summary of major 2020 control measures compared to 2018

Element	2018 Decision	2020 Decision
Spray drift	110 ft downwind in-field buffer	240 ft downwind in-field buffer
Volatility – timing of applications	-Limit of two OTT applications of dicamba per field per year for both DT cotton and DT soybeans -Applications only permitted between one hour after sunrise and two hours before sunset -Use allowed until specified crop growth stage	-Limit of two OTT applications of dicamba per field per year for both DT cotton and DT soybeans -Applications only permitted between one hour after sunrise and two hours before sunset -Calendar cutoff dates for applications (June 30th for soybeans and July 30th for cotton)
Volatility – maintaining tank pH	Advisory language	Require use of a qualified VRA/pH buffering adjuvant in the tank for every application
ESA – spray drift	110 ft downwind buffer	310 ft downwind buffer
ESA – volatility	57 ft omni-directional buffer in areas with federally listed species	57 ft omni-directional buffer in areas with federally listed species, in combination with the generally applicable cut-off date and VRA/pH buffering adjuvant in counties with federally listed species
Label clarity	Included uses for both non-DT crops beyond the cotton and soybean DT crops	-Only includes pre- and postemergent uses for cotton and soybean DT crops-Cleaner label structure and restrictions for increased usability -Simplified early season restriction (crop growth stage

		cut-off vs. calendar cut-off date)
Hooded sprayer option for partial relief of certain control measures	N/A	When using a qualified hooded-sprayer the spray-drift buffer is reduced to 110 ft and 240 ft for FIFRA and ESA, respectively (for use in soybeans only)
Spray Tank Contamination	Equipment clean-out requirements	Equipment clean-out requirements
Expiration Date	2 years	5 years
Terms of the registrations	-Testing and approval of tank mixes -Herbicide resistance management plan -Enhanced reporting of adverse effects information -Studies to address uncertainties	-Testing and approval of tank mixes -Revised herbicide resistance management plan -Revised enhanced reporting of adverse effects information -Assuring availability of approved VRA/pH buffering adjuvant -Testing alternate hooded sprayer equipment
Training requirements	Training required per labeling	Training required, with addition of new requirements to include specific information on 2020 control measures in training materials.
Compliance assurance	- Recordkeeping requirements - Restricted use	- Additional recordkeeping requirements related to the new control measures - Restricted use

II. Chemical Information

This memorandum supports three[5] dicamba registrations for use on DT soybean and DT cotton (EPA Registration Numbers 264-1210, 100-1623, and 7969-472), as described below.

Registrants: BASF; Bayer CropScience (formerly Monsanto Company); and Syngenta Crop Protection

Product Numbers:

[5] Two of the three registrants (Bayer and BASF) that owned products impacted by the 2020 vacatur have submitted new product applications to the Agency. This memorandum addresses those two product applications, as well as the amendment Syngenta submitted to extend the expiration date for the non-vacated product, Tavium.

1. EPA Reg. #100-1623: A21472 Plus VaporGrip Technology (Alternate Brand Name (ABN) Tavium Plus VaporGrip Technology) (referred hereafter as Tavium)
2. EPA Reg. #264-1210: XtendiMax with VaporGrip Technology (referred hereafter as XtendiMax)
3. EPA Reg. #7969-472: Engenia Herbicide (referred hereafter as Engenia)

Chemical Names:
The three pesticide products covered by this memorandum contain two forms of dicamba, as seen in Table 2 below:

Table 2. Chemical Name Identification for Dicamba

Chemical Name	Alternate Chemical Name	Common Name	Chemical Abstract Service (CAS) Number
Dicamba (benzoic acid, 3,6-dichloro-2-methoxy-, aka 3,6-dichloro-*o*-anisic acid)	Diglycolamine salt of dicamba (3,6-dichloro-o-anisic acid)	Dicamba DGA salt	104040-79-1
Dicamba: N,N-Bis-(3-aminopropyl) methylamine salt of 3,6-dichloro-o-anisic acid	None	Dicamba BAPMA salt	1286239-22-2

Mode of Action: Dicamba is in the Benzoic Acid family that is used for selective control of emerged broadleaf weeds. Like the phenoxy herbicides, dicamba mimics auxins, a type of plant hormone and causes abnormal cell growth by affecting cell division.

Summary of Product Information:
The information from this chemical information section is summarized in Table 2 below:

Table 3. Master Table of Dicamba Products Registered for Use on DT Cotton and DT Soybeans

EPA Reg. #	Product Name	Registrant	Form of Dicamba
100-1623	A21472 Plus VaporGrip Technology (ABN Tavium)	Syngenta	DGA salt
264-1210	XtendiMax with VaporGrip Technology	Bayer	DGA salt
7969-472	Engenia Herbicide	BASF	BAPMA salt

III. Background

In January 2015, under the Plant Protection Act, the United States Department of Agriculture (USDA) deregulated the genetically modified DT cotton and DT soybean seeds. This seed was sold commercially in late 2015 and 2016 prior to EPA registering a pesticide product for use on

these DT crops. In late 2016, following a public comment period,[6] EPA registered three dicamba products for use with the DT trait in soybean and cotton[7]. These registrations were time-limited with automatic expiration dates in late 2018, unless EPA granted an extension of this time limitation.

Prior to the 2016 registration actions for dicamba, dicamba uses on soybeans and cotton were limited to use on preplant and preharvest soybeans and on preplant and postharvest cotton. The new uses registered in 2016 under FIFRA section 3(c)(7)(B) expanded the timing of dicamba applications by allowing a new use for postemergence over-the-top (OTT) applications to DT cotton and DT soybean crops. Registrations for the OTT uses were granted for the lower volatility products when compared to other registered dicamba products for non-OTT uses. Any use of the earlier registered products on DT cotton or DT soybean crops that are not registered specifically for postemergent use on DT cotton or DT soybean crops is inconsistent with the pesticide's labeling and a violation of the FIFRA.

Reports of Incidents

In 2016, EPA began receiving reports of crop injury alleged to be caused by off-target movement from the use of dicamba. Because the registrations for OTT use had not yet been issued, EPA concluded these 2016 incidents were related to misuse of previously registered, more volatile dicamba pesticide products on DT cotton and DT soybeans. In 2017, over 2,700 official cases of crop damage were reported to state departments of agriculture, estimated to be over 3.6 million acres of soybeans[8] (nearly 4% of a total 90.2 million acres planted in 2017 according to USDA). There was a lack of scientific consensus regarding the exact cause of these dicamba reported incidents. Input from state agencies, farm bureaus, associations, industry, farmers, and non-governmental organizations indicated that causes could have included not following the label or use of an older, more volatile formulation inconsistent with those products' labeling and thus in violation of FIFRA, physical drift, tank contamination, and/or volatility. In response, EPA worked with the pesticide registrants to strengthen the pesticide label directions for use for the 2018 season to further minimize the potential for off-target movement. The restrictions for all OTT registrations of dicamba were amended in 2017 to include labeling restrictions to minimize the potential for off-site movement of dicamba. The original expiration set for the end of 2018 remained a term of the registrations.

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[6] Beyond the requirement of FIFRA 3(c)(4) to publish a notice of receipt for certain applications and accept comments on the limited information in such notice, FIFRA does not require EPA to provide a public comment opportunity for a proposed decision to register a pesticide. EPA, nevertheless, provided more robust information for public comment on its proposed 2016 dicamba decision under its public participation policy (see: https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions). Similar to the 2018 registration actions where EPA did not provide a formal public comment period, again in 2020 EPA did not provide a formal public comment opportunity, but the Agency did receive over 120 unsolicited comments from stakeholders. EPA considered the content of these submissions.

[7] EPA Registration Number 524-617 (M1768 Herbicide/XtendiMax With Vaporgrip Technology) was the first registration issued in 2016 as described in *Final Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2016-0187); two additional OTT dicamba use registrations were approved later in 2016 (EPA Registration Numbers 352-913 (DuPont Fexapan Herbicide) and 7969-345 (Engenia Herbicide)).

