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

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I. INTRODUCTION

This memorandum presents the rationale to support the proposed decision of the U.S. Environmental Protection Agency (referred hereafter as EPA or the Agency) to register under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), three end use dicamba products for weed control in dicamba tolerant (DT) cotton and DT soybean.

II. CHEMICAL INFORMATION and BACKGROUND

Dicamba is a systemic benzoic acid herbicide that is used for selective control of emerged broadleaf weeds in a variety of food and feed crops and in non-agricultural settings. The Weed Science Society of America (WSSA) classifies dicamba as a Group 4 synthetic auxin type herbicide. Dicamba mimics auxins, a type of plant hormone, and causes abnormal cell growth by affecting cell division. The three pesticide products covered by this memorandum contain two forms of dicamba, as described in Table 1 below:

Table 1. 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

Dicamba was first registered for “over-the-top" (OTT) use on dicamba tolerant (DT) cotton and DT soybean in 2016. 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. These 2016 registrations (M1768 HERBICIDE/XtendiMax with VaporGrip Technology (EPA Registration Number 524-617), Engenia Herbicide (EPA Registration Number 7969-345), and DuPont FeXapan (EPA Registration Number 352-913)) were time-limited with automatic expiration dates in late 2018. In November 2018, EPA granted requests from the registrants (Bayer, BASF, and DuPont) to extend the expiration dates to December 20, 2020. At the same time, EPA approved amendments to the terms and conditions of the registrations as well as amendments to add labeling restrictions to further reduce the potential for off-site movement of dicamba from the treated fields. In April 2019, EPA approved an application from Syngenta Crop Protection, LLC to register a product containing a combination of dicamba and S-metolachlor (Tavium Plus VaporGrip Technology (EPA Registration Number 100-1623)) for OTT use on DT cotton and DT soybeans with an expiration date of December 20, 2020.

In June 2020, the 9th Circuit Court of Appeals vacated the registrations of three of the four dicamba products registered for use on DT cotton and DT soybean on the basis that EPA “substantially understated risks that it acknowledged and failed entirely to acknowledge other risks.”

Following the vacatur, in July 2020, Bayer CropScience LP and BASF submitted applications to register new XtendiMax with VaporGrip Technology (EPA Registration Number 264-1210) and Engenia Herbicide (EPA Registration Number 7969-472) products, respectively, for use on DT cotton and DT soybean. Shortly thereafter, Syngenta Crop Protection, LLC submitted an application to extend its registration of Tavium Plus VaporGrip Technology (EPA Registration Number 100-1623), which was not vacated by the 9th Circuit and was set to expire in December 2020. On October 27, 2020, EPA granted the registrations and registration amendment and established an expiration date of December 20, 2025 for these three registrations. That decision is described in the '*Memorandum Supporting Decision to Approve Registration for the Uses of Dicamba on Dicamba Tolerant Cotton and Soybean*' in Docket EPA-HQ-OPP-2020-0492 on regulations.gov.

On December 23, 2020, Center for Biological Diversity, Center for Food Safety, National Family Farm Coalition, and Pesticide Action Network North America filed a complaint in the District of Arizona challenging EPA's October 27, 2020 approval of the registrations of XtendiMax (EPA Registration Number 264-1210) and Engenia (EPA Registration Number 7969-472) and of the registration amendment for Tavium (EPA Registration Number 100-1623). On February 6, 2024, the court issued an order and judgment vacating the registrations for XtendiMax (EPA Registration Number 264-1210), Engenia (EPA Registration Number 7969-472), and Tavium (EPA Registration Number 100-1623), holding that EPA had violated FIFRA section 3(c)(4) by approving these registrations without providing notice and an opportunity for public comment. The vacatur of these registrations became effective on February 6, 2024. Accordingly, as of that date, these products were unregistered. On February 14, 2024, EPA issued an existing stocks order[1] ("2024 Existing Stocks Order") containing EPA's provisions for the disposition of any existing stocks of the formerly registered products. Except as described in the 2024 Existing Stocks Order, sale or distribution of these products was deemed unlawful as of February 6, 2024.

III. REQUESTED ACTION and USE PROFILE

Bayer CropScience LP (Bayer), BASF Corporation (BASF), and Syngenta Crop Protection, LLC (Syngenta) each submitted a registration application for a new dicamba product between March and June 2024. These applications all proposed new uses for dicamba postemergent, "over the top" (OTT), of DT cotton and DT soybean. Syngenta's proposed product also contains s-metolachlor in the product formulation. The use of s-metolachlor on DT cotton and DT soybean is not considered a new use, because s-metolachlor is currently registered for postemergent use on cotton and soybean; thus, this document is focused on the proposed registration of dicamba for postemergent use on DT cotton and DT soybean.

The proposed KHNP0090 HERBICIDE (EPA File Symbol 264-REUR) and Tavium Plus VaporGrip Technology (EPA File Symbol 100-RTLG) are restricted use pesticide products formulated as a liquid concentrate and a capsule suspension, containing 42.8% and 17.7% of the active ingredient (ai) dicamba diglycolamine (DGA) salt, respectively. In addition, the proposed Tavium Plus VaporGrip Technology (EPA File Symbol 100-RTLG) contains 24% s-metolachlor. The proposed Engenia Herbicide (EPA File Symbol 7969-LNT) is also a restricted use pesticide product and is formulated as a liquid concentrate containing 60.8% of the ai dicamba N, N-bis-(3-aminopropyl) methylamine (BAPMA) salt.

[1] https://www.epa.gov/system/files/documents/2024-02/dicamba-notice-existing-stocks-order_02142024.pdf

Table 2. Dicamba Products Proposed for Registration for Use on DT Cotton and DT Soybean

EPA File Symbol	Product Name	Registrant	Form of Dicamba
100-RTLG	Tavium Plus VaporGrip Technology	Syngenta	DGA salt
264-REUR	KHNP0090 Herbicide	Bayer	DGA salt
7969-LNT	Engenia Herbicide	BASF	BAPMA salt

For all three products proposed for use in DT cotton and DT soybean, broadcast, banded, or spot treatment applications are proposed via ground equipment only. The proposed single use maximum application rate is 0.5 lb acid equivalents (ae)/acre (A). These applications are proposed during preplant, at-plant, preemergence, and/or postemergence crop stages, where specified. Aerial and chemigation applications of these products are prohibited on the proposed product labels. No more than two applications are proposed per growing season for a maximum annual application rate of 1.0 lb ae/A. A minimum retreatment interval of 7 days is specified on the proposed KHNP0090 HERBICIDE (264-REUR) and Engenia Herbicide (7969-LNT) product labels.

All three proposed product labels are intended for application by certified applicators to agricultural use sites only and require workers to wear baseline attire (i.e., long-sleeve shirt, long pants and shoes plus socks) along with personal protective equipment (PPE) including chemical resistant gloves when handling these products. A NIOSH-approved dust/mist filtering respirator with any R, P, or HE filter is also required for all handlers of the BAPMA salt formulated product. A restricted entry interval (REI) of 24 hours is listed on all three proposed labels.

IV. EVALUATION

In evaluating a pesticide registration application, EPA assesses a wide variety of exposure information (i.e., where and how the pesticide is used) as well as environmental fate (i.e., how the chemical will move in the environment) and toxicity studies (i.e., effects on humans and other non-target organisms) to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the proposed use of the product. Risk assessments are developed to evaluate the environmental fate of the compound as well as how it might affect a wide range of non-target organisms including humans, terrestrial wildlife, and aquatic wildlife (plants and animals). In addition, a benefits and impacts assessment may be conducted.

FIFRA provides that EPA shall approve a registration if the Agency determines that the pesticide will not generally cause "unreasonable adverse effects on the environment." This standard consists of two parts: the pesticide may neither cause an "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide" nor, in the case of a pesticide resulting in residues in food or feed, cause a human dietary risk that is not safe.

Sections IV.A and IV.B describe the costs of the use of the pesticide in terms of the risk posed by use of the pesticide on human health and the environment. These 'costs' of the use a) are measured using terms such as margins of exposure (MOEs) for human health and risk quotients (RQs) for ecological risks, b) can be described qualitatively, or c) may be described in both quantitative and qualitative terms. Risk assessments also describe who or what organism bears the identified risk. EPA considers a wide range of potential adverse effects and the potential costs that could result. In the case of OTT dicamba, for example, there could be adverse effects on crops in areas adjacent to fields treated with dicamba,

potentially imposing economic and social costs on neighboring farmers. Section IV.C summarizes the history of dicamba-related incidents and consequences of off-target movement. Section IV.D describes the benefits associated with the use of the pesticide. Benefit assessments use a weight of evidence approach to describe who will use the pesticide and how it will potentially improve outcomes (e.g., agricultural production).

Based on these assessments, EPA evaluates the risks and benefits to determine whether the use of the pesticide will generally cause unreasonable adverse effects. As part of this evaluation, EPA reviews language on draft pesticide labeling submitted as part of an application for registration, and then works with the applicant to revise the label as needed to ensure the directions for use are appropriate to mitigate potential risks to a level that they are not unreasonable. In this way, the pesticide label communicates essential directions for use, including limitations and mitigations that are necessary to avoid unreasonable adverse effects to human health and environment. It is a FIFRA violation to use a pesticide in a manner inconsistent with its labeling. EPA also met its obligations under the Endangered Species Act (ESA) Section 7 by assessing the potential effects of the proposed use of dicamba on federally listed threatened or endangered (hereafter referred to as "listed") species and their designated critical habitats (CHs) and determined whether mitigations would be needed.

A. Assessment of Risks to Human Health

The EPA requires a wide range of studies in order to assess a pesticide use scenario (see 40 CFR Part 158[2]). For the proposed uses of dicamba on DT cotton and DT soybean, the database of studies required to support the assessment of risk to human health is complete.

This section summarizes EPA's '*Dicamba and Dicamba BAPMA Salt. Human-Health Risk Assessment for Proposed Section 3 Registration on Dicamba-tolerant Cotton and Dicamba-tolerant Soybean*.' The complete assessment can be found in docket ID number EPA-HQ-OPP-2024-0154 at www.regulations.gov.

1. Toxicology Profile

Dicamba (3,6-Dichloro-o-anisic acid) is a selective benzoic acid herbicide currently registered in various acid and salt formulations for use on a variety of agricultural and non-agricultural use sites. Dicamba is an auxin agonist that induces abnormal and uncontrolled growth to disrupt normal plant functions at high concentrations. For dicamba-tolerant varieties, the dicamba mono-oxygenase (DMO) gene is introduced into seeds to encode the enzyme dicamba *O*-demethylase to convert dicamba into the non-herbicide metabolite 3,6-dichlorosalicylic acid (DCSA), thus causing the plant to tolerate the herbicidal effect of dicamba. Dicamba-tolerant varieties demonstrate further hydroxylation of DCSA to form the 2,5-dichloro-3,6-dihydroxybenzoic acid (DCGA) metabolite.

EPA considered available study data for the dicamba acid, dicamba salt forms [isopropylamine (IPA) and DGA, and BAPMA], and metabolites [DCSA, DCGA, and 5-hydrocydicamba (5-OH dicamba)] when assessing human health risks from exposures to dicamba. Based on available toxicity studies and structural similarities, the various forms of dicamba are generally considered to be of comparable toxicity and are assessed concurrently. Because the use patterns, restrictions, and application rates

[2] eCFR :: 40 CFR Part 158 -- Data Requirements for Pesticides

across the three proposed products and two proposed use sites are similar, these actions were evaluated concurrently.