[8] *Dr. Kevin Bradley Univ. of Missouri, IPM,* https://ipm.missouri.edu/IPCM/2017/10/final_report_dicamba_injured_soybean/

Information for the 2018 growing season provided by state agencies and others also included reports of crop injury alleged to be related to off-site movement of dicamba. The registrants submitted adverse effects aggregated reports to EPA as required by FIFRA section 6(a)(2). The Association of American Pesticide Control Officials (AAPCO) reported that approximately 1,400 official complaints of alleged dicamba injury were reported to the state regulatory authorities. Damage alleged to be related to OTT dicamba applications was reported not only for non-tolerant soybeans but also for neighboring trees, orchards, vineyards, berries, melons, tomatoes and other vegetable crops. As to reporting of crop injury in general, AAPCO, university researchers, and some growers state that they believe that these types of complaints tend to be underreported. EPA received feedback that underreporting could be associated with a desire to maintain good relationships with neighbors; fear that a damaged 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 in response to filing a report. Conversely, there may have been issues of overreporting. The reasons provided included: damage was caused by use of older more volatile formulations of dicamba or other chemistries; and damage reports given in terms of acreage that reflects the size of an entire crop field and not just the portion of the crop field that was actually damaged.

2018 Decision, Label Amendments, Conditions of Registration, and Expiration Date:
On November 1, 2018, EPA granted Bayer's requests to extend the expiration date for their product registered for DT crop uses (EPA Reg. No. 524-617) for two years to December 20, 2020. On November 2 and 5, 2018, EPA granted similar extension requests for BASF (EPA Reg. No. 7969-345) and DuPont (EPA Reg. No. 352-913), respectively. In each case EPA approved amendments to the terms and conditions of the registration as well as adding labeling restrictions to further reduce the potential for off-site movement of dicamba from the treated fields. Supporting documents and registration notices can be found on regulations.gov, Docket ID: EPA-HQ-OPP-2016-0187. This action was informed by input from state regulators, farmers, academic researchers, pesticide manufacturers, and other stakeholders. EPA reviewed substantial amounts of new information and concluded that the continued registration met FIFRA's registration standards. The Agency also determined that extending these registrations would not affect endangered species.

The additional labeling requirements for the 2018 dicamba OTT uses included the following:

- a limit of two OTT applications of dicamba per field per year for both DT cotton and DT soybeans
- no applications to DT crops 60 days or later after planting cotton and 45 days or later after planting soybeans or until a specified crop growth stage
- OTT dicamba applications only permitted between one hour after sunrise and two hours before sunset
- applications may be made only by certified applicators
- equipment clean-out requirements
- an omnidirectional application buffer to protect endangered species from off-target movement of dicamba

EPA determined that these label changes would result in a minimal reduction of the flexibility of growers to use dicamba as a tool for resistance management. EPA also determined that the

labeling changes would further minimize the potential for off-site movement. New conditions of registration were also associated with this two-year extension. These included enhanced reporting and additional data requirements. This was a two-year registration set to automatically expire on December 20, 2020, unless EPA further extended it.

2019 New OTT Dicamba Product Registration

On April 5, 2019, EPA registered a product containing a combination of dicamba and S-metolachlor for OTT use on DT cotton and DT soybeans (EPA Registration Number 100-1623, A21472 Plus VaporGrip Technology (ABN Tavium)). This combination of active ingredients was previously an approved tank mix, and as such, the combination of active ingredients was already being used as a tank mix for OTT on DT cotton and DT soybeans. The registration for this dicamba product was set to automatically expire on December 20, 2020, unless EPA extended it.

2019 Incidents

During the 2019 use season, based on reporting to AAPCO, there was an approximate 10% increase in number of incidents from 2018 with 1,218 reported in 2018 compared to 1,345 incidents reported to the states in 2019. According to EPA's Incident Data System, there were 1,400 incidents reported in 2017, 2,600 reported in 2018 and nearly 3,000 reported to EPA in 2019. Although, reports have continued to increase nationally, there is variability in numbers of reports from individual. Some states (e.g., Kentucky, Missouri, Minnesota, Ohio) have seen a decrease.

2020 Court Order

On June 3, 2020, the Ninth Circuit Court of Appeals issued a decision in *National Family Farm Coalition, et. al., v. EPA*, 960 F.3d 1120 (aka Dicamba II), ordering the immediately effective vacatur of three pesticide registrations containing the active ingredient dicamba for use on DT crops (XtendiMax with Vaporgrip Technology (EPA Reg. No. 524-617); Engenia (EPA Reg. No. 7969-345); and FeXapan (EPA Reg. No. 352-913)). The Court found that EPA's decision to approve these dicamba products was not based on substantial evidence in that "EPA substantially understated risks that it acknowledged and failed entirely to acknowledge other risks." The product containing dicamba plus s-metolachlor (Tavium) was not vacated, so it remained registered with the expiration date of December 20, 2020.

On June 8, 2020, EPA issued a cancellation order providing growers, commercial applicators and distributors with direction on how to effectuate the vacatur. This cancellation order outlined the limited and specific circumstances under which existing stocks of the three affected dicamba products could be used for a limited period of time. Growers and commercial applicators were allowed to use existing stocks that were in their possession as of June 3, 2020, as long as the use was consistent with the product's previously approved label, but only until July 31, 2020.

IV. 2020 Registration Actions

Bayer and BASF submitted registration applications on July 2, 2020 for new product registrations (XtendiMax and Engenia) for use on DT cotton and DT soybeans. Syngenta submitted an application to amend its Tavium registration on August 12, 2020, including a request that the upcoming expiration date be extended.

The documents supporting the decision to grant these applications can be found in docket number EPA-HQ-OPP-2020-0492 at regulations.gov. In coming to its decision, EPA's record includes consideration of earlier submitted relevant studies and information as well as new studies and information received post the earlier registration actions. Therefore, some documents that were considered in earlier registration actions are referenced in these new supporting documents.

V. Stakeholder Feedback

The Agency received comments from various stakeholders in the form of calls, emails, and letters concerning the use of dicamba on DT cotton and DT soybeans. The comments were both in favor of and opposed to the continued or renewed registration of dicamba for pre- and postemergent use on DT cotton and DT soybeans.

Included in these comments was correspondence from a variety of stakeholders seeking to share their experience with dicamba, including state agencies, farm bureaus, industry, growers, non-governmental organizations, academia, congressional committees, and Members of Congress. These correspondences can be found in the document titled *2020 Dicamba Decision Comments* on regulations.gov in Docket ID: EPA-HQ-OPP-2020-0492. The information provided different viewpoints, and EPA considered these comments prior to approving these registration actions.

Many letters representing significant economic sectors strongly encouraged EPA to register these products. These letters indicated that growers need as many tools as possible and that dicamba for use in DT cotton and soybean is critically important to combat troublesome weeds (Palmer amaranth). Some of the letters provided information about the adoption rate of this technology as an indicator of importance to growers and how regulation can hamper the development of new technologies to help growers control weeds. As of October 19, 2020, examples of letters received were from *agricultural coalitions* from the states of: Alabama, Georgia, Kansas, Mississippi, Nebraska, Virginia; *seed dealers/Co-Ops*: Beck's Hybrids, LG Seeds, Wilbur-Ellis, Proseed, Latham High-Tech Seeds; c*ommodity groups*: National Cotton Council (NCC), American Soybean Association (ASA), Georgia Cotton Commission, Plains Cotton Growers, American Seed Trade Association; *commercial applicator groups:* Southern Crop Protection Association (SCPA); *registrant representatives:* Crop Life America; *governmental entities*: Iowa Department of Agriculture and Land Stewardship, Kansas Department of Agriculture, Pennsylvania Department of Agriculture, the Governor of Nebraska, the U.S. House of Representatives Committee on Agriculture, and Members of Congress; and *state organizations*: the National Association of State Department of Agriculture (NASDA) and American Association of Pest Control Officials (AAPCO). There were also letters from various individuals, including one academic who stated that the DT system is an important tool, but there have been incidents despite mitigation measures, and additional control measures should be considered (Hartzler).

Letters from other stakeholders provided varying details describing incidents and views on the nature of incident reporting, including possible underreporting. These letters describe damage to vineyards, non-DT soybeans, and numerous species of trees and other broadleaf herbaceous plants. These incidents were documented on small farms, residential areas, public lands (*e.g.*, parks, natural areas, wildlife refuges), industrial landscapes (*e.g.*, cemeteries and business store fronts) and roadsides. Additionally, the issue of "right to farm" was raised (*i.e.*, growers have the

right to grow crops without concern for loss or damage to an organic or sensitive crop because of offsite movement of dicamba). In addition to concerns about effects to single-season crops, letters also cited concerns about long-term economic impacts of dicamba damage to orchards and vineyards. These letters were received from a *coalition* for specialty crop growers (Save our Crops Coalition); *non-governmental organizations*: Audubon Arkansas, National Wildlife Federation, Prairie Rivers Network, The Land Connection, and Center of Food Safety; a *state organization*: American Association of Pest Control Officials (AAPCO); and various individuals.

VI. Risk Assessments

A. Human Health

The potential for human health risks from OTT uses of dicamba was first assessed in March 2016[9]. At that time, EPA found the toxicology database for dicamba complete and sufficient for assessing the toxicity and characterizing the hazard of dicamba.

In 2020, EPA became aware of mutagenicity studies not previously submitted as well as a new dicamba epidemiology study conducted as part of the Agricultural Health Study (AHS).[10] The AHS study reported an association between dicamba exposure in pesticide applicators and increased risk of liver and intrahepatic bile duct cancer. EPA reviewed this study and identified several deficiencies. EPA notes an earlier incident/epidemiological memorandum[11] that reviewed a study which investigated cancer incidence among pesticide applicators exposed to dicamba which concluded that "Exposure was not associated with overall cancer incidence nor were there strong associations with any specific type of cancer." The AHS study does not alter EPA's earlier findings because it does not provide any additional information, therefore, the EPA human health risk conclusions for dicamba remain unchanged since the original assessment in 2016.

Several additional studies addressing dicamba mutagenicity were also reviewed in 2020, including two comet assays, a kinetics assay, and a transgenic mouse assay. The results do not impact or change the current cancer classification or risk conclusions for dicamba, which are summarized in the document *Dicamba: Consideration of Newly Submitted Mutagenicity Data and Human Health Risk Assessment Summary* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2020-0492). Because there was no change in EPA's cancer classification as "*Not Likely to be Carcinogenic to Humans*," EPA determined that no additional human-health focused control measures were necessary for these actions.

B. Ecological

[9] See *Dicamba and Dicamba BAPMA Salt: Human Health Risk Assessment for Proposed Section 3 New Uses on Dicamba-tolerant Cotton and Soybean* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2016-0187)
[10] See https://aghealth.nih.gov/about/
[11] See *Dicamba: Tier I (Scoping) Review of Human Incidents and Epidemiology* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2016-0223)

A summary of the environmental fate and ecological effects, and potential environmental risks from the pre- and postemergent uses of dicamba on DT cotton and DT soybeans is provided below. The full assessment can be found in EPA's *2020 Ecological Assessment of Dicamba Use on Dicamba-Tolerant (DT) Cotton and Soybean Including Effects Determinations for Federally Listed Threatened and Endangered Species* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2020-0492).

The ecological assessment for these registration actions included a screening-level risk assessment for the pre- and post-emergent uses of dicamba on DT cotton and DT soybeans. The Agency also included species-specific assessments for threatened and endangered (hereafter referred to as "listed") species present within the 34 states approved in these registration actions (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).

Dicamba is an herbicide in the Benzoic Acid family that is used for selective control of emerged broadleaf weeds. In addition to the dicamba parent, the major degradate of toxicological concern produced under anaerobic conditions for all dicamba products is 3,6-dichlorosalicylic acid (DCSA). DCSA is persistent, accounting for > 60% of the applied dicamba after a year in an anaerobic laboratory-based environment. DCSA is also formed in aerobic soil under laboratory conditions at a maximum of 17.4% of the applied parent dicamba. DCSA is not persistent when formed under aerobic conditions and degrades roughly at the same rate as the parent dicamba (8.2 days). DCSA is less toxic or equally toxic as the parent for aquatic organisms on an acute basis but may be substantially more toxic on a chronic basis to terrestrial organisms, specifically mammals. Therefore, EPA's assessment considered the parent and its degradate DCSA in the aquatic assessment (with the assumption that dicamba and DCSA are equally toxic), while the terrestrial assessment for mammals considered parent dicamba and DCSA separately.

Ecological Risk Assessment (not including listed species):

EPA's conservative screening level assessment relies on the risk quotient (RQ) where a measure of exposure is divided by a measure of effect. The RQ is then compare to a Level of Concern (LOC) depending on whether the taxonomic group is located in terrestrial or aquatic habitats and whether the route of exposure is for an acute or chronic exposure duration[12]. EPA's conservative screening level assessment found no risks of concern for: aquatic animals or aquatic plants, or terrestrial animals from the inhalation of volatile emissions of dicamba. For non-listed non-target wildlife located on the treated soybean or cotton field, potential acute dietary risk concerns for birds (on treated soybean and cotton fields; RQs up to 2.1 compared to a LOC of 0.5) and potential dietary chronic risk concerns for birds (treated soybean fields only; dicamba based RQs up to 0.35 and DCSA degradate-based RQs up to 1.7 compared to a LOC of 1), chronic dietary risk concerns for mammals (treated soybean fields only; dicamba-based RQs up to 0.79 and DCSA degradate-based RQs up to 3.3 compared to a LOC of 1) and individual bees and other

[12] EPA's Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations

terrestrial invertebrates (on treated soybean and cotton fields; RQs 1.3-2.4 compared to a LOC of 1). Given the herbicidal action of dicamba, available laboratory toxicity endpoints, and intended effect of application at the treatment site, risk to nontarget plants within the confines of the treated soybean or cotton field is expected.

Determining Distances to Effects and Appropriate Infield Buffers

In its assessment, EPA reviewed multiple field-level and laboratory studies from a variety of sources (registrants, academics, and published literature) to conservatively select effects endpoints protective of off-field effects to non-target plants and establish conservative estimates of the potential distances to these endpoints. More information on this is available in the assessment and its associated appendices *2020 Ecological Assessment of Dicamba Use on Dicamba-Tolerant (DT) Cotton and Soybean Including Effects Determinations for Federally Listed Threatened and Endangered Species* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2020-0492).

Spray Drift Evaluation

EPA's evaluation of the potential for off-field (near field and wide area) transport of dicamba by spray drift and volatility informed the finding that mandatory control measures on the product labeling were necessary to approve these registrations. The product labels list multiple spray drift reduction requirements, including a 240-foot downwind in-field spray drift buffer (i.e., applications may only occur at distance greater than or equal to 240 ft within the downwind boundary of the treated field). This in-field downwind buffer requirement eliminates risk concerns outside of the treated field for non-listed mammals, birds, terrestrial phase herpetic species, and terrestrial invertebrates with greater than 90 percent certainty. The same spray drift requirements (namely the 240 ft in-field buffer) eliminate risk concerns outside of the treated field for conservatively established non-target plant effects to non-listed species with 90 percent certainty.