The dietary, incidental oral, and dermal endpoint determinations for dicamba acid are protective for assessing anticipated exposures from the dicamba DGA salt and dicamba BAPMA salt formulations because of their comparable toxicity. However, due to differences in the toxicological inhalation endpoints between the dicamba acid (which is protective of the DGA salt form) and BAPMA salt forms, separate inhalation points of departure (PODs) have been selected for these assessments. The toxicological endpoints and PODs for assessing human health risks from exposures to the dicamba DGA salt and the BAPMA salt formulations are summarized below.

The acute dietary POD for dicamba is based on ataxia, unsteady gait, and convulsions in the dams (considered a single-dose effect since the signs occurred within 3 hours after dosing) observed at the lowest observed effects level (LOAEL) of 86 mg/kg/day in a rat developmental study for the dicamba BAPMA salt. The no observed adverse effects level (NOAEL) of 29 mg/kg/day is selected for deriving the acute reference dose (RfD). An uncertainty factor of 100X (which includes 10X to account for interspecies extrapolation, 10X for intraspecies variation, and a Food Quality Protection Act (FQPA) Safety Factor (SF) of 1X) is applied to the NOAEL to obtain an acute RfD of 0.29 mg/kg/day. A separate acute dietary risk assessment was not conducted for females since developmental toxicity endpoints of concern attributable to a single dose (exposure) were not identified in the database.

The chronic dietary POD for dicamba is based on decreased pup body weights observed at 37 mg/kg/day (LOAEL) in a two-generation reproduction toxicity study with the DCSA metabolite. The NOAEL of 4 mg/kg/day is selected for deriving the chronic RfD. An uncertainty factor of 100X (10X to account for interspecies extrapolation, 10X for intraspecies variation, and 1X for FQPA SF) is applied to the NOAEL to obtain a chronic RfD of 0.04 mg/kg/day.

The incidental oral POD was selected from the two-generation reproductive toxicity study in rats dosed with parent compound (dicamba acid) and based on impaired pup growth observed at the LOAEL of 450 mg/kg/day; the NOAEL of 136 mg/kg/day was selected as the POD for this scenario. The Level of Concern (LOC) for incidental oral exposures is 100, which includes the 10X factor to account for interspecies extrapolation, a 10X factor to account for intraspecies variation, and a 1X FQPA SF.

Dermal endpoints were not selected for dicamba acid or its salts, as there are no adverse systemic effects in the database from dermal exposure at the limit dose (1000 mg/kg/day) and no evidence of susceptibility in available developmental and reproductive studies.

Route-specific inhalation studies are currently available for the dicamba acid and dicamba BAPMA salt formulations. Because the dicamba BAPMA salt is demonstrated to be more toxic than the dicamba acid, separate inhalation PODs have been selected for assessing risk from inhalation exposures to the dicamba DGA salt and dicamba BAPMA salt formulations. For the dicamba DGA salt, the inhalation POD was based on the route-specific dicamba acid inhalation toxicity study in Wistar rats with a lowest observed adverse effect concentration (LOAEC) of 0.050 mg/L based on local effects of hyperplasia in the lungs and lymph nodes (no observed adverse effect concentration (NOAEC) = 0.005 mg/L, non-systemic, pulmonary regional deposited dose ratio (RDDR) = 0.590). For the dicamba BAPMA salt, the inhalation POD is based on the dicamba BAPMA salt inhalation toxicity study in rats with a LOAEC of 0.0014 mg/L based on local effects of hyperplasia and ulceration of the larynx (no NOAEC, non-systemic, extra-thoracic RDDR = 0.190). The standard interspecies extrapolation uncertainty factor (UF) is reduced

from 10X to 3X for dicamba acid (and DGA salt) and BAPMA salt due to the calculation of human equivalent concentrations (HECs) accounting for pharmacokinetic (not pharmacodynamic) interspecies differences. The LOC for dicamba BAPMA salt inhalation exposures is 300 (3X for interspecies extrapolation, 10X for intraspecies variation, and a 10X UF_L (uncertainty factor for use of a LOAEC) is applied due to lack of a NOAEC). For all other forms of dicamba, the inhalation exposure LOC is 30 (3X for interspecies extrapolation, 10X for intraspecies variation, and 1X for FQPA SF when applicable).

Dicamba is classified as "Not Likely to be Carcinogenic to Humans" based on an absence of treatment-related tumors in mice and rats.

A summary of the PODs selected for human health risk assessments can be found in Tables 3, 4, and 5.

Table 3. Toxicological Doses and Endpoints for Dicamba Acid and Dicamba BAPMA Salt for use in Human Health Risk Assessments

Exposure/ Scenario	POD	UF, FQPA SF/ RfD, PAD, LOC	Study and Toxicological Effects
Acute Dietary (General population including infants and children)	NOAEL = 29 mg/kg/day (20 mg/kg/day as acid equivalent)	UF_A = 10X UF_H = 10X FQPA SF = 1X aRfD = 0.29 mg/kg/day aPAD = 0.29 mg/kg/day	**Dicamba BAPMA Salt** **Rat Prenatal Developmental Study (MRID 49441802)** **Maternal** LOAEL = 86 mg/kg/day in dams, based on ataxia, unsteady gait and convulsions observed shortly after dosing (60 mg/kg/day as acid equivalent) **Developmental** NOAEL > 288 mg/kg/day (200 mg/kg/day as acid equivalent)
Acute Dietary (Females 13-49 years of age)	N/A	N/A	No developmental toxicity attributed to acute exposure in the toxicology database. The abortions in the rabbit developmental study occurred at gestation day 22.
Chronic Dietary (All populations)	Offspring NOAEL = 4 mg/kg/day	UF_A = 10X UF_H = 10X FQPA SF = 1X cRfD = 0.04 mg/kg/day cPAD = 0.04 mg/kg/day	**DCSA Metabolite** **Rat Reproductive Toxicity Study (MRID 47899517)** Offspring LOAEL = 37 mg/kg/day based on decreased pup weights in F1 generation on PND 14 and 21 (both sexes) and week 18 (females)
Short-Term (1 - 30 Days) Incidental Oral	Offspring NOAEL = 136 mg/kg/day	Residential LOC = 100 UF_A = 10X UF_H = 10X FQPA SF = 1X	**Dicamba Acid** **Rat Reproductive Toxicity Study (MRID 43137101)** Offspring LOAEL = 450 mg/kg/day based on decreased pup weights.
Short- and Intermediate-term Dermal	No dermal assessment for dicamba acid or salts since the dermal toxicology studies for dicamba acid, IPA and DGA salts all had NOAELs of 1000 mg/kg/day.		
Dicamba Acid Short- and Intermediate-Term Inhalation	NOAEC = 0.005/0.005 mg/L (M/F) See Table 4.5.3.2 for HEC/HED Calculations	Residential/ Occupational LOC = 30 UF_A = 3X UF_H =10X FQPA SF = 1X	**Dicamba Acid** **Rat Aerosol Inhalation Study (MRID 49461101)** NOAEC = 0.005/0.005 mg/L (M/F) LOAEC = 0.050/0.050 mg/L (M/F), based on minimal multifocal bronchiole-alveolar hyperplasia in males; multiple microscopic findings in the lung and associated lymph nodes in females

Table 3. Toxicological Doses and Endpoints for Dicamba Acid and Dicamba BAPMA Salt for use in Human Health Risk Assessments			
Exposure/ Scenario	**POD**	**UF, FQPA SF/ RfD, PAD, LOC**	**Study and Toxicological Effects**
Dicamba BAPMA Salt Short- and Intermediate-Term Inhalation	LOAEC = 0.0014 mg/L (0.001 mg/L as acid equivalent) See Table 4.5.3.3 for HEC/HED Calculations	Residential/Occupational LOC = 300 UF_A = 3X UF_H =10X UF_L = 10X	**Dicamba BAPMA Salt** **Rat Inhalation Study (MRID 49441803)** NOAEC = NA LOAEC = 0.0014 mg/L (LDT), based on ulcers in epithelial tissues of the larynx and single/multi-focal hyperplasia in the larynx (0.001 mg/L as acid equivalent)
Cancer (Oral, dermal, inhalation)	Dicamba is classified as "Not Likely to be Carcinogenic to Humans".		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Table 4. Summary of HEC/HED values used for interspecies extrapolation for Dicamba Acid*.

Population	Scenario[§]	Toxicity Duration Adjustment[A]		HEC[B]		HED (mg/kg/day)[H]
		Daily	Weekly	mg/L	mg/m^3	
Occupational	Handler	8	5	0.002[C]	2.21	0.21[I]
Residential	Handler	NA	NA	0.003[D]	2.95	0.07[J]
	Outdoor post-application	NA	NA	0.003[E]	2.95	0.08[K]
	Indoor post-application	NA	7	0.002[F]	2.11	0.05[L]
	Bystander	24	7	0.001[G]	0.53	--

*The inhalation values have been calculated based on the 2016 revised spreadsheets. The HED calculation has been revised to be based on the same breathing rate used to derive the HEC – resulting in a single HED as the toxicological point of departure. In terms of risk estimates, the effect of this error correction is not unidirectional – some previously-calculated risks will be higher, while some will be lower.

NA = not applicable (the expected duration of the exposure scenario is less than the duration in the available inhalation toxicity studies; downward adjustments are not permitted).

[§] While all possible scenarios are included in this table, the relevant scenarios for the proposed use pattern include occupational handler and residential bystander.

[A] Toxicity duration adjustment from 6 hours/day, 5 days/week in the route-specific inhalation study.

[B] HEC = human-equivalent concentration; HEC = rat POD x daily duration adjustment x weekly daily duration adjustment x RDDR.

[C] Occupational Handler HEC (portal of entry endpoint) = 0.005 mg/L * (6 hrs/8 hrs) * (5 days/5 days) * 0.59 = 0.002 mg/L

[D] Residential Handler HEC (portal of entry endpoint) = 0.005 mg/L * 0.59 = 0.003 mg/L

[E] Residential Outdoor Post Application HEC (portal of entry endpoint) = 0.005 mg/L * 0.59 = 0.003 mg/L

[F] Residential Indoor Post Application HEC (portal of entry endpoint) = 0.005 mg/L * (5 days/7 days) * 0.59 = 0.002 mg/L

[G] Residential Bystander HEC (portal of entry endpoint) = 0.005 mg/L* (6 hrs/24 hrs) * (5 days/7 days) * 0.59 = 0.001 mg/L

[H] HED = human-equivalent dose; HED = HEC (mg/L) x human specific conversion factor (11.8 L/hr-kg) x respiratory tract to oral absorption ratio (1) x duration of daily exposure for activity (occupational handler = 8 hrs/day, residential handler and indoor post-application = 2 hrs/day, residential outdoor post-application = 2.3 hrs/day).

[I] (0.0022 mg/L) x (11.8 L/hr/kg) x 1 x (8 hrs)= 0.21 mg/kg/day

[J] (0.003 mg/L) x 1 x (11.8 L/hr/kg) x (2 hrs)= 0.07 mg/kg/day

[K] (0.003 mg/L) x 1 x (11.8 L/hr/kg) x (2.3 hrs)= 0.08 mg/kg/day

[L] (0.002 mg/L) x 1 x (11.8 L/hr/kg) x (2 hrs)= 0.05 mg/kg/day

Table 5. Summary of HEC/HED values used for interspecies extrapolation for Dicamba BAPMA Salt*.						
Population	**Scenario[§]**	**Toxicity Duration Adjustment[A]**		**HEC[B]**		**HED (mg/kg/day)[H]**
		Daily	**Weekly**	**mg/L**	**mg/m^3**	
Occupational	Handler	8	5	0.00[C]	0.20	0.02[I]
Residential	Handler	NA	NA	0.00[D]	0.27	0.01[J]
	Outdoor post-application	NA	NA	0.00[E]	0.27	0.01[K]
	Indoor post-application	NA	7	0.00[F]	0.19	0.00[L]
	Bystander	24	7	0.00[G]	0.05	--

*The inhalation values have been calculated based on the 2016 revised spreadsheets. The HED calculation has been revised to be based on the same breathing rate used to derive the HEC – resulting in a single HED as the toxicological point of departure. In terms of risk estimates, the effect of this error correction is not unidirectional – some previously-calculated risks will be higher, while some will be lower.