Use of hooded sprayers also has the potential to reduce spray drift and therefore change what other control measures are necessary to achieve the same results. A hooded sprayer is an example of a drift reduction technology that can cover the entire spray boom and shields pesticide droplets from the wind from the height of release to the canopy reducing the potential for pesticide drift. EPA has received data on tests of a particular hooded sprayer (RedBall 642E) which demonstrated a substantial reduction in spray drift. A limited number of field studies on bare soil and soybean crops were conducted and the data received indicate dicamba drift would be limited to approximately 20 ft from the point of application. These data show great reductions in the possible movement off-field when using this particular hooded sprayer, but based on the limited information provided to EPA, the Agency determined that a 5X safety factor would address the uncertainties with this limited set of data. Therefore, the use of this hooded sprayer would allow the 240-foot in-field spray drift buffer to be reduced to 110 feet and still be protective of non-listed plant species with a high level of confidence (see section IX for discussion of the spray drift buffer zone distance when using hooded sprayers in areas where listed species are present). It should be noted that these trials did not evaluate the use of other types of sprayers (alternative hooded broadcast, hooded in-row and layby sprayers) nor did they evaluate the use of a hooded sprayer over cotton crops. As a result, the reductions in buffer

distance permitted when using hooded sprayers is limited to this one sprayer for use on soybean crops. Additional brands or models of hooded sprayers can qualify for the reduced downwind buffers for soybeans if they meet the performance standard established by testing according to EPA's approved protocol in comparison to the currently assessed hooded sprayer. Hooded sprayers eligible for the reduced downwind buffers for soybeans will be listed on the registrants' websites; only those hooded sprayers so listed are eligible for the reduced downwind buffers. downwind buffers.

Volatility Evaluation

Field data using dicamba products for use on DT crops without the addition of any VRAs (pH buffering adjuvants) to tank mixes indicate the potential for risk to non-target non-listed terrestrial plants from exposure to volatile emissions beyond the field's edge. Importantly, when certain VRAs (pH buffering adjuvants) are included in the tank mix, laboratory and field studies demonstrate much lower dicamba volatility. Based on many studies, EPA determined that the volatile emissions would not go beyond the field's edge with a high degree (89%) of certainty.

An evaluation of incident data, coupled with laboratory and field-based volatility data, shows that avoiding application when air temperatures are favorable to volatility would decrease the conditions that may have led to some dicamba-related non-target plant incidents. The imposition of mandatory application cut-off dates (June 30th soybean, July 30th cotton) on the product labels reduces the probability of dicamba application on days more favorable for dicamba volatilization. The June 30 and July 30 dates were informed by data on the effect of temperature on volatility. EPA utilized historical incident information and meteorological data to conduct its analysis. First, EPA compared the maximum temperature data on the day of each reported incident and determined that over 94% and 82% of the incidents occurred at temperatures above 75 ^{o}F and 80 ^{o}F, respectively. EPA then reviewed historical meteorological data to determine the proportion of total days less than 75 ^{o}F and 80 ^{o}F. Based on this analysis, the soybean cut-off of June 30th would mean that application temperatures will be below 80 ^{o}F between 12% (Texas) to 89% (Minnesota) of the time, and below 75 ^{o}F between 3.2% (Texas) to 72% (Minnesota) of the time. The cotton cut-off of July 30th would mean that application temperatures will be below 80 ^{o}F, between 8% (Florida) to 66% (Virginia) of the time, and below 75 ^{o}F between 0.3% (Florida) and 36% (Virginia) of the time. EPA notes that this analysis did not consider the impact of the mandatory VRA (pH buffering adjuvant) combined with the cut-off date.

When considering favorable volatility temperatures in the context of crop planting schedules and meteorological data, labeled dicamba application cutoff dates reduce applications coinciding with temperatures favoring dicamba volatility and by extension incidents. Because the dates are the same in all 34 states and the meteorological data vary across these geographies, the magnitude of the protective certainty of cut-off dates is not uniform across the 34 states, but in no state was the probability of avoiding a threshold temperature on the day of application zero. The use of a cut-off date produced avoidance of applications of dicamba on days with temperatures favoring volatility and is expected to provide protection of both effects at the near field level as well as on scales suggested by available incident data.

VII. Benefits and Impacts Assessments

In accordance with FIFRA, EPA considers both risks and benefits when considering the registration of a given pesticide. A summary of the assessed benefits of dicamba use on DT cotton and DT soybeans, and the impacts of these registration actions appears in this section. To see EPA's current assessment of the benefits and impacts of dicamba use in DT crops, please refer to *Dicamba Use on Genetically Modified Dicamba-Tolerant (DT) Cotton and Soybean: Incidents and Impacts to Users and Non-Users from Proposed Registrations; Assessment of the Benefits of Dicamba Use in Genetically Modified, Dicamba-Tolerant Soybean Production;* and *Assessment of the Benefits of Dicamba Use in Genetically Modified, Dicamba-Tolerant Cotton Production* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2020-0492).

A. Benefits of the Registration of Dicamba Use in DT Cotton and DT Soybeans

Cotton and soybeans are extremely important agricultural commodities in the U.S. USDA estimates the gross value of soybean production at approximately 40 billion dollars in the United States, and the gross value of cotton production at 6.6 billion dollars in the United States.[13] USDA's Economic Research Service describes soybeans as the world's largest source of animal protein feed and the second largest source of vegetable oil and describes cotton as one of the most important textile fibers in the world, accounting for around 25 percent of total world fiber use. The United States is the world's leading soybean producer and second leading exporter, and soybeans comprise about 90% of the United States' oilseed production. Between 2014 and 2017, soybean production, processing, and use, including biodiesel and livestock feed, generated about $115.8 billion in economic activity, supporting the equivalent of 280,000 full-time jobs[14]. The United States is the world's third-largest cotton producer and the leading cotton exporter, accounting for one-third of global trade in raw cotton. Per USDA's Economic Research Service, the U.S. cotton industry accounts for more than $21 billion in products and services annually, generating more than 125,000 jobs in the industry sectors from farm to textile mill. This does not include other jobs that may be created further in the supply chain.

Soybean and cotton growers throughout the United States continue to experience crop yield and economic losses due to the prevalence of herbicide-resistant weed biotypes. For example, when glyphosate resistant weeds were present in soybeans there was a reduction of $22.50 or 14% of total returns per planted acres. Herbicide resistance has become a significant financial, production and pest management issue for many cotton and soybean growers, and agriculture as an industry.

The significant adoption of DT technology is directly responsive to the need to prevent economic losses, and these products benefit soybean and cotton growers. In some states (i.e., Mississippi), DT soybean may account for nearly 80% of planted acres; however, nationally, ERS shows a 41% adoption rate in 2018, which is similar to the adoption rate in the primary states producing

[13] USDA/NASS. 2020. Quick Stats, searchable database. Query for acreage, production, and value, by state, 2014-2018. Available at www.nass.usda.gov/Data_and_Statistics/index.php. Accessed March 2020.

[14] LMC International Ltd. 2019. The Economic Impact of U.S. Soybeans and End Products on the U.S. Economy, Report for the United Soybean Board and National Oilseed Processors Association, November. Available at http://www.nopa.org/wp-content/uploads/2020/03/LMC_U.S.-Soy-Economic-Impact-Study-for-USB_FINAL-31320.pdf. Accessed October 2020.

soybean (e.g., Illinois, Indiana and Iowa)[15]. ERS shows a DT adoption rate of 69% in cotton in 2019[15]. However, DT soybean or cotton provides growers with the option of using dicamba, but not all of those growers will ultimately apply dicamba. In 2017 and 2018, growers used dicamba on 8% and 17% of all U.S. soybean and cotton acres prior to crop emergence, respectively, and on 17% and 34% of all U.S. soybean and cotton acres after crop emergence, respectively.[16] Dicamba is primarily used to target herbicide-resistant Palmer amaranth, waterhemp, kochia, ragweed, and marestail in soybeans, and herbicide-resistant Palmer amaranth and redroot pigweed in cotton, and is effective at controlling a wide range of broadleaf weed species.

For areas where dicamba products cannot be used on DT cotton and DT soybeans, there are effective alternative weed control programs currently available for the control of problematic broadleaf weeds in cotton and soybeans. However, the number of postemergence herbicide options is very limited; therefore, cotton and soybean growers can benefit from the registration of dicamba for use in DT cotton and DT soybean. The dicamba tolerant system was created to address weed populations with resistance to glyphosate (Weed Science Society of America [WSSA] Group 9 herbicide), ALS (acetolactate synthase) inhibitor herbicides (WSSA Group 2) and PPO (protoporphyrinogen oxidase) inhibitor herbicides (WSSA group 14). The registration of dicamba in DT cotton and DT soybean will give growers additional flexibility for managing herbicide-resistant weed populations, thereby prolonging the effectiveness of currently available control options for herbicide-resistant weed species.

In addition to post emergence application, dicamba in DT cotton and DT soybean has utility prior to crop emergence. Older, more volatile dicamba products allow preemergent use, but only with a preplant restriction of a specified number of days and rainfall or irrigation water between dicamba application and planting to avoid crop injury. Because DT crops are tolerant of dicamba, these crops do not require preplant restrictions that would otherwise be required to protect emerging soybean and cotton from dicamba damage; this provides greater flexibility to growers.

In soybean, a postemergence dicamba-based herbicide program may be less expensive than alternative herbicide programs. A postemergence dicamba program may reduce grower costs by $12-$14 per acre (4%-7% of grower net operating revenue, depending on region), not including the cost of adjuvants or of other mitigation measures relative to some herbicide programs (e.g., a 2,4-D based program). Growers who chose a glufosinate program could see similar costs to the postemergence dicamba program. In cotton, relative to other alternative herbicide programs, postemergence dicamba may reduce grower costs by $8-$14 per acre (5%-10% of grower net operating revenue), not including the cost of adjuvants or of other mitigation measures. Seed costs and rebates offered by seed and chemical manufacturers can affect the overall cost of the herbicide program, as can the additional costs of adjuvants.

In certain locations performance of dicamba has been poor owing to dicamba-resistant weed populations. In areas where Palmer amaranth is exhibiting decreased susceptibility to dicamba, additional herbicide applications or other weed management measures may be

[15] USDA ERS (United States Department of Agriculture, Economic Research Service), 2020. Special tabulation, based on the Agricultural Resources Management Survey: Crop Production Practices data. Compiled by Dodson, Laura.
[16] Source: Kynetec, 2019.

necessary to achieve adequate weed control where species are experiencing decreased susceptibility, increasing the cost of the postemergence dicamba program.

Considering all the information, the Agency concludes that the registration of dicamba for use in DT cotton and DT soybeans will provide growers of these crops with additional flexibility in choosing products 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 alternative postemergent herbicides available for users.

Based on experience, resistance occurs over time and can be expected for many pesticides. When dicamba resistance spreads, the benefits of dicamba in DT cotton and DT soybean will decrease, with decreased benefits concentrated in those areas where dicamba-resistant broadleaf weed species are established. The Herbicide Resistance Management (HRM) plan required as part of each registration is designed to preserve the efficacy and benefit of this important weed management tool. EPA believes such plans, including proactive information sharing, represent the best strategy for managing resistance because they are consistent with recommendations from experts in the field. These plans include enhanced notification and reporting requirements, additional education and training requirements, and follow up measures to contain and control as best as possible the spread of populations identified as resistant or likely to be resistant.

B. Impacts Assessment

Impacts of Registration to Non-Users of Dicamba:

EPA finds negative impacts to non-users from the registration of these OTT dicamba products will be minimal due to the new control measures addressing drift and volatility. Incidents of plant damage consistent with exposure to dicamba have been documented in a variety of sensitive crops including non-DT soybean, fruit trees, and vegetables. The level of damage is variable and may range from slight leaf cupping to plant death. The level of damage depends on the magnitude and length of exposure, the number of times exposed, the growth stage of the affected plants when exposure occurs, and the response of the injured plant after exposure. Not all of the reports of alleged dicamba damage are associated with yield loss.

Without appropriate controls, the impacts of offsite movement to non-users may be substantial. High value crops may suffer yield and quality losses, organic growers could lose organic certification, research and crop breeding programs could be disrupted, and plantings in residential areas (e.g., home gardens) and landscapes could be damaged. Offsite movement of dicamba from products registered for use on DT crops that injures adjacent crops has resulted in conflict between neighbors. Injured parties may make reports to state authorities or sue for damages. State lead agencies have been receiving drift complaint calls; all of this may create social impacts which EPA is obligated to consider under FIFRA. EPA approved a suite of control measures to ensure dicamba stays on the treated field, addressing offsite movement and therefore the likelihood of damage.

Overall, negative impacts to non-users from the registration of these OTT dicamba products will be minimal, as the mandatory control measures give EPA a 90% confidence that there will be no offsite movement of dicamba. Some measures only address one type of offsite movement

(e.g., volatility) while others may address both volatility and particle drift. When used in combination as required, the suite of control measures has been determined to be protective with 90% confidence.

For example, the calendar-based application restriction (no applications are allowed after June 30th in soybeans and after July 30th in cotton) is intended to limit applications of OTT dicamba to earlier in the growing season when temperatures are more likely to be cooler than later in the season. In addition, earlier application can reduce risks because sensitive plants in adjacent areas may not be in their most vulnerable growth stage. The calendar cut-off dates, in combination with the mandatory use of the VRA (pH buffering adjuvant), addresses offsite movement from volatility. While varying temperatures do not have an impact on spray drift, the calendar cut-off addresses the potential risk from spray drift, because applications are not allowed to be made later in the season when nearby plants are likely in their reproductive stages and are more sensitive. Spray drift is also addressed by important control measures including limitations regarding wind speed, spray droplet size, spray nozzles, and an infield buffer downwind of the treatment area. When fewer incidents result from volatility and spray drift, more sustainable use is achieved, preserving states' limited investigation resources.

Impacts of Control Measures to Users:

Having separate product labels for just DT soybean and DT cotton will simplify use for users and improve compliance. Several of the control measures on the newly registered product labels may increase applicator/grower costs and may involve more elaborate user practices than similar herbicides. For instance, cutoff dates may prevent some growers from making applications for late season weed control. Mandatory use of adjuvants (VRAs/pH buffering adjuvants and drift reducing agents) have the potential to increase per-acre costs. Infield buffers will complicate weed control in the field and adjacent to the field borders. For example, there may be limited approved alternate herbicides for weed management within the buffer area. Hooded sprayers, if utilized, may benefit growers by reducing the buffer distance, but would increase the time needed to make applications because these sprayers require reduced tractor speeds.

VIII. Registration Decision

In accordance with FIFRA section 3(c)(5), EPA must register a pesticide when it finds that the use will not generally cause unreasonable adverse effects[17] on human health or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. FIFRA section 3(c)(5) specifically requires approving of a registration if EPA determines:

> (A) its composition is such as to warrant the proposed claims for it;
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and

[17] FIFRA section 2(bb) defines, in pertinent part, "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide…."

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

EPA reviewed the compositions of all three products and determined that the claims made are warranted and the information supports the approval of the registrations. The labeling from the registrants contains all the necessary requirements and restrictions and complies with the requirements of FIFRA. EPA received studies and other information, necessary to comply with the data requirements for the uses of these products. The Agency also reviewed a large body of data and information to determine how these products have been and will be used to determine the risks and benefits. All of these evaluations informed EPA's determination that registering these products will not generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

In making a determination as to unreasonable adverse effects, EPA is charged with considering the economic, social, and environmental costs and benefits of the use of the pesticide. EPA must determine if the benefits outweigh any potential risks of concern as well as adverse impacts in order for the Agency to determine the product will not generally cause unreasonable adverse effects.

In the case for the use of dicamba on DT soybeans and DT cotton, and in consideration of all best available data and assessment methods, the EPA determines that registering these uses would meet the requirements of FIFRA.

The database submitted to support the assessment of human health risk is sufficient for a full hazard evaluation and is considered complete and adequate to evaluate risks to the general population including infants and children. The Agency has not identified any risks of concern for human health, including all population subgroups, or for occupational handlers. EPA also considered the potential for risks to plants and wildlife, and identified control measures appropriate to address those risks and consideration of benefits and impacts of the use, as discussed in the next section.