NA = not applicable (the expected duration of the exposure scenario is less than the duration in the available inhalation toxicity studies; downward adjustments are not permitted).

[§] While all possible scenarios are included in this table, the relevant scenarios for the proposed use pattern include occupational handler and residential bystander.

[A] Toxicity duration adjustment from 6 hours/day, 5 days/week in the route-specific inhalation study.

[B] HEC = human-equivalent concentration; HEC = rat POD x daily duration adjustment x weekly daily duration adjustment x RDDR.

[C] Occupational Handler HEC (portal of entry endpoint) = 0.0014 mg/L * (6 hrs/8 hrs) * (5 days/5 days) * 0.19 = 0.0002 mg/L

[D] Residential Handler HEC (portal of entry endpoint) = 0.0014 mg/L * 0.19 = 0.0003 mg/L

[E] Residential Outdoor Post Application HEC (portal of entry endpoint) = 0.0014 mg/L * 0.19 = 0.0003 mg/L

[F] Residential Indoor Post Application HEC (portal of entry endpoint) = 0.0014 mg/L * (5 days/7 days) *0.19 = 0.0001 mg/L

[G] Residential Bystander HEC (portal of entry endpoint) = 0.0014 mg/L* (6 hrs/24 hrs)*(5 days/7 days)* 0.19 = 0.00005 mg/L

[H] HED =human-equivalent dose; HED = HEC (mg/L) x human specific conversion factor (11.8 L/hr-kg) x respiratory tract to oral absorption ratio (1) x duration of daily exposure for activity (occupational handler = 8 hrs/day, residential handler and indoor post-application = 2 hrs/day, residential outdoor post-application = 2.3 hrs/day).

[I] (0.0002 mg/L) x (11.8 L/hr/kg) x 1 x (8 hrs) = 0.02 mg/kg/day

[J] (0.0003 mg/L) x 1 x (11.8 L/hr/kg) x (2 hrs) = 0.01 mg/kg/day

[K] (0.0003 mg/L) x 1 x (11.8 L/hr/kg) x (2.3 hrs) = 0.01 mg/kg/day

[L] (0.0001 mg/L) x 1 x (11.8 L/hr/kg) x (2 hrs) = 0.002 mg/kg/day

2. Dietary (Food + Water) Risks

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose that EPA has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population-adjusted dose (PAD). The PAD is equivalent to the point of departure (POD) divided by all applicable uncertainty factors (UFs), including the Food Quality Protection Act (FQPA) Safety Factor (SF). EPA is concerned when estimated non-cancer dietary risk exceeds 100% of the PAD. Acute and chronic aggregate dietary (food and drinking water) risk assessments were conducted to include all registered and proposed uses of dicamba. These assessments assume 100 percent crop treated (PCT) and EPA default processing factors, where applicable. Estimated drinking water concentrations (EDWCs) were modeled and incorporated directly into these dietary assessments. An unrefined acute dietary assessment was conducted using tolerance level residues. Acute dietary risk estimates are not of concern for the general U.S. population and all population subgroups assessed (<100% acute population-adjusted dose (aPAD)) at the 95th percentile; with the most highly exposed population subgroup being all infants (<1 year old) at 39% of the aPAD. A refined chronic dietary assessment was conducted using average field trial residues for crops, and tolerance level residues for livestock commodities. Chronic dietary risk estimates are not of concern for the general U.S. population and all population subgroups assessed (<100% chronic population-adjusted dose (cPAD)); with the most highly exposed population subgroup being children ages 1-2 at 51% of the cPAD.

3. Occupational Handlers Risks

Occupational exposure is anticipated based on the proposed uses. For occupational assessments, risk is presented as a Margin of Exposure (MOE) which is the ratio of the point of departure to the predicted or estimated human exposure dose. EPA is concerned when non-cancer MOEs are less than the level of concern (LOC). Since no dermal hazard has been identified for dicamba, quantitative occupational handler and/or post-application dermal risk assessments were not conducted at this time. Only occupational handler inhalation exposures were assessed. All occupational handler inhalation risk estimates are not of concern; MOEs range from 470 to 770 (i.e., MOEs ≥ inhalation LOC of 30 for the DGA salt; and ≥ inhalation LOC of 300 for the BAPMA salt) assuming 'baseline' attire (defined as a single layer of clothing consisting of a long-sleeved shirt, long pants, shoes plus socks) and label required PPE (i.e., waterproof gloves for all three labels and a respirator for BAPMA salt formulation only).

4. Residential Exposure

The proposed end-use products are labeled as restricted use pesticides intended for application by certified applicators to agricultural use sites only. Since there are no residential uses and/or use sites proposed as part of these registration applications, quantitative residential handler and/or post-application assessments were not conducted at this time. However, existing residential uses of dicamba have been assessed in previous risk assessments. There were no residential handler and/or post application risk estimates of concern (i.e., all inhalation margins of exposure (MOEs) ≥ inhalation LOC of 30; and all incidental oral MOEs ≥ incidental oral LOC of 100) identified for currently registered uses of dicamba. Since no dermal hazard was identified for dicamba, quantitative residential handler and/or post-application dermal risk assessments were not conducted.

5. Aggregate Risk

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from food, drinking water, and residential exposures. Since there are no acute or chronic residential exposures expected from the proposed or registered uses, the acute and chronic aggregate risk estimates for dicamba include food and drinking water only and are equivalent to the acute and chronic dietary risk estimates, which are not of concern. No dermal hazard has been identified for dicamba, and the inhalation and incidental oral endpoints are selected based on different toxicological effects, therefore, the short-term aggregate risk assessment only includes applicable oral exposures (e.g., food, water and residential incidental oral). As a result, a short-term aggregate assessment was not conducted for adults, because it would be equivalent to the dietary assessment (i.e., no residential incidental oral exposures for adults; only food and water). For children, the short-term aggregate [(food, water, and residential (incidental oral)] MOE is above the LOC of 100 and not of concern.

6. Cumulative Risk

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to dicamba and any other substances and dicamba does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that dicamba has a common mechanism of toxicity with other substances.

7. Non-Occupational Spray Drift Risk

EPA conducts human health spray drift assessments to determine potential risk from indirect exposure to pesticides that may drift during or immediately after an application. Pesticide applications made in the form of a spray and applied with ground equipment may result in pesticide drift and deposition in non-target areas adjacent to the application site.

Since dicamba is currently registered for use on turf, it was considered whether the risk assessment for the turf use would be considered protective of any type of exposure expected to result from spray drift. The maximum crop application rate (0.5 lb ae/A), adjusted for maximum anticipated spray drift deposition potential (0.26), was found to be less than or equal to the existing turf application rate (1 lb ae/A). Therefore, the conducted post-application exposure assessment for turf is considered protective of anticipated spray drift exposures from the proposed agricultural uses of dicamba DGA salt and a quantitative spray drift assessment is not conducted at this time. As determined, there were no residential post-application risks of concern identified for the registered use on turf.

A quantitative non-occupational spray drift assessment was conducted for dicamba BAPMA salt. Adult dermal and children (1 to <2 years old) dermal exposures were not assessed since there were no adverse effects observed in the route specific dermal toxicity study up to and including the limit dose. Therefore, only incidental oral exposures for children (1 to <2 years old) are quantitatively assessed. Using default turf transferable residues (TTR) assumptions, children (1 to <2 years old) incidental oral risk estimates from exposure to dicamba BAPMA salt associated with spray drift residues results in no risks of concern (i.e., MOEs ≥ LOC of 100) at the field edge for ground boom applications.

8. Non-Occupational Bystander Inhalation Exposure and Risk

The potential for non-occupational exposures to vapor phase dicamba residues emitted from treated fields for application rates up to 2.0 lb ae/A were evaluated previously using the Probabilistic Exposure and Risk model for FUMigants (PERFUM) and chemical/formulation-specific flux data. EPA concluded that while volatilization of dicamba from treated crops (at rates up to 2.0 lb ae/A) does occur and could result in bystander exposure, airborne concentrations, even at the edge of the treated fields, were not of concern. EPA notes that the volatilization assessment SOPs, methodologies, and data assumptions remain current. Since the proposed agricultural uses of dicamba DGA salt and dicamba BAPMA salt are at application rates lower (0.5 lb ae/A) than those previously assessed (2.0 lb ae/A), these assessments are considered protective for the proposed agricultural uses. Therefore, there are no non-occupational bystander inhalation risks of concern anticipated from these proposed uses.

B. Assessment of Environmental and Ecological Risks

EPA prepared a draft ecological risk assessment (ERA) that examines the potential for adverse effects to non-listed non-target organisms associated with proposed uses of dicamba and accounts for any mitigations on the label as submitted by the registrant in its application or proposed by EPA and agreed to by the registrants. The EPA also prepared a draft Biological Evaluation (BE) that assesses the effects on listed species and designated critical habitat and includes EPA's predictions of the potential likelihood of future jeopardy (J) for listed species and adverse modification (AM; collectively referred to as J/AM) of designated critical habitats (CHs), as well as the EPA's assessment of how mitigations are identified to avoid such findings. However, while EPA is predicting whether there is the potential likelihood of future

J/AM, the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service (collectively referred to as the Services) are responsible for making the final J/AM findings.

The taxa evaluated in the draft ERA include mammals, birds (which serve as surrogates for reptiles and terrestrial-phase amphibians), bees (which serve as surrogates for terrestrial invertebrates), fish (where freshwater fish serve as surrogates for aquatic-phase amphibians), aquatic invertebrates, and aquatic and terrestrial plants. Ecological risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic (RQ = Exposures/Toxicity). RQs are then compared to the EPA's acute and chronic risk levels of concern (LOCs) for each taxon. The LOCs are used by the EPA to indicate a level above which there is a potential risk of concern to non-target organisms from a pesticide, when used as directed. RQs equal to or below an LOC indicate there are no risks of concern for that taxon. The LOCs for non-listed species are meant to be protective of community-level effects. If the RQ exceeds the LOC, then the EPA further characterizes and describes the associated risk of concern.

EPA considered and applied as appropriate the Agency's Herbicide Strategy[3] (HS). This strategy provides a framework that describes how EPA intends to identify potential mitigations to reduce identified potential population-level impacts to listed species from the agricultural use of conventional herbicides in the contiguous 48 states from spray drift and runoff. The HS describes the calculation of the magnitude of difference (MoD), which is the ratio of the herbicide estimated environmental concentration to its corresponding toxicity threshold value for population-level impacts to a single species. EPA also considered and applied as appropriate the Vulnerable Species Action Plan (VSAP). The VSAP provides a framework for EPA to identify the need for mitigation to address potential population-level impacts for 27 listed species that EPA identified as particularly vulnerable to pesticides.

This section summarizes EPA's '*Draft Ecological Risk Assessment and Biological Evaluation Including Effects Determinations for Federally Listed Endangered and Threatened Species and Designated Critical Habitat for the Proposed Section 3 New Use Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean*'. The complete assessment can be found in docket ID number EPA-HQ-OPP-2024-0154 at www.regulations.gov.