A. Addressing Ecological Risk under FIFRA

In EPA's screening level ecological assessment, the Agency found some risks to certain wildlife on the treated fields. These include birds, mammals, and bees and other invertebrates. These assessments included conservative risk estimates using screening-level assumptions that assume maximum exposures to the birds, mammals, bees and other invertebrates. For example, the risk assessment assumes that the wildlife will forage exclusively in the treated area, which is a conservative assumption and will overestimate risk for the majority of wildlife utilizing agricultural fields.

The risk assessment presumes that if there were non-dicamba tolerant plant species on treated fields, given the herbicidal mode of action of dicamba, those plants would be at risk. Because growers that use dicamba for weed control are managing their fields for the highest level of production of soybean or cotton on their own land, EPA concluded that any non-tolerant plants would be considered a target pest and therefore there would be no non-target plants on the fields, except for the DT crops.

Based on the mandatory control measures to address spray drift and volatility, EPA determined that risks are restricted to those individuals in the treated fields and there are no risks of concern for birds, mammals and bees or other invertebrates outside of the field with greater than 90% certainty. EPA identified risks of concern for non-target plants via runoff in adjacent areas. While control measures to address runoff risk to plants are included in the labeling, EPA concluded that these measures reduce but do not eliminate risk. For plant risk from spray drift and volatility, EPA concluded that risks were below levels of concern, taking into account the mandatory control measures, at the 90% and 89% confidence level, respectively, based on conservative plant effects endpoints.

Additionally, in making determinations under FIFRA, EPA considers the benefits in order to determine whether any remaining risks are unreasonable. EPA considered the fact that herbicide resistance has become a significant financial, production and pest-management issue for many cotton and soybean growers and concluded that dicamba will be a cost-effective way to control herbicide-resistant broadleaf weed species and delay the further development of herbicide resistance. Based upon those considerations, EPA has determined that the benefits outweigh the remaining risks to wildlife and plants on treated fields and nearby.

EPA has determined that the mandatory control measures on these registrations address spray drift and volatility. In order to determine the appropriate control measures, the Agency did consider whether there could have been risks of concern outside the treated field without these measures. Over the period in which the OTT uses of dicamba have been available, many reports of off-site movement on agricultural land and alleged crop injury have been received from state agencies, agricultural researchers, and growers. Although not as widely reported, off-site plant damage in natural areas and in residential and commercial properties has also been reported and alleged to have occurred due to off-field transport of dicamba by spray drift and volatility. EPA's registrations have extensive mandatory control measures on the labels to address spray drift and volatilization which are further described below.

An important example of a mandatory control measure is the cutoff date of June 30 and July 30 for the postemergent applications of the dicamba products use in DT soybeans and DT cotton, respectively[18]. Certain conditions that may promote higher volatility, such as higher temperatures, increase as the summer months progress. These conditions may increase the movement of dicamba as a result of an increase in volatility. Prohibiting applications later in the season when temperatures are higher will directly address this issue. In addition, nearby non-target crops are less likely to be at vulnerable growth stages earlier in the season, so limiting the use of dicamba to early season application will further reduce crop injury in neighboring areas. In the September 2020 AAPCO survey, some states have issued cutoff dates[19] for dicamba OTT

[18] EPA considered regional cutoff dates as well as temperature thresholds as alternatives and determined that a nationwide cutoff offers the greatest label clarity.

[19] FIFRA section 24(a) allows a state to regulate pesticides more restrictively than EPA under the state's own authority. However, some of the states that have imposed cut-off dates on dicamba uses have done so under section 24(c). Section 24(c) only authorizes states to issue registrations for additional uses of federal registrations to meet special local needs; if states wish to impose further restrictions on the dicamba products, or any other federally registered pesticides, they should do so under section 24(a) of FIFRA

use in soybeans in their states and associated the cutoff date with lowering levels of offsite dicamba movement and damage.

To further address volatility, the label requires an important new mandatory control measure requiring users to add an approved VRA (pH buffering adjuvant) to the tank with every application of the product. This results in the spray solution having a higher pH and therefore less volatility. Specific VRAs (pH buffering adjuvants) have been tested with rigorous scientific data that supports this determination. By stabilizing the pH in the spray solution, the lower volatility characteristics of these products are preserved, reducing the risk of pH changes that result in higher volatility with the addition of other components to the spray mix.

Based on rigorous review of all the scientific information, EPA has determined that an increased infield buffer was necessary to address spray drift and to protect non-target plants. Based on conservative regulatory endpoints, these labels include a mandatory downwind buffer of 240 ft (310 ft in areas where it is necessary to protect listed species as described in Section IX).

In addition to the enhanced new control measure approach described above, the labels also involve a simpler format that is easier to understand and follow, which will help to prevent potential misuse of these dicamba products for use on DT crops. Importantly, these products are registered for use on DT soybean and cotton crops only, thereby minimizing the confusion from earlier labels that contained more than just these two DT crops. By restricting use only on DT soybean and cotton crops, the restrictions and requirements of the label can be very straightforward and prominent for the user and make enforcement easier for state regulatory officials. In addition, the labels have been rewritten and reformatted to make the restrictions very clear and apparent, which also clarify the requirements of the label.

Other important control measures will continue to help address risks of damage from off-site movement, such as restricted use classification, strict training and recordkeeping requirements, time-of-day restrictions, and temperature-inversion restrictions. The overlapping risk control measures minimize the potential risks of movement and any associated damage posed by these dicamba products and enable the utilization of a very important tool to control extremely problematic herbicide-resistant weeds.

In addition to the mandatory control measures, EPA is supporting the adoption of the latest drift reducing technology because greater use of such technology could be useful in mitigating risks for a variety of pesticides. As such, and supported by data on soybeans, EPA is allowing the option of using an approved-hooded sprayer with reduced downwind spray drift buffers of 110 ft in areas with no listed species and 240 ft in areas with listed species for soybeans only. These buffer distances were informed by data from field studies showing dicamba drift was confined to approximately 20 feet. Owing to the limited database and to ensure protection, EPA applied conservative safety factors to select 110 ft and 240 ft infield downwind buffers for non-listed species and for listed species, respectively, when using a qualified hooded sprayer on soybeans. As more data becomes available in the future, EPA will consider applications to amend the registrations to allow smaller buffers, and/or to allow reduced buffers for cotton.

On the benefits side of the analysis, use of dicamba on DT soybeans and DT cotton is an important part of a resistance management strategy. Soybeans and cotton are extremely

important agricultural commodities in the United States and the world. According to the USDA's National Agricultural Statistics Service, soybeans are harvested from approximately 84.8 million acres and cotton is harvested from approximately 9.3 million acres. USDA's Economic Research Service describes soybeans as the world's largest source of animal protein feed and the second largest source of vegetable oil and describes cotton as one of the most important textile fibers in the world, accounting for around 25 percent of total world fiber use. The United States is the world's leading soybean producer and second leading exporter, and soybeans comprise about 90% of the United States' oilseed production. The United States is the world's third-largest cotton producer and the leading cotton exporter, accounting for one-third of global trade in raw cotton. The U.S. cotton industry accounts for more than $21 billion in products and services annually, generating more than 125,000 jobs in the industry sectors from farm to textile mill. Weed control experts warn that the problem of herbicide resistance is increasing, and that significant economic consequences will continue to increase without effective alternatives for weed control. In addition, 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 as well.

Use of dicamba on DT soybeans and DT cotton is beneficial as it provides an effective tool to treat especially problematic weeds, such as marestail, giant ragweed, common waterhemp, and Palmer amaranth, including glyphosate-resistant biotypes that threaten soybean and cotton production today. For example, when glyphosate resistant weeds were present in soybeans there was a reduction of 14% of total returns per planted acres. By adding an effective tool to combat glyphosate-resistant and other weeds, dicamba can help reduce this difficult weed pressure and aid significantly in production, reducing economic losses to soybean and cotton growers. In addition, effective treatment of glyphosate-resistant weeds can help control the spread of resistance. EPA finds these benefits significant and important for mitigating production and economic losses for these growers.