1. Environmental Fate Profile

In laboratory studies, dicamba was found to be soluble (6,100 mg/L) and mobile (K_{oc} = 13.4 L/mg o.c.). Dicamba is an anion at environmental pHs (pKa = 1.9) and is not expected to bioaccumulate in aquatic organisms. Dicamba degrades rapidly via aerobic metabolism with half-lives on the order of days, while it is generally stable to abiotic processes, and it is generally more persistent under anaerobic conditions. Dicamba may reach surface water via runoff, by spray drift during application, and by vapor drift from volatilization. Based on academic and registrant studies, incident data from the Incident Data System (IDS), and the potential for increased volatility during warmer temperatures and in later season applications, EPA completed an analysis of movement of vapor volatilized from the treated field. Dicamba is less likely to be available to leach to groundwater because it is susceptible to aerobic degradation. However, any dicamba reaching groundwater would be somewhat persistent (due to its relative stability to hydrolysis).

[3] https://www.regulations.gov/document/EPA-HQ-OPP-2023-0365-1137

Dicamba (acid and salt forms), 3,6-dichlorosalicylic acid (DCSA) and 2-chloro-6-hydroxybenzoic acid (6-CSA) are the residues of concern for the ecological risk assessment based on exposure potential for each compound. The DCSA degradate is produced under anaerobic conditions, is soluble, and is slightly to moderately mobile. DCSA is persistent, accounting for > 60% of the applied dicamba after 365 days of anaerobic incubation in a laboratory-based environment consisting of sediment and water phase. DCSA is not persistent when formed under aerobic conditions and degrades roughly at the same rate as the parent. Based on a log KOW of -0.53, bioconcentration of DCSA is not a primary concern. DCSA may be transported to surface water via runoff or to groundwater via leaching. DCSA tends to be more stable to aerobic metabolism than dicamba with most half-lives ranging from 2 to 6 weeks. Data are not available to assess DCSA's stability to abiotic processes or anaerobic conditions. Based on structural modeling, DCSA is classified as being intermediately volatile from dry non-adsorbing surfaces. DCSA may be transported to surface water via runoff or to groundwater via leaching. DCSA is less likely to be available to leach to groundwater because it is susceptible to aerobic degradation. 6-CSA is similar in structure to DCSA; therefore, EPA assumed that it is similar in toxicity to DCSA. Based on previous assessments, EPA assumes parent only modeling captures the potential exposure of dicamba degradates for cotton and soybean uses (i.e., DCSA + 6-CSA).

2. Ecological Effects Profile and Potential Impacts

EPA considers the ecological risk database to be complete with respect to the proposed OTT uses (see **Section 1.4** of the draft ERA). In the ecological risk assessment conducted for dicamba, EPA identified potential on-and off-field risks of concern for terrestrial and wetland plants, and aquatic non-vascular plants in the Wetland Plant Exposure Zone (WPEZ). Additionally, there are potential on-field risks to aquatic-phase amphibians, terrestrial invertebrates (chronic exposure of honey bee larvae to dicamba), mammals, and birds (surrogates for terrestrial-phase amphibians and reptiles). There were no concerns for aquatic invertebrates.

Chronic effects from dicamba exposure have been observed in laboratory studies in mammals (reduced weight and delayed sexual maturation), birds (reduced number of offspring), and honey bees (reduced weight, survival, and adult emergence). No effects have been observed for fish or aquatic invertebrates (up to the highest concentration tested in available chronic exposure studies). In plants, dicamba acts by mimicking auxins (a type of plant growth hormone) and causing abnormal cell growth, generally showing greater toxicity to the tested dicot terrestrial plant species (up to an order of magnitude or more comparing the most sensitive dicots and monocots) and widely varying toxicity to the tested aquatic vascular and non-vascular plant species. Except where noted, the LOC for non-listed species is 1.0.

Non-Listed Species Conclusions

Terrestrial and Wetland Plants

Vegetative vigor endpoints are the most sensitive endpoints for dicamba. Considering the submitted toxicity data, dicamba has targeted toxic effects to dicots in comparison to observed effects to monocot species. EPA identified potential on- and off-field risks of concern for non-listed terrestrial and wetland plants from drift, runoff and volatility exposure. Volatility exposure is expected both near the field and across wide landscape areas. For spray drift, EPA determined that potential impacts to individual non-listed species may extend out to approximately 240 feet. For runoff exposure in the terrestrial plant exposure zone (TPEZ), there are LOC exceedances for non-listed dicots (RQs = 116-181), and no LOC

exceedances for non-listed monocots (RQs = 0.42-0.68). For runoff exposure in the WPEZ, there are LOC exceedances for both non-listed dicots (RQs = 294-1310) and monocots (RQs = 1.1-4.9).

Aquatic Plants

Aquatic plants may be exposed to dicamba from spray drift, runoff and volatility. Runoff and spray drift are dominant exposure pathways for aquatic plants. As a result of volatilization, atmospheric concentrations of dicamba may be deposited into the waterbody, but concentrations resulting in water would be far below those than from runoff and spray drift contribution. Therefore, the assessments for spray drift and runoff are expected to be protective of volatility-based exposure for aquatic plants. Additionally, the extent of spray drift exposure to terrestrial habitats is expected to account for exposure to aquatic habitats given that the terrestrial spray drift assessment accounts for a relatively higher exposure relative to aquatic spray drift assessment. For runoff exposure in the Aquatic Plant Exposure Zone (APEZ), there are no LOC exceedances for non-listed aquatic vascular or non-vascular plants (RQs = <0.01-0.19). For runoff exposure in the WPEZ, there are no LOC exceedances for non-listed aquatic vascular plants (RQs = 0.07-0.42), there are LOC exceedances for non-listed aquatic non-vascular plants (RQs = 1.5-9.0).

Terrestrial Vertebrates

EPA determined there is a potential for acute risk to on-field birds (and terrestrial-phase amphibians and reptiles) from exposure to dicamba (RQs = <0.01-1.6; LOC = 0.5), however, a low potential for chronic risk to birds from exposure to dicamba (RQs = 0.02-0.27). EPA determined that there is not an acute or chronic risk concern for birds from chronic exposure to DCSA.

EPA determined there are no acute (RQs = <0.01- 0.03) or chronic (RQs = <0.01-0.60) non-listed LOC exceedances for mammals from exposure to dicamba. Additionally, there are no chronic non-listed LOC exceedances from exposure to DCSA from DT-cotton use (RQs = <0.01-0.34). EPA identified a potential for chronic risk to non-listed on-field mammals from exposure to DCSA residues in common dietary items following dicamba applications to dicamba-tolerant soybeans only (RQs = <0.01-3.3).

Terrestrial Invertebrates

For terrestrial invertebrates, honey bees (*Apis mellifera*) serve as surrogates for both social and solitary *Apis* and non-*Apis* bees and for other terrestrial invertebrates in the absence of data for non-honey bee terrestrial invertebrate species. Overall risks to honey bees from dicamba are expected to be low. For dicamba, comparison of the acute non-definitive contact endpoint to estimated environmental concentrations indicates low likelihood of adverse effects on adult bees from acute contact and oral exposure. The acute RQ for larval honey bees is below the acute LOC (max RQ = 0.06; LOC = 0.4), and the on and off-field chronic risk to adult bees is low, as the chronic RQs for dicamba are less than the chronic LOC honey bees (RQ = 0.85). However, chronic RQs for dicamba for honey bee larval dietary exposure are above the chronic risk LOC of 1.0 (RQ = 1.3).

For other terrestrial invertebrates, EPA determined that the use of the most sensitive life stage (larval) honey bee data indicates potential risk concerns using insect residue estimates modeled for non-bee terrestrial invertebrates (RQ = 1.8). There were no LOC exceedances for vegetation residues (RQ = 0.81) and contact risk using the insect residue data is expected to be low.

Aquatic Vertebrates

There are no LOC exceedances for fish toxicity endpoints for dicamba on both an acute (RQ < 0.01-0.02) and chronic basis (RQ <0.01-0.01), as all RQs are below the acute LOC of 0.05 and chronic LOC of 1.0,

respectively. Non-definitive fish endpoints are several orders of magnitude above the estimated environmental concentrations. For aquatic-phase amphibians, there is potential risk in the WPEZ on an acute exposure basis for both soybean and cotton uses (RQs = <0.01-0.05; LOC = 0.05).

Aquatic Invertebrates
There are no LOC exceedances for aquatic invertebrates for dicamba on a chronic basis, as freshwater invertebrate chronic RQs are <0.01 and estuarine/marine invertebrate chronic RQs are <0.01-0.01. Non-definitive aquatic invertebrate endpoints on an acute basis are several orders of magnitude above the estimated environmental concentrations. Therefore, EPA concludes low risk to aquatic invertebrates from the proposed uses on an acute and chronic basis.

Listed Species Conclusions

Terrestrial and Wetland Plants
EPA identified on- and off-field risks of concern for listed individuals, populations and communities of terrestrial and wetland plants from drift, runoff and volatility exposure. Volatility exposure is expected both near the field and across wide landscape areas. For spray drift, EPA determined that potential impacts to individual listed species may extend out to approximately 310 feet, while potential impacts to populations of listed species may extend out to 15 feet. For runoff exposure in the terrestrial plant exposure zone (TPEZ), there are listed LOC exceedances for individual listed dicots (RQs = 246-385) and monocots (RQs = 0.81-1.3). Population- and community-level impacts are not expected in the TPEZ (MoDs = 0.07-0.73). For runoff exposure in the WPEZ, there are listed LOC exceedances for individual listed dicots (RQs = 625-2790) and monocots (RQs = 2.1-9.2). Additionally, population-level and community-level impacts are expected in the WPEZ (population-level MoDs for dicots = 26-29; population-level MoDs for monocots = 2.9-3.3; community-level MoDs = 7.9-9.0).

Aquatic Plants
Listed aquatic plants may be exposed to dicamba from spray drift, runoff and volatility. Runoff and spray drift are dominant exposure pathways for listed aquatic plants. As a result of volatilization, atmospheric concentrations of dicamba may be deposited into the waterbody, but concentrations resulting in water would be far below those than from runoff and spray drift contribution. Therefore, the assessment for spray drift and runoff are expected to be protective of volatility-based exposure for listed aquatic plants. Additionally, the extent of spray drift exposure to terrestrial habitats is expected to account for exposure to aquatic habitats given that the terrestrial spray drift assessment accounts for a relatively higher exposure relative to aquatic spray drift assessment. For runoff exposure in the APEZ, there are no listed LOC exceedances for listed aquatic vascular plants (RQs = <0.01-0.06). There are listed LOC exceedances for listed non-vascular plants in the APEZ (RQs = 0.13-2.3). The potential for impacts to aquatic plant communities in the APEZ is 'not likely' (MoDs = <0.01-0.11). For runoff exposure in the WPEZ, there are LOC exceedances for listed aquatic vascular plants (RQs = 0.46-2.7) and non-vascular plants (RQs = 28-110). EPA determined the potential for impacts to aquatic plant communities in the WPEZ is considered 'low' (MoDs = 2.8-3.0).

Terrestrial Vertebrates
For dicamba, EPA determined that there is potential for individual-level impacts to on-field federally listed birds, terrestrial-phase amphibians and reptiles on an acute exposure basis (RQs = <0.01-0.56). Because all RQs are <1, the potential for population-level impacts based on dicamba exposure is considered 'not likely' from use of dicamba on dicamba-tolerant cotton and soybean. EPA determined

that there is not an acute or chronic risk concern for listed birds, terrestrial-phase amphibians or reptiles from chronic exposure to DCSA.

EPA determined there are no acute (RQs = <0.01- 0.03) or chronic (RQs = <0.01-0.60) listed LOC exceedances for mammals from exposure to dicamba. Additionally, there are no chronic listed LOC exceedances from exposure to DCSA from DT-cotton use (RQs = <0.01-0.34). EPA identified a potential for chronic risk to individual listed on-field mammals from exposure to DCSA residues in common dietary items following dicamba applications to dicamba-tolerant soybeans only (RQs = <0.01-3.3). The potential for population-level impacts to listed mammals from exposure to DCSA residues in common dietary items following dicamba applications to dicamba-tolerant soybeans is considered 'not likely' (MoDs = <0.01-0.56).

Terrestrial Invertebrates

For terrestrial invertebrates, EPA determined that the use of the most sensitive life stage (larval) honey bee data indicates potential impacts to individuals using insect residue estimates modeled for non-bee terrestrial invertebrates (RQ = 1.8). Using insect residue estimates, EPA determined the potential for population-level impacts to listed terrestrial invertebrates to be 'not likely' (MoD = 0.9). There were no listed LOC exceedances for vegetation residues (RQ = 0.81) and contact risk using the insect residue data is expected to be low. There are no listed honey bees. Therefore, a listed species assessment was not conducted for honey bees.

Aquatic Vertebrates

There are no individual-level listed species LOC exceedances for freshwater or estuarine/marine fish on an acute or chronic exposure basis in the WPEZ or APEZ (RQs = <0.01-0.01). For individual-level effects to aquatic-phase amphibians, there are listed species LOC exceedances in the APEZ for soybean uses (RQs = 0.01-0.05) and for all proposed uses in the WPEZ (RQs = 0.42-2.5). Because the RQs in the APEZ were <1, MoDs were not calculated and the potential for population-level impacts is considered 'not likely'. The MoDs in the WPEZ are >1 but <10 for considering potential population-level effects. Therefore, the potential for population-level impacts to aquatic-phase amphibians in the WPEZ is considered 'low'.

Aquatic Invertebrates

All dicamba RQs for aquatic invertebrates are less than the listed species LOC in the APEZ and WPEZ (RQs = <0.01-0.01). Therefore, direct effects to federally listed aquatic invertebrates are not expected for dicamba.

3. Draft Effects Determinations under the Endangered Species Act

Consistent with ESA section 7(a)(2) and its implementing regulations at 50 CFR Part 402, EPA drafted a biological evaluation (BE) to assess the potential effects of the proposed uses of dicamba on listed species and critical habitats (CHs). The federal action area considered in the BE is the overall geographic extent or footprint of the federal action plus any additional areas where effects are reasonably expected to occur and is based on the potential use sites associated with the proposed uses of dicamba. EPA conducted an overlap analysis to determine which listed species and designated CHs occur within this action area. EPA also considered life history, toxicity, and exposure information to determine if the proposed uses of dicamba have no effect (NE) or may affect (MA) listed species and designated CHs.

EPA's Herbicide Strategy (HS) provides a framework that describes how EPA plans to identify potential mitigations to reduce the potential for population-level impacts to listed species from the agricultural use of conventional herbicides in the contiguous 48 states. EPA's Vulnerable Species Action Plan (VSAP) provides a framework for EPA to identify the need for mitigation to address potential population-level impacts for 27 listed species that EPA identified as particularly vulnerable to pesticides. The mitigations identified herein are informed by and consistent with expected mitigation outcomes for spray drift and runoff as described in these strategies and cover the same listed species as each of the documents. Because one of the products contains both dicamba and s-metolachlor, Tavium Plus VaporGrip Technology (EPA File Symbol 100-RTLG), EPA also completed a draft ESA assessment for the use of s-metolachlor on DT cotton and DT soybean in addition to dicamba. The effects determinations below apply to the proposed products containing dicamba only and containing dicamba and s-metolachlor.

EPA completed draft effects determinations for all listed and proposed species and their designated and proposed CHs related to these applications. In its assessment, EPA considers use data layer (UDL) overlaps inclusive of the farthest off-field drift and runoff distances when making effects determinations. EPA assessed 1,736 species and 951 CHs for the proposed uses of dicamba. EPA determined NE for 1,324 species and 831 designated CHs, based primarily on low overlap, no direct toxicity, and/or the lack of an exposure pathway based on the habitat of the species. For those listed species (412) and CHs (120) with MA determinations, EPA determined whether the proposed uses of dicamba or S-metolachlor are likely to adversely affect an individual when considering the species-specific habitat, life history, and other considerations of exposure and toxicity. EPA made not likely to adversely affect (NLAA) determinations for 83 species and 39 CHs including both U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) species. EPA based a majority of the NLAA determinations upon unlikely exposure due to a species' habitat or when specific physical or biological features (PBFs) for the CH are not expected to be impacted by the proposed uses of dicamba. EPA made likely to adversely affect (LAA) determinations for 329 species and 81 CHs, all under the authority of FWS. With the proposed mitigations that EPA has identified as necessary (see below), EPA is predicting no potential likelihood of future jeopardy (J) or adverse modification (AM) for listed species or designated critical habitat. If, after considering the public comments received, EPA determines the applications meet the standard for registration under FIFRA and the effects determinations include LAAs, then prior to issuing the registrations, EPA would initiate formal consultation with FWS and informal consultation with NMFS based on these effects determinations. EPA has worked with the applicants to ensure agreement on identified necessary mitigation measures beyond those provided with the initial application submission to address the initial predicted likelihood of future J/AM. With these mitigations in place, EPA has initially predicted that the registration of dicamba for the proposed uses is not likely to jeopardize any listed species nor lead to adverse modification of any listed species' designated CH.

Table 6. Number of Listed Species Effects Determinations and Predictions of Potential Likelihood of Future Jeopardy by Taxon[1] based on the Proposed Mitigations as of June 2025.

Taxon	Number of Species[2]	NE	NLAA	LAA/No J Predicted	LAA, J Predicted
Plants	942	751	0	191	0
Mammals	96	65	1	30	0
Birds	96	69	0	27	0
Amphibians[3]	47	36	1	10	0
Reptiles	59	32	2	25	0

Taxon	Number of Species[2]	NE	NLAA	LAA/No J Predicted	LAA, J Predicted
Terrestrial Invertebrates[4]	122	80	12	30	0
Fish	172	129	33	10	0
Aquatic Invertebrates	202	162	34	6	0
Total Listed and Proposed Species	1736	1324	83	329	0

[1] NE = no effect; NLAA = not likely to adversely affect; LAA = likely to adversely affect; J = predicted potential likelihood of future jeopardy

[2] Reflects listed and proposed threatened and endangered species as of January 2025.

[3] "Amphibians" include those species that have both a terrestrial and aquatic phase.

[4] "Terrestrial Invertebrates" includes 7 species of damselflies and 1 species of dragonfly which have both a terrestrial and aquatic phase.

Table 7. Number of Designated and Proposed Critical Habitat NE, NLAA, and LAA Determinations

Taxon	Number of CH[2]	NE	NLAA	LAA/No Future AM Predicted	LAA/Future AM Predicted
Designated and Proposed Critical Habitat	951	831	39	81	0

[1] CH = designated and proposed critical habitat; NE = no effect; NLAA = not likely to adversely affect; AM = Adverse Modification

[2] Reflects the species and critical habitats listed and proposed threatened and endangered as of October 15, 2024.

C. Incident Assessment

This section summarizes EPA's '*Status of Over-the-Top Dicamba: Summary of 2021 Usage, Incidents and Consequences of Off-Target Movement, and Impacts of Stakeholder-Suggested Mitigations* and *Dicamba Use on Genetically Modified Dicamba-Tolerant (DT) Cotton and Soybean: Incidents and Impacts to Users and Non-Users from Proposed Registrations'* and the '*Draft Ecological Risk Assessment and Biological Evaluation Including Effects Determinations for Federally Listed Endangered and Threatened Species and Designated Critical Habitat for the Proposed Section 3 New Use Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean*'. The complete assessments can be found in docket ID numbers EPA-HQ-OPP-2020-0492 and EPA-HQ-OPP-2024-0154 at www.regulations.gov.

The Agency found that reported incidents involving dicamba continued during the 2022, 2023, and 2024 seasons but at a lower rate than previous years. The factors that contributed to incidents were generally consistent with findings in the 2021 memorandum. The majority of incidents continue to be associated with non-DT soybean, but reports also included dicamba exposure on specialty crops, ornamental plants, home gardens, and trees, as well as university and registrant research and soybean seed production fields.

Generally, incident reports provided few details, making it difficult to quantify the impacts of off-target dicamba exposure on sensitive plants and crops. The Agency previously concluded that the magnitude of

impact depends on several factors including the frequency, duration, and dose of exposure; growth stage at the time of exposure; and species sensitivity. Therefore, there are likely a range of consequences and impacts experienced by people who have been affected by the off-target movement of dicamba. Potential consequences of dicamba exposure include distorted leaf tissue, which may be cosmetic or severe enough to cause yield and quality losses. For ornamental nursery trees, cosmetic injury can be significant since aesthetics, rather than yield, determine financial loss. Trees that are too damaged may be considered a total loss.

The direct impacts to non-target plants may impose other costs. For example, due to potential damage from off-target movement, some growers are likely still engaging in defensive planting of DT traits. Additionally, growers in some areas may be starting to collaborate to reduce dicamba injury. This involves growers in a geographic area planting crop varieties with the same herbicide tolerance traits, imposing various costs to coordinate and reach consensus. It is unknown if community planning would reduce impacts on non-crop areas or regions with specialty crop production; however, the efforts could reduce the number and/or severity of direct impacts. Incidents also impose burdens on state lead agencies. The magnitude of that cost depends on the number of incidents received and whether the state has changed how incidents are handled (e.g., reported but not investigated versus reported with an investigation). Given resource constraints, agencies may have to forego other important activities impose costs in lost services.

A lower number of reported incidents could be due to several factors, including increased adoption of DT traits through grower preference, defensive planting, or community planting efforts or increased familiarity with label mitigations, like the addition of a VRA, through training. Earlier cutoff dates in select states may have led to applications occurring when temperatures were lower, and volatilization was less likely compared to later in the season. Weather conditions could also play a role; for instance, a wet spring could delay planting such that applications cannot be made because the timing falls after the cutoff date for applications. Additionally, underreporting might occur for reasons such as jeopardizing crop insurance payouts, reporting fatigue, fear of damaging relationships with neighbors, or pressure from stakeholders wanting to preserve OTT dicamba use. The interaction of these factors is complex, so the Agency does not view changes from one year to the next as predictive of future incident levels.

Details provided to the Agency from registrants, state lead agencies, and university extension suggest that spray drift and volatility were the main causes of reported incidents. These incidents resulted from factors such as the presence of sensitive vegetation near dicamba applications, applicator error (e.g., applying to the wrong field), tank contamination due to inadequate cleaning, and potential non-compliance with label instructions. This includes not adhering to buffer requirements, cutoff dates, and temperature restrictions (in states with such restrictions), applying when a sensitive crop was downwind, using higher than labeled rates, applying non-OTT products to DT crops, and potentially not adding VRA to the tank during applications. Applications of non-OTT dicamba products to registered use sites, such as corn or pastures, and a reduced number of applicators attending training also contributed. In many cases, investigators could not determine the exact source of dicamba exposure or concluded that multiple factors likely contributed to the incident. Overall, each factor can contribute to a reported dicamba-related incident, but the Agency cannot quantify the proportion of incidents attributable to any single variable.

D. Benefits Assessment

This section summarizes the benefits of the OTT dicamba products and potential impacts of the proposed registration as described in EPA's '*Assessments of the Benefits for Dicamba Use in Genetically Modified, Dicamba Tolerant Cotton and Soybean Production*.' The complete assessment can be found in docket ID number EPA-HQ-OPP-2024-0154 at www.regulations.gov.

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. In the U.S., 84.9 million acres of soybean are harvested on average annually, valued at around $57.6 billion. The U.S. is the world's leading soybean producer and second leading exporter, and soybeans comprise about 90% of the U.S.'s oilseed production.