After weighing the risks of concern mentioned earlier against the benefits of these uses, EPA finds that when the required control measures for these uses are applied, the benefits of the use of the pesticide outweigh the risks. Therefore, registering and renewing these products will not generally cause unreasonable adverse effects on human health or the environment and therefore meets the FIFRA Section 3(c)(5) registration finding for these registrations.

Therefore, EPA will be registering two end use dicamba products (EPA Registration Numbers 264-1210 and 7969-472) and extending the registration for one dicamba product (EPA Registration Number 100-1623), all for applications only on DT cotton and DT soybeans, with an automatic expiration date of December 20, 2025. As part of these registrations and registration extension, EPA is requiring label language as described in Section VII B Label Requirements. When used in accordance with the control measures on the product label, EPA expects that this registration action will not generally cause unreasonable adverse effects to human health or the environment.

B. Label Requirements

The labels approved by EPA for these products contain certain control measures for dicamba use on DT cotton and DT soybean, including additional control measures to protect listed species. This includes both enforceable as well as advisory statements. The only currently available

products for use on DT cotton and DT soybeans are Tavium, XtendiMax, and Engenia (EPA Registration Numbers 100-1623, 264-1210, and 7969-472). The specific labeling requirements for these dicamba product labels with registered uses on DT cotton and DT soybeans are outlined here.

New Registrations are for DT-Crops Only:
Previous registrations of dicamba for use on DT crops also included label directions for use on many other non-DT crops such as asparagus, corn, turf, sorghum, and sugarcane, including directions for use on non-DT soybeans and DT cotton. This led to complicated and lengthy labeling.

The new approved labeling for Engenia, XtendiMax, and Tavium includes only directions for use on DT cotton and DT soybeans.

Certified Applicator Provision:
These products are restricted use pesticides (RUP) and include a provision that they may only be used by certified applicators. Because the Agency finds that the complexity of the chemistry warrants ensuring that only the most highly trained individuals apply it, individuals who are not themselves certified applicators may not make an application of dicamba to DT crops, even under the direct supervision of a certified applicator. By ensuring only those individuals with the highest level of pesticide application training may make such applications allowing the tool to be available for growers.

Record Keeping Requirements:
As RUPs, these products include record keeping requirements that certified applicators must generate as soon as practical but no later than 72 hours after application. The certified applicator must keep these records for a period of two years. In addition to records that certified applicators are already required to keep, records specific to the application of the products for use on DT crops are required, including information concerning the VRA (pH buffering adjuvant) used, application date, proof of training, and infield buffer distances observed.

Mandatory Applicator Training:
The labels include a dicamba-specific training requirement. Strong training requirements will reduce the likelihood of application errors.

Mandatory Tank Mix with Volatility Reduction Adjuvant(Agent)/pH Buffering Adjuvant:
All applications of XtendiMax, Engenia, and Tavium must be applied in a tank mix with an approved VRA (pH buffering adjuvant). Users are directed to a registrant website that lists approved VRAs (pH buffering adjuvant). The proper use of the required VRA (pH buffering adjuvant) is also covered in the mandatory dicamba-specific training.

Calendar Date Cut-off:
The labels prohibit application after June 30 and July 30 for DT soybeans and DT cotton, respectively. Previous dicamba registrations for DT crop use only allowed use on cotton prior to mid-bloom stage or no more than 60 days after planting, whichever occurs first, and on soybeans prior to beginning bloom (R1 stage) or no more than 45 days after planting, whichever occurs first. To simplify labeling and improve consistency, new restrictions replace these previous

prohibitions to address dicamba risk, whereby applications to DT soybeans may not occur after June 30th, and applications to DT cotton may not occur after July 30th.

Inversion (Sunrise/Sunset Timing) Restriction:
The labels contain a control measure that prohibits application during temperature inversions, and a time-of-day restriction that requires applicators to only apply between one hour after sunrise and two hours before sunset. This restriction will reduce applications being made at times of day when temperature inversions often occur.

Equipment Clean-out Instructions:
Poor practices for maintaining pesticide application equipment may lead to cross-contamination. Because even trace amounts of dicamba can cause crop injury, residues that are accidentally left in application equipment can carry over to subsequent applications to non-dicamba tolerant crops. The labels include equipment clean out instructions and advisory language on the subject of application equipment hygiene. Additionally, the training covers equipment cleanout.

Buffers:
The labeling includes a 240-foot downwind in-field buffer. Also, the labeling includes a Listed Species Protection Requirement of a 310-foot downwind in-field buffer and an omnidirectional in-field buffer of 57 feet in areas where listed species are present. To determine if a particular area is subject to the 310-foot downwind in-field and 57-foot omnidirectional in-field buffer restrictions, applicators must check Bulletins Live! Two (BLT) prior to making an application. Instructions on how to access Bulletins Live! Two are included on the label. EPA is in the process of updating Bulletins Live! Two. In addition, the label allows the optional use of approved hooded sprayers with a 110-foot in-field spray drift buffer, and 240-ft in-field buffer in areas with listed species, for soybeans only. Any approved hooded sprayers will be listed on the registrant websites for each product.

In addition to the in-field buffers described above, in all areas, application is prohibited when sensitive crops or certain plants are immediately downwind.

Advisory Language/Best Management Practices:
In addition to the mandatory label language, there are advisory statements on factors that can further protect against the potential for off-target movement of dicamba.

C. Terms of Registration

As part of its decision to register and extend a registration of dicamba for use on DT cotton and DT soybeans, the registrants have agreed to certain terms as elements of the registration. These terms will include monitoring requirements, an herbicide resistance management plan, requirements for adding additional VRAs (pH buffering adjuvants), requirements for adding additional tank mix partners, and requirements for adding hooded sprayers that can be used in order to obtain reduced infield buffer distances.

Monitoring Requirements
The Agency is specifying various monitoring requirements that will aid EPA in assessing both the market for dicamba products registered for OTT uses and the impacts of the new control measures included in this decision. The Agency's monitoring requirements for dicamba use on

DT crops are listed below:

1. Enhanced incident reporting that aggregates reports of potential damage to non-target vegetation.
2. Information concerning dicamba-resistant weeds and cases of weed control failure.
3. Information by state and acres regarding sales of product used for OTT dicamba applications.

Herbicide Resistance Management Plan
The EPA is issuing this registration with a term that requires the registrants to conduct education and training and maintain an Herbicide Resistance Management (HRM) Plan. The HRM requirements strengthen the notification and reporting requirements, include additional education and training requirements, and requires enhanced follow up measures to contain and control, as best as possible, populations identified as resistant or likely to be resistant. The education program focuses on educating growers on the appropriate use of the products for OTT use on DT crops and the associated dicamba-tolerant seeds. The EPA is requiring that the HRM plan include measures that will reduce the potential for the development of weed resistance, including the investigation of lack of herbicide efficacy, engagement with growers to control and prevent spread of "likely resistance", annual reporting to EPA, reporting of "likely resistance" to other interested parties, and educational programs to provide growers with the best available information on herbicide resistance management.

Requirements for Additional Volatility-Reduction Adjuvants/Agents (pH Buffering Adjuvants)
The VRAs (pH buffering adjuvants) mandated for use as a tank mix when applying these products have been tested with scientific data to verify their efficacy in reducing off-site movement due to volatility. Because it is critically important to ensure that this reduced volatility is maintained, any additional VRA (pH buffering adjuvants) proposed for this use must also be proven with acceptable testing methods to ensure the same level of volatility-reduction before they can be approved for use. Strict testing protocols are required for this purpose. VRAs (pH buffering adjuvants) that are deemed acceptable after being tested with these protocols may then be added to a website maintained by the registrant that lists the approved options for tank mix partners available for use with their product.

In addition, because the number of VRAs (pH buffering adjuvants) deemed acceptable for these uses may be limited after the initial registration in the immediate future, additional terms are added requiring the registrants to provide assurance that these VRA/pH buffering adjuvants will be available in amounts sufficient to ensure availability for lawful use with all dicamba products released for use on DT crops.