Weeds compete with crops like cotton and soybean for limited resources such as space, nutrients, moisture, and may serve as reservoirs or hosts for insect pests and/or pathogens. To effectively manage weeds in fields producing cotton and soybean, growers rely on several management tactics that can include tillage, cultivation, and herbicides. Hand weeding is usually not economically feasible for soybean and cotton and cultivation is rarely practiced due to crop row spacing, the relatively slow speed of cultivation operations compared to herbicide application, and soil erosion concerns. Weeds can be removed prior to planting using conventional tillage practices or with non-selective herbicides as part of a burndown herbicide program. Depending on the weed species present and the weed pressure in the field, preemergence residual herbicides are used to control or suppress weeds during early-season growth.

The primary uses of the proposed dicamba products would be postemergence applications to DT cotton and DT soybean, also referred to as "over the top" or OTT use, to remove emerged target broadleaf weed species. The proposed OTT dicamba products would be used primarily to target pigweed species, such as Palmer amaranth and waterhemp, that have developed resistance to other primary OTT herbicides, particularly Acetolactate Synthase (ALS) inhibitor herbicides and glyphosate, as well as other problematic broadleaf weeds present in soybean and cotton cropping systems. The proposed dicamba products for use in DT cotton and DT soybean would also provide increased flexibility in timing for preemergence applications of these products in DT crops as compared to currently registered dicamba products.

The primary alternative OTT herbicides to dicamba are 2,4-D and glufosinate. Since similar OTT dicamba products were previously registered, target weed species, particularly Palmer amaranth and waterhemp, have developed resistance to dicamba, as well as to 2,4-D and glufosinate. The benefits of the OTT dicamba to cotton and soybean producers will, therefore, vary at the farm level or even at the field level and will depend on the specific resistance characteristics of the weed population at that particular site. On soybean and cotton acres where pigweeds have developed resistance to dicamba, the benefits of OTT dicamba products would be low. On acres where resistance to dicamba, 2,4-D and glufosinate is not present, then the benefits of OTT dicamba products would be primarily for resistance management and can be considered moderate. However, on acres where resistance to glufosinate or 2,4-D is present, the benefits of an OTT dicamba product would be high.

Additionally, OTT dicamba is less expensive than OTT 2,4-D and glufosinate. However, the addition of the pH buffering volatility reducing agent (VRA) or a drift reduction agent (DRA) would increase the costs of making an application of dicamba. With the inclusion of either a VRA or DRA, the costs to make an

application of OTT dicamba are roughly equivalent to the costs of making an application of OTT 2,4-D but still cheaper than an application of glufosinate. But when the cost of the DRA is combined with the cost of the VRA, the cost of OTT dicamba is largely the same as glufosinate, decreasing the benefits for OTT dicamba over alternative herbicides. Moreover, other proposed mitigations may also reduce the benefits of use of OTT dicamba for growers who require an application in higher temperatures because they would increase the costs of making an application of OTT dicamba. This is discussed in further detail in Section VI.

V. PUBLIC COMMENTS

On 5/3/2024, 6/4/2024, and 7/23/2024, the EPA published Notices of Receipt (NORs) in the Federal Register of applications for registration of Bayer, BASF, and Syngenta dicamba products, respectively, for use on DT Cotton and DT soybean, including proposed product labeling, and announced three separate 30-day public comment periods. 18,548 comments were received during the three comment periods. Comments were both in support of and against the applications for registration discussed in this memorandum. The comments can be found in Docket ID EPA-HQ-OPP-2024-0154 at www.regulations.gov. EPA has reviewed the comments and was able to consider many of them in this proposed decision. EPA will address all comments received on the NORs and this proposed decision memorandum at the time of publication of the final decision in order to respond to all comments on these proposed registrations comprehensively.

On 8/18/2022, the EPA posted revised human health and draft ecological risk assessments supporting the registration review of dicamba and announced a 60-day public comment period on the risk assessments. 1,778 comments were received during that comment period. As the registration review process is ongoing, those comments have yet to be addressed. Any commenters on the registration review of dicamba whose comment would be relevant to this proposed decision are encouraged to submit their comment during the 30-day comment period associated with this proposed decision so that EPA can address them.

VI. PROPOSED REGULATORY DECISION

In accordance with FIFRA section 3(c)(5), the EPA only registers a pesticide when it determines that it will not cause unreasonable adverse effects on humans or the environment, while taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. Under FIFRA, the EPA is charged with balancing costs (or risks) posed by the use of a pesticide against its benefits. The EPA must determine if the benefits in light of its use outweigh the risks in order for the EPA to register a pesticide.

FIFRA 3(c)(5) requires EPA to approve registration of a pesticide if the Agency determines that: (a) its composition is such as to warrant the claims for it; (b) its labeling and other material required to be submitted comply with the requirements of this subchapter; (c) it will perform its intended function without unreasonable adverse effects on the environment; and (d) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

A. Rationale and Risk Mitigation

EPA is proposing to issue unconditional registrations under FIFRA section 3(c)(5) for the following products for use on DT cotton and DT soybean:

- Engenia Herbicide (EPA File Symbol 7969-LNT)
- Tavium Plus VaporGrip Technology (EPA File Symbol 100-RTLG)
- KHNP0090 Herbicide (EPA File Symbol 264-REUR)

To determine whether the products will cause unreasonable adverse effects under FIFRA, EPA is charged with considering the economic, social, and environmental costs and benefits of the use of the pesticide. To determine the risks and benefits, the Agency reviewed a large body of information to determine how these products would be used according to the draft labeling and any other identified necessary mitigations. EPA determines whether a product will generally cause unreasonable adverse effects by considering whether the benefits of the product outweigh any potential risks of concern or adverse impacts from its use. Considering the assessed risks to human health and the environment, and the evaluated prospective benefits, the Agency is proposing that dicamba use on DT cotton and DT soybean, as outlined in this proposed decision, meets the regulatory standard under FIFRA.

EPA has determined that the database is complete for assessment of risks to human health and the environment for the proposed use of dicamba on DT cotton and DT soybean. Based on these data, EPA has not identified any dietary, aggregate, non-occupational or occupational risks of concern for potential human health exposure. Additionally, EPA has not identified any risks of concern for aquatic invertebrates, fish, or aquatic plants. EPA identified on-field chronic risk to terrestrial invertebrates, mammals, and birds and acute risk to on-field birds and aquatic-phase amphibians. EPA has identified low risk for honey bees and other non-listed bees from the proposed uses of dicamba. However, as expected of an herbicide, dicamba does pose risks of concern to certain plants. EPA identified on-and off-field risks of concern for non-listed terrestrial and wetland plants, and aquatic non-vascular plants. These off-field risks also include the potential for dicamba to volatilize in certain conditions and damage, for example, ornamental gardens, desirable trees, or a neighbor's soybean field if not planted with seed with the dicamba tolerant trait. The impacts of offsite movement of dicamba 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 and landscapes could be damaged. Offsite movement of dicamba has resulted in conflict between neighbors. EPA is proposing mitigation to ensure dicamba stays on the treated field, addressing offsite movement. EPA is proposing that these mitigations be on the product labels to reduce the risks (costs) while also considering the benefits of the use.

EPA is proposing to require mitigations on the product labels to reduce the likelihood of adverse effects on both listed and non-listed species, such that use of the pesticide according to certain specifications will not generally cause unreasonable adverse effects on the environment, as provided by the FIFRA registration standard. However, these proposed mitigation measures would not address potential population-level effects to some listed plants and obligates to plants. To avoid such population-level impacts and the potential likelihood of future J/AM, these species would require the implementation of additional mitigation measures in Pesticide Use Limitation Areas (PULAs), which would restrict pesticide application in specific geographic areas and crops to protect listed species and/or their designated critical habitats. Users would be directed to Bulletins Live! Two to view mitigations specific to their

PULA. The mitigations contained in the PULAs would address the initial prediction of potential population-level impacts and the likelihood of future J for these species.

Spray drift mitigation measures proposed for inclusion on the label would address direct effects to listed terrestrial and wetland plants and effects to species that rely on terrestrial and wetland plants for diet and/or habitat. These measures include a 240 ft wind directional spray drift buffer for ground applications from the application site to surrounding habitats. This buffer distance is based on the distance from the treatment area at which impacts would extend to non-listed individuals to the degree that they would display 10% visual signs of injury. Most of the data set on which the buffer was based includes a drift reducing agent (DRA), therefore EPA is proposing to require a DRA in every application of these proposed products. To address both potential drift from the application site and to provide growers/applicators increased flexibility, EPA is proposing that the product labels would include a list of mitigation measures that reduce spray drift to areas adjacent to the treated area and can, therefore, be used to reduce the size of the buffer as well as a list of managed areas that may be included in the buffer. Therefore, growers/applicators would have flexibility in selecting options which best fit their circumstances while providing a sufficient level of protection. These lists are based on similar lists found on EPA's Mitigation Menu website, but the buffer reduction options have been edited to remove those that are already required on the label and are thus accounted for in calculating the 240 ft buffer. In addition, the list of managed areas that can be included in the buffer has been reduced for these proposed products based on risk management decisions to limit exposure to non-target species that may be sensitive and thus could cause unreasonable impacts if damaged. Similarly, EPA is proposing the label would include 3 points of runoff mitigation to reduce direct effects of runoff to terrestrial, wetland and aquatic areas. By implementing these mitigations on the label, the risk to these areas would decrease by approximately one order of magnitude. These runoff mitigation measures would therefore be expected to fully address impacts to generalist species (*i.e*., species that can thrive in a wide variety of environmental conditions and utilize a variety of different resources). EPA is proposing that the labels would include a direction for use that directs the user to access EPA's Mitigation Menu website, which includes a menu that aims to provide flexibility for growers/applicators to select runoff mitigations that are best for their situation when applying dicamba. EPA has scored the efficacy of each proposed mitigation measure using a point system, and for dicamba the number of runoff mitigation points needed to avoid population-level impacts to listed species and designated CH ranges between 3-6 points depending on the exposure zone. Generalist risk from runoff would be addressed with 3 points on the label for all uses and application sites outside of a species-specific PULA. For the listed plants and listed species that have obligate relationships to plants in non-flowing wetland areas that require mitigations in PULAs to avoid potential likelihood of future J/AM, EPA has determined 6 points would be necessary. These species-specific PULAs are being refined at this time. As appropriate, these refinements would be incorporated prior to a final decision on this action. EPA has sought to provide growers and/or applicators with as many options as possible to tailor mitigation to their specific field to achieve the necessary points, including consideration of measures already in place. The flexibility allows for growers and/or applicators to weigh the burden of implementing a specific mitigation measure against the agronomic benefit it can provide to adjust the overall set of mitigation measures adopted to what best suits their situation.

EPA has also identified risks of concern from volatility associated with the use of OTT dicamba products on DT cotton and DT soybean. EPA is proposing that the labels would include measures to mitigate

direct effects of volatility on terrestrial and wetland plants and prey, pollination, habitat and/or dispersal (PPHD) effects to listed species that rely on plants. With the implementation of the proposed mitigations on the labels, as described below in Table 8, the likelihood of impacts to terrestrial and wetland plants would decrease. These volatility mitigation measures are expected to address the initial prediction of population-level impacts to generalist species as well as reduce the likelihood of damage to other economically and socially valuable species.

To minimize volatility from use sites to non-target areas, EPA is proposing that the labels would include temperature dependent requirements that aim to provide flexibility for growers/applicators to only increase mitigations at higher temperature situations when applying dicamba, because the likelihood of volatility of dicamba increases at higher temperatures. Maximum temperature restrictions are proposed to be for the day of application and the day after application. EPA is proposing to require the use of a pH buffering volatility reducing agent (VRA) for all applications of OTT dicamba products. The three VRAs that have been evaluated are VaporGrip Xtra Agent, Sentris, and Suralta. Other VRAs may be evaluated and approved for use in the future. When temperatures are forecasted to be < 75˚F on the day of and the day after treatment, EPA is proposing requiring 20 fl oz of VRA.[4] An increased amount of VRA[5] (40 fl oz per acre) would be required when temperatures are forecasted to be ≥ 75˚F. Continued use of an increased amount (40 fl oz per acre) of VRA and a 40% reduction in treated area is proposed to be required when temperatures are forecasted to be ≥ 85˚F. This option to reduce treated area by 40% would allow growers to return to the third day after the initial OTT dicamba application to treat the remaining untreated part of the field. All label restrictions, including these temperature based restrictions would also apply for the second treatment. At temperatures between 85 and 95˚F, EPA is proposing an alternative to reducing the treated area where applicators may choose to apply dicamba, a DRA, and a VRA at 40 oz per acre without any other tank mix partners instead of reducing the treated area. This provides the user with flexibility depending on their specific circumstance. Applications are proposed to be prohibited when temperatures are forecasted to be ≥ 95˚F. These options are described below in Table 8. Growers would need to obtain a forecast by NOAA/National Weather Service on the day of application showing the forecasted maximum temperature prediction for the day of and day after application to determine which temperature cutoff category that they fall into. EPA expects this mitigation to minimize volatility, thus addressing the landscape level impacts that have been reported in the past.

[4] Approximately 1:1 dicamba OTT DGA salt formulation to VRA product ratio or 1:2 dicamba BAPMA salt formulation to VRA product ratio.

[5] Approximately 1:2 dicamba OTT DGA salt formulation to VRA product ratio or 1:4 dicamba BAPMA salt formulation to VRA product ratio.

Table 8. Proposed options for application of OTT dicamba products at varying temperatures.

Air Temperature*	Rates of OTT dicamba product + Required VRA**
< 75˚F	0.5 lb dicamba + 20 fl oz VRA
≥ 75˚F - < 85˚F	0.5 lb dicamba + 40 fl oz VRA
≥ 85˚F - < 95˚F	0.5 lb dicamba + 40 fl oz VRA) **PLUS** 40% reduction in area treated*** **OR** No tank mix partners****
≥ 95˚F	No application allowed

* Maximum temperature must be forecasted by NOAA/National Weather Service not to exceed what's noted for both the day of application and the day after application.
** VRAs approved for use include VaporGrip Xtra Agent, Sentris, and Suralta.
*** Remaining untreated 40% of field may be treated the third day after initial treatment. Do not apply these products to the untreated part of the field the day of or the day following initial treatment.
**** A DRA and VRA are always required to be in the tank with the proposed OTT dicamba products.

The proposed requirement of the addition of a VRA will increase the cost of using the proposed OTT dicamba products. With the increased cost, EPA expects that soybean growers currently utilizing an OTT 2,4-D tolerant soybean system would be unlikely to make the switch to an OTT dicamba system, however, if it was known that 2,4-D resistant weeds were present or likely present in their field a soybean grower may switch to the dicamba OTT system in order to achieve better weed control. Cotton growers currently utilizing an OTT 2,4-D system may switch to an OTT dicamba system to obtain the advantages of desirable plant incorporated insecticide traits found in the DT cotton varieties.

EPA has received feedback that OTT dicamba products in the past have had complicated and reportedly difficult to follow labeling. The proposed labeling with identified mitigations for spray drift and runoff is consistent with the Herbicide Strategy, which is used, as appropriate, to inform mitigations for all new herbicidal active ingredient registrations and registration review of conventional herbicides since its release and in the future. The labeling requirements that EPA is proposing for volatility mitigation are unique but are intended to allow for growers to use OTT dicamba products while mitigating potential volatility risks. The Agency acknowledges that the proposed addition of varying amounts of VRA and requirement to follow certain requirements for different actual and forecasted temperatures is more complex than what would typically be required on an herbicide label. However, the newly developed label language is expected to be simpler to follow than for previous OTT dicamba registrations. The proposed temperature restrictions allow for more flexibility in application timing than crop growth stage and calendar date restrictions implemented for previously registered OTT dicamba products. Because the mitigations are based on temperature rather than calendar date, variability in application restrictions across the different regions of the country will be reduced. Mitigations are also consistent for both DT cotton and DT soybean, reducing confusion. Previously registered OTT dicamba products restricted applications to 1 hour after sunrise through 2 hours before sunset to prevent applications at times of day when temperature inversions often occur. The proposed label restrictions will allow applicators to determine if a temperature inversion is actually occurring, allowing for more flexibility in application timing while still protecting against offsite movement. Additionally, the newly proposed

label language provides more nozzle choice flexibility, as it does not require users to access a website to determine which nozzles are acceptable to use. Similarly for tank mixing, previously registered OTT dicamba products required users to access a website to deem which tank mix partners were allowed. In the newly proposed labeling, a tank mix restriction is just one option at certain temperatures. Also, the required buffer distance proposed in this document is the same for all areas, making it more straightforward than location-specific buffer requirements on previously registered dicamba OTT products, increasing the ease of use for applicators. EPA has begun discussions with the registrants to move towards structured labeling for these proposed products. The goal is that a uniform structure would make the label easier to read, understand, and follow.

Many cotton and soybean growers may find it difficult to achieve the proposed 40% reduction in area treated due to equipment constraints. This is partially because pigweeds are fast growing, especially in higher temperatures, and growers must treat before pigweeds reach a certain height in order to obtain adequate control. The 3-day window between treating 60% of the field and the remaining 40% would allow for further growth and would increase the difficulty of controlling these problematic weeds. The proposed option to make a stand-alone (no tank mix partners) application of dicamba would offer a solution for growers who cannot reduce the area treated but need to make an application at temperatures between 85˚F and 95˚F. The Agency recognizes that to make a standalone application of dicamba means that a separate application of another herbicide may be required for control of grass weeds. These separate applications would increase the costs of control as they would require increased fuel, labor, time, and equipment usage. However, EPA found that applications in higher temperatures are not only likely to occur but are also important for certain growing areas, especially soybean and cotton production areas in the Southern US. EPA acknowledges that the proposed mitigations to apply between 85˚F and 95˚F may increase costs of using OTT dicamba products, however, EPA also acknowledges that achieving maximal control of problematic broadleaf weeds, like Palmer amaranth, throughout the growing season is imperative for cotton and soybean production thereby supporting the inclusion of the volatility mitigation measures under consideration.

Considering the assessed risk to human health and the environment, and the associated economic, social, and environmental costs, and the benefits, consistent with the requirements of FIFRA section 3(c)(5), EPA proposes that dicamba use in DT cotton and DT soybean meets the regulatory standard under FIFRA and proposes to conclude that registering the proposed products would not cause unreasonable social or economic impacts or adverse effects on human health or the environment. The Agency proposes that the benefits of having a broad spectrum, non-selective foliar-applied herbicide for control of broadleaf weeds as a rotational tool, partnered with the mitigation measures for any risks, outweigh any potential risks of concern.

B. Endangered Species Assessment

ESA section 7(a)(2) provides that "[e]ach Federal agency shall, in consultation with [FWS] ensure that any action authorized, funded, or carried out by such agency. . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species. . . ."

The EPA completed draft effects determinations for federally listed threatened and endangered species (listed species) for the proposed uses of dicamba in the areas where it may be applied. The EPA evaluated whether the registration of the products containing this active ingredient for the proposed uses may affect listed species and designated CH within the action area in the listed species effects

determination. The effects determination makes use of the best available scientific and commercially available information and considers both direct and indirect effects. The term "direct effects" refers to decreases in the survival, growth, or reproduction of individuals of a listed species due to exposure to dicamba. The term "indirect effects" refers to impacts on individuals of a listed species that may be the result of the effects of dicamba on organisms on which the listed species depends upon for prey, pollination, habitat, and/or dispersal.

In the draft effects determinations, EPA evaluated whether the proposed action, inclusive of the EPA proposed mitigations, may affect any of the 1,736 species which the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as the Services) had listed or proposed as threatened or endangered and 951 critical habitats (CHs) designated as final or proposed as of January 2025. For those federally listed species and CHs with may affect (MA) determinations, EPA evaluated whether OTT dicamba is likely to adversely affect (LAA) an individual when considering the species-specific habitat, life history, and other considerations of exposure and toxicity. EPA made draft not likely to adversely affect (NLAA) determinations for 83 species and 39 CHs including both FWS and NMFS species. EPA made draft LAA determinations for 329 listed species and 81 CHs, all under the authority of FWS. For the CHs with LAA determinations, adverse effects on essential physical and biological features (PBFs; or inferred PBFs) related to invertebrates, habitat quality for the listed species, and water quality were the primary factors leading to the determinations. With the EPA proposed mitigations which have been identified, EPA is predicting no potential likelihood of future jeopardy (J) or adverse modification (AM) for listed species or designated critical habitat. If these proposed mitigations or equivalent mitigations are not implemented, EPA would predict potential likelihood of future J/AM as part of its effects determinations. The Services are responsible for making the final J/AM findings in their biological opinions.

If EPA determines that initiating formal consultation is appropriate on a FIFRA action, the Agency may still be able to proceed with the action before completing consultation if it determines that doing so will not result in "any irreversible or irretrievable commitment of resources . . . [that] has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures which would not violate [ESA section 7(a)(2)]." See 16 U.S.C. § 1536(d). EPA expects to consider whether such a finding is appropriate after considering public comment on the proposed registration actions and the draft effects determinations.

C. Proposed Label Requirements

The Agency is continuing to work with the applicants on the label language below. Bayer, BASF, and Syngenta have committed to revising their labeling to be in line with these proposed requirements, as well as to making any future revisions to the labeling that are necessary based on further analysis as a result of public comments received on this proposed decision. In addition, any future registration may include terms and conditions necessary to support EPA's decision.

EPA is proposing the following label requirements be included on the product labels (EPA File Symbols 100-RTLG, 264-REUR, and 7969-LNT):

1. Restricted Use Pesticide (RUP): This product is to be used by certified applicators only. This product is NOT to be used by uncertified persons working under the supervision of a certified applicator, except that uncertified persons may transport containers.

2. This product is for use on dicamba-tolerant soybean and cotton only in the following states:

   Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, 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, Wisconsin.

3. This product may only be used on Dicamba-Tolerant cotton and Dicamba-Tolerant soybean fields.

4. The user must check [Insert label-specific URL directing to a registrant website] no more than 7 days before application of this product for additional labeling and any additional state restrictions. Where applicable, users must comply with additional requirements found on this website.

5. Personal Protective Equipment (PPE): All mixers, loaders, applicators, and other handlers must wear: Long-sleeved shirt and long pants, Waterproof gloves, and Shoes plus socks. (As Engenia is a BAPMA salt product, that label must also require a respirator.)

6. To address effects to non-target vulnerable species and the Critical Habitats of those species included in the "Bulletins Live! Two" web-based system (BLT), the end-use product must direct all users to access the BLT prior to application, according to the label statement below: **ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS:** Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov.

7. Restricted entry interval: Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours.

8. Mandatory Training: Prior to applying in any calendar year, the applicator must complete dicamba-specific annual training. Only certified applicators may apply this product. This product must not be used by uncertified persons working under the supervision of a certified applicator, except that uncertified persons may transport containers. If training is available and required by the state where the applicator intends to apply this product, the applicator must complete that training before applying this product in-crop. If your state does not require dicamba-specific training, then the applicator must complete dicamba specific training provided by one of the following sources: a) a registrant of a dicamba product approved for in-crop use with dicamba-tolerant crops, or b) a state or state-authorized provider.