Requirements for Additional Tank Mixes
Additional components to an application solution are commonly used for a variety of reasons, including reducing costs and increasing efficacy. Because the addition of tank mix partners can affect the drift potential of the resulting spray solution, potential tank mix partners must first be tested with wind tunnel data to ensure that higher drift potential does not occur as a result of applying the mixture. Strict wind tunnel testing protocols are required to verify that tank mixtures will not increase drift potential before they can be approved for actual field use.

Requirements for Qualifying Additional Hooded Sprayer Equipment for Reduced Infield Buffers
The Agency encourages the use of drift reduction techniques as a general risk management technique with any pesticide application. Hooded sprayers are an equipment option that can provide significant drift reduction benefits to agricultural pesticide applications. However, different types of hooded sprayers can provide different levels of drift reduction. A reduced downwind buffer has been approved for these products in association with the use of certain hooded sprayers after acceptable data demonstrated that this reduction is appropriate. For additional hooded sprayers to be similarly approved for use with reduced downwind buffers, they must first be tested using the specific testing protocols required for this purpose.

D. Registration Expiration

EPA's determination that the benefits of the use of dicamba on DT cotton and DT soybeans outweigh the potential risks is based in part on the requirement that EPA Registration Numbers 264-1210, 100-1623, and 7969-472 automatically expire on December 20, 2025, unless the EPA takes further action to amend the registration. As noted in Section VII of this decision, approving the registration of dicamba use on DT cotton and DT soybeans until December 20, 2025 will enable cotton and soybean growers to have continued access for at least a limited time for a tool that is important to control glyphosate-resistant weeds, while simultaneously allowing EPA and states to monitor the impacts of the new control measures and positioning the Agency to be responsive to any unexpected impacts.

E. Geographic Limitation of the Registration

Dicamba products registered for use on DT cotton and/or DT soybeans may only to be sold and used in Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, West Virginia, and Wisconsin.

IX. EPA's Effects Determinations under the ESA

In order to protect listed species, EPA conducted species-specific analyses to make its effects determinations under section 7(a)(2) of the ESA for these registration actions. The ESA effects determination makes use of the best available scientific information and considered both direct and indirect effects. These analyses and effects determinations are contained in *2020 Ecological Assessment of Dicamba Use on Dicamba-Tolerant (DT) Cotton and Soybean Including Effects Determinations for Federally Listed Threatened and Endangered Species* (available on regulations.gov, Docket ID: EPA-HQ-OPP-2020-0492). The listed species effects determination evaluates whether the federal action poses any discernible effects to listed species and any designated critical habitats that are reasonably expected to occur within the action area. The following summarizes these determinations.

In conducting this effects analysis, EPA used the methods described in the EPA's *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations* (USEPA 2004), and relied on location information provided by NMFS and USFWS (collectively referred to the Services),for the purposes of establishing whether listed species and any designated critical

habitats occur within the action area for these pesticide registration actions. EPA also used the Services published materials describing the biology and behavior of the species and the characteristics of any designated critical habitats.

EPA used the best available scientific information related to dicamba effects on non-target plants and animals. These include: 1) pesticide registrant submissions to the EPA, 2) published scientific literature, 3) submissions to the EPA from various academic researchers, and 4) non-governmental organization submissions. Where applicable, EPA relied on conservative taxa-specific risk assessment methods and their associated conservative assumptions regarding pesticide exposure and organism biology and behavior to identify taxonomic groups of non-target organisms that either 1) are not reasonably expected to be affected by the federal action or 2) require additional evaluation in a more biologically accurate and exposure appropriate species specific quantitative evaluation.

Taxonomic groups considered unaffected by the federal action include the aquatic taxa: fish and amphibians, invertebrates, and multicellular plants. Aquatic unicellular plants were identified as a possible taxon for additional evaluation for effects to listed species, however no unicellular plants are identified by the Services' as listed species, so no further effects determination refinement efforts were necessary for this taxon. Terrestrial mammals and birds (and reptiles as well terrestrial phase amphibians) and invertebrates were identified as taxa requiring effects determinations. For these animal taxa, EPA assessed whether the listed species would be reasonably expected to occur within the borders of the treated crop field (i.e., the action area). Once the listed species were determined to be in the action area, EPA assessed whether there were any discernible effects to these species.

In contrast to animals, effects to terrestrial non-monocot plants have the potential to be more geographically extensive without mandatory dicamba control measures. Available data indicated that, without these measures, these effects may extend beyond the treated field. EPA reached this preliminary finding after consideration that 1) non-monocot plants were the most sensitive taxa to dicamba exposure and therefore likely to define the boundaries of the action area, 2) the large number reports of plant incidents related to off-field dicamba exposure, and 3) the availability of a large body of evidence characterizing the plant effects associated with transport of dicamba from the treatment site. Therefore, EPA's evaluation of risks to non-monocot plants incorporated more comprehensive methods for risk assessment to characterize the potential for direct effects on this taxon.

For this ESA assessment, EPA evaluated the mandatory control measures against the following criteria:

- whether there was any discernible effect to species or habitat using at least 95% certainty of no effects when considering all of the control measures
- quantitatively assess effects related to growth, survival, and reproduction
- consideration of incident information
- whether the control measures addressed any wide area effects

EPA evaluated the potential for off-field (near field and wide area) transport of dicamba by the combination of spray drift and volatility, taking into account the mandatory control measures on the product labeling. The Agency concludes the following related to spray drift:

- The mandatory 310 feet in-field downwind spray drift setback to address spray drift achieved a 95% probability that any effects would be limited to the treated field in counties where required. Therefore, there are no discernible effects for listed species off of the treated field.
- If an approved hooded sprayer is used (optional, not mandatory on the labels), EPA determined that the in-field downwind spray drift setback could be decreased from 310 feet to 240 feet in soybeans only. EPA determined this reduction in the setback does not change the effects determinations.

EPA then considered the mandatory control measures that address volatile emissions. For the effects determinations, EPA evaluated the combined volatile emissions control measures (VRAs, application cut-off dates, and an in-field 57-ft omnidirectional volatile emissions application buffer). The combination of these control measures results in a greater than 95% certainty that dicamba exposures will remain within the confines of the field (i.e., the action area). Because these combined control measures confine exposure to the treated field, EPA finds these measures also address the potential for area wide exposures and loading to the downwind atmosphere. Similarly, the prohibition against application after a certain date (depending on the crop) reduces the timing of applications that would have occurred when temperature conditions favor volatility, additionally reducing loading to the downwind atmosphere.

The requirement of an in-field 57-ft omnidirectional buffer also provides certainty that the action area is confined to the treated field when considering pesticide runoff. This buffer in combination with label instruction to prohibit application to saturated soils, or within 48 hours of predicted rainfall events, further supports EPA's conclusion that any discernible effects related to the possibility of runoff are not reasonably expected to occur in the 287 counties where the 57-ft buffer is required.

For these registration actions, EPA determined that 22 of 23 species and one critical habitat overlap with the action area and the determination for these species and critical habitat is No Effect. The remaining species (Eskimo Curlew) is "May Affect, Not Likely to Adversely Affect." Under the ESA section 7(a)(2) and its implementing regulations, EPA initiated informal consultation with the U.S. Fish and Wildlife Service (USFWS). On October 22, 2020, EPA received concurrence from FWS on our determination.

All listed other species and designated critical habitat within the 34 states of dicamba product use are outside the action area. EPA concludes these listed species and designated critical habitat are unaffected by this federal action, therefore the Agency does not need to make effect determinations for all of the species outside the action area. For example, the Karner blue butterfly *(Lycaeides melissa samuelis*) range occurs within some of the 34 states for use. This species has an obligate relationship with wild lupines (*Lupinus perennis*) upon which the adults lay eggs and the larvae develop. However, the species range does not overlap with the action area, and an effects determination is not needed for a species outside the action area.