9. Record Keeping: Records must be created within 72 hours of every application. Records must be kept for a period of two years. Records must be made available to State Pesticide Control Official(s), USDA, and EPA upon request. The following information must be recorded and kept as required by the Federal Pesticide Record Keeping Program, 7 CFR Part 110:
    1. Full name of the certified applicator
    2. Certification number of the certified applicator
    3. Product name
    4. EPA registration number
    5. Total amount applied of this product
    6. Application month, day, and year
    7. *Start and Finish Times:* the time the applicator begins and the time the applicator completes applications of this product.
    8. Location of the application
    9. Crop or site receiving the application
    10. Size of area treated
    11. *Training Requirement:* proof that the applicator completed dicamba-specific training described in this section
    12. *Application Timing:* whether the applicator applied this product preemergence or postemergence in relation to the crop.
    13. *Receipts of purchase:* receipts for the purchase of this product, and for the purchase of the required VRA and required DRA.
    14. *Product Label:* A copy of the product label and any labeling that supplements the product label such as BLT labeling.
    15. *Sensitive Areas, Sensitive Crops, and Residential Awareness* (see Downwind Spray Buffer Areas and Sensitive Crops, Areas and Residential Areas): Document/record that the applicator checked an applicable sensitive crop/specialty crop registry; and document that the applicator surveyed all adjacent fields for any sensitive areas, sensitive crops, or residential areas surrounding the field prior to application. At a minimum, records must include the date the applicator consulted the sensitive crop registry/specialty crop registry and the date the applicator surveyed within the required spray buffer distance Downwind Spray Buffer Areas and Sensitive Crops, Areas and Residential Areas adjacent fields, and the name of the sensitive crop registry/specialty crop registry the applicator consulted. The applicator must be aware that WIND DIRECTION may vary during the application. If wind direction shifts such that the wind is blowing toward adjacent sensitive crops or residential areas, STOP the application.
    16. *Spray Buffer Requirement:* Record of the required downwind buffer distance (240 ft) determination and any areas included within the buffer distance determination.
    17. *Spray System Cleanout:* Document that the applicator complied with the section of this label titled: “Spray System Equipment Clean-out”. At a minimum, records must include the date the applicator performed the required cleanout, and cleanout method that the applicator followed.
    18. *Tank Mix Products:* a list of all products (pesticides, adjuvants, and other products) that the applicator tank mixed with this product for each application. Include EPA registration numbers in the case of any pesticides.
    19. *Required Tank Mix pH Buffering Volatility Reducing Agent:* list the VRA and use rate that was tank mixed with this herbicide.

20. *Required Tank Mix Drift Reducing Agent:* list the DRA and use rate that was tank mixed with this product.
21. *Nozzle Selection:* which spray nozzle the applicator used to apply this product, and the nozzle pressure the applicator set the sprayer to.
22. *Air Temperature:* the air temperature at boom height at the time the applicator starts and finishes applications of this product, and documentation of a weather forecast by NOAA/National Weather Service on the day of application showing the forecasted maximum temperature prediction for the day of and day after application.
23. *Wind Speed and Direction:* the wind speed at boom height at the time the applicator starts and finishes applications of this product, and the wind direction at the time the applicator starts and finishes applications of this product.

10. Required Adjuvants: For every application of this product, an approved pH buffering Volatility Reduction Agent (VRA) must be included in the spray solution. An approved Drift Reduction Agent (DRA) must also be included in the spray solution. Refer to the [Insert label-specific URL directing to a registrant website]] for a list of acceptable DRAs and VRAs. The amount of VRA required depends on the forecasted maximum temperature on the planned day of treatment and day after treatment. Refer to Table 8 to determine the amount of VRA needed at the specific forecasted temperatures for day of treatment and day after treatment.

11. Rate and Timing:
    DT Cotton:
    - This product may be applied Preplant, At-Planting, Preemergence, and Postemergence.
    - A maximum of two applications each of 0.5 lb. acid equivalent (a.e.) dicamba per acre may be made up to 7 days prior to harvest.
    - Do not exceed 1 pound acid equivalent (a.e.) dicamba per acre per DT crop per year from all combined dicamba-containing products.

    DT Soybean:
    - This product may be applied Preplant, At-Planting, Preemergence, and Postemergence
    - A maximum of two applications each 0.5 lb. acid equivalent (a.e.) dicamba per acre may be made.
    - Soybean Forage: Allow at least 7 days between final application and harvest or feeding of soybean forage.
    - Soybean Hay: Allow at least 14 days between final application and harvest or feeding of soybean hay.
    - Do not exceed 1 pound acid equivalent (a.e.) dicamba per acre per DT crop per year from all combined dicamba-containing products.

12. Spray volume: Apply in a minimum of 15 gallons of spray solution per acre.

13. Application Equipment:
    Spray system equipment cleanout: Ensure entire sprayer system is properly cleaned before and after application.
    Droplet requirement: Apply this product with appropriate nozzles calibrated to apply coarse or coarser droplets only.
    Spray boom height: Maximum boom height is 24 inches above target pest or crop canopy.

Ground speed: Do not exceed 15 mph.
Do not apply this product aerially.

14. Environmental Conditions:
    Wind speed: Apply only when wind speed, measured at boom height, is 3-10 mph.
    Inversions: Do not spray during a temperature inversion. Temperature inversions restrict vertical air mixing, which causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

15. Downwind Requirements:
    Sensitive crops and certain plants downwind: Do not apply if sensitive crops and/or certain plants are planted on an adjacent downwind field or area.
    Sensitive crops in agricultural and/or residential settings can include, but are not limited to:
        - non-DT soybeans
        - cucumber and melons (EPA Crop Group 9)
        - flowers
        - fruit trees
        - grapes
        - ornamentals including greenhouse-grown and shadehouse-grown broadleaf plants
        - peanuts
        - peas and beans (EPA Crop Group 6)
        - peppers, tomatoes, and other fruiting vegetables (EPA Crop Group 8)
        - potato
        - sweet potato
        - tobacco

Downwind buffer: After determining no adjacent sensitive crops and/or certain plants are downwind, maintain a 240 ft downwind buffer. The practices in the buffer reduction table, Table 9 below, may be used to reduce the size of the buffer. After determining your total % reduction in the buffer distance, determine the distance that may be reduced in feet, subtract that distance from the 240- foot buffer distance, then round to the nearest 5-foot increment for your final buffer distance.

No ecological drift buffer is required if:
use of the buffer reduction options results in a buffer reduction ≥100%.
use of the buffer reduction options results in a buffer <10 feet, after rounding to the nearest 5 ft increment.

Table 9. Options for Reducing 240 ft Downwind Buffer Distance

Option	Qualifying Practice	Reduction in Buffer Distance
Reduce number of passes (applies to upwind part of the treated field)	Field border application/1 pass (or 1/10 acre to 1 acre) or < 1.5 acre	75%
	2-4 Passes (or >1 acre to 4 acres)	35%
	5-10 Passes (or 4 acres to 10 acres)	15%
Downwind Drift Barrier	Basic windbreak/hedgerow/artificial screen	50%
	Advanced windbreak/hedgerow/artificial screen	75%
Use of directed sprayer equipment	Over-the-top Hooded Sprayer	50%
	Row-middle Hooded Sprayer	75%
	Sprays below crop canopy using drop nozzles or layby applications (difference between the crop height and release height is ≥ 1 ft, and that there are more than 4 consecutive rows of crop on the field that meet this parameter)	50%

These areas can be included in the buffer if they are immediately adjacent/contiguous to the treated field in the downwind direction and people are not present in those areas (including inside closed buildings/structures). Buffer reduction options do not apply to the following managed areas, as they are included in the buffer distance:

- Untreated portions of the treated field;
- Roads, paved or gravel surfaces, mowed areas adjacent to field, and areas of bare ground from recent plowing or grading that are contiguous with the treated area;
- Areas present and/or maintained as a drift buffer reduction measure as listed on the buffer reduction table above. Examples include vegetative windbreaks and hedgerows;
- On-farm contained irrigation water resources that are not connected to adjacent water bodies, including on-farm irrigation canals and ditches, water conveyances, managed irrigation/runoff retention basins, farm ponds, and tailwater collection ponds.

16. Management of Runoff:
You must achieve a minimum of three runoff/erosion mitigation points for the crop uses listed on this label unless otherwise stipulated below.

Access EPA's Mitigation Menu Website at www.epa.gov/pesticides/mitigation-menu for a full list of field/application parameters to evaluate whether your field is subject to runoff/erosion mitigation. If the application does not meet the specified field/application parameters, a minimum of three points for the crop uses listed on this label must be achieved before the application unless otherwise specifically provided in the measure's description on EPA's Mitigation Menu Website. The applicator must choose among the mitigation and/or mitigation relief measures on EPA's Mitigation Menu Website to meet or exceed these points before applying this product. The website includes the full menu of runoff/erosion mitigation and mitigation relief measures. The following are examples:

- Location in a very low, low, or medium runoff vulnerability county
- Field slope
- Soil incorporation
- Conservation tillage
- Vegetative strips
- Cover crop or continuous ground cover
- Irrigation water management
- Mulching
- Grassed waterway
- Vegetated ditch
- Constructed and natural wetlands
- Water retention systems
- Following recommendations from a runoff/erosion specialist or participating in a qualifying Conservation program (see the www.epa.gov/pesticides/mitigationmenu for minimum elements).

To achieve mitigation points for the application, the mitigation and mitigation relief measures must be:

- Employed in accordance with the instructions and descriptions on EPA's Mitigation Menu Website.
- In place during the application unless a different timing (such as before or after application) is specifically provided in the measure's description on EPA's Mitigation Menu Website.

17. Rainfall Restriction:
DO NOT apply during rain.
DO NOT apply when soil in the area to be treated is saturated (if there is standing water on the field or if water can be squeezed from soil) or if NOAA/National Weather Service predicts 50% chance or greater of a 1 or more inches of rainfall to occur within 48 hours following application. Detailed National Weather Service forecasts for local weather conditions may be obtained on-line at: http://www.nws.noaa.gov, on NOAA weather radio, or by contacting your local National Weather Service Forecasting Office.

18. Management of Volatility:
Do not tank mix ammonium sulfate (AMS) with this product.
Temperature Restrictions:

- Air temperature on the day of treatment and the day after treatment, as predicted by the NOAA/National Weather Service, must not exceed 95˚F. On the day of application, applicator must obtain a forecast for the day of and the day after application.
- If temperatures are forecasted to be 95˚F or above either on the day of treatment or the day after treatment, do not apply this product.
- If temperatures are forecasted to be 85-<95˚F on the day of treatment or the day after treatment, applicators must choose one of two options available:
    1) The treatment area must be reduced by 40% and tank mix must include DRA and 40 fl oz of VRA, OR,
    2) Treatment must be applied with no additional tank mix partners besides this product, DRA, and 40 fl oz of VRA.

If the user chooses the option to reduce treatment area, remaining untreated area may be treated the third day after initial treatment. All label restrictions including temperature-based restrictions apply to the second treatment also.
If the user chooses the option to restrict tank mixing, no pesticide products may be applied to that field the day of treatment or the day after treatment except for the OTT dicamba product with the required DRA and VRA.

- If temperatures are forecasted to be 75-<85˚F on the day of treatment or the day after treatment, the application must include DRA and 40 fl oz of VRA.
- If temperatures are forecasted to be less than 75˚F on the day of treatment or the day after treatment, the application must include DRA and 20 fl oz of VRA.

VII. SUPPORTING DOCUMENTS

All supporting documents can be found in docket ID number EPA-HQ-OPP-2024-0154 at regulations.gov.