Final Registration of Dicamba on Dicamba-Tolerant Cotton and Soybean

Approved by: _____

Jack E.Housenger, Director
Office of Pesticide Programs

Date: 11/9/16

Summary

This document announces that the U.S. Environmental Protection Agency (the EPA or the agency) has granted a conditional registration under Section 3(c)(7)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the new uses of the herbicide dicamba for use on genetically-engineered (GE) cotton and GE soybean that have been engineered to be resistant to dicamba in the following states: Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, West Virginia, and Wisconsin.

These new dicamba uses were originally proposed by the Monsanto Company to be added to the currently registered herbicide product M1691 (the EPA Registration Number 524-582). This is the specific formulation that was listed in the agency's Proposed Decision released for public comment earlier this year. Since the proposed decision was published, the agency also assessed a lower volatility dicamba formulation (M1768, with the brand name Xtendimax™ with VaporGrip™ Technology, the EPA Registration Number 524-617). the EPA expects the lower volatility formulation to further reduce the potential off site movement of generic dicamba formulations and is included in today's regulatory decision.

The M1768 product contains the same active ingredient as M1691, diglycolamine (DGA) salt of dicamba, and is to be used with equivalent application rates and the same application techniques. Because the two products contain the same active ingredient used at the same rates with the same methods, all of the environmental and human health assessments completed and made public in connection with the proposed registration decision for the M1691 apply to M1768. After assessing volatility studies conducted on the M1768 formulation (discussed later in this document), the EPA has determined that the new lower volatility formulation of M1768 offers the user a product with less potential to volatilize and move off the target area. The volatility analysis is included in the docket for this final decision. Therefore, the new uses were granted for the M1768 formulation.

This final decision document discusses several agency considerations of the new uses for dicamba on GE soybean and GE cotton, including discussions of human health and environmental risks associated with the new uses as well as the benefits associated with these uses. the EPA considered all relevant data associated with the active ingredient when assessing its risks. For example, the assessment for human health included the N, N-Bis-(3-aminopropyl) methylamine (BAPMA) salt of dicamba (M1768 contains the DGA salt of dicamba) because the data on the BAPMA salt was relevant to the analysis and presented the most conservative risk estimation to be used in each exposure scenario to be protective of all exposures of dicamba. But, when product specific considerations were necessary for the analysis, the EPA reviewed the effects of the DGA salt. For example, to determine appropriate spray drift buffers, the agency examined drift potential using studies conducted on the DGA salt formulation.

Under the Plant Protection Act, the United States Department of Agriculture (USDA) deregulated the GE cotton and GE soybean seeds tolerant to dicamba on January 15, 2015.

ED_002642_00002678-00002

I. Chemical Information

Chemical Name: Dicamba (benzoic acid, 3,6-dichloro-2-methoxy-, aka 3,6-dichloro-*o*-anisic acid)

EPA PC Code: 128931

Chemical Abstract Service (CAS) Number: 104040-79-1

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

Registrant: Monsanto Company

Product: M1768 Herbicide (Xtendimax™ with VaporGrip™ Technology) EPA Registration Number 524-617

Background

On April 28, 2010 and July 30, 2012, respectively, the EPA received applications from the Monsanto Company (Monsanto) to register new uses of dicamba, as the DGA salt, on GE soybean and GE cotton. The application also requested the establishment of new tolerances for residues resulting from the new uses. The tolerances for these new uses have been established.

Dicamba is an active ingredient that is currently used through acid formulations and a variety of salt formulations, and is registered for a variety of food and feed uses. The new uses will expand the current timing of dicamba applications to post-emergence (over-the-top) applications to GE cotton and GE soybean crops. Until this registration, dicamba was only registered for use on preplant and pre-harvest soybeans and on preplant and postharvest cotton. It is important to note that using registered dicamba products on GE cotton or GE soybean crops that are not registered specifically for post-emergence use on GE cotton or GE soybean crops is inconsistent with the pesticide's labeling and a violation of FIFRA.

New Uses

<u>Cotton</u>

Dicamba products that are currently registered on conventional cotton are used for preplant, at-planting and/or pre-emergent treatments at application rates that range from 0.25 to 1.0 pounds acid equivalent (lb a.e.) dicamba per acre. The maximum annual application for all preplant, at planting and pre-emergence applications combined on conventional cotton is 1.0 lb a.e. dicamba per acre per season.

For the new use, for post-emergence (in-crop) application of dicamba for use on GE cotton, the maximum single in-crop application rate is 22 fluid ounces (0.5 lb a.e. dicamba) per acre. This rate is also the minimum single application in order to reduce the selection for resistant weeds. The total of all in-crop applications for GE cotton is 88 fluid ounces (2.0 lb a.e. dicamba) per acre per season.

For preplant, at-planting, and pre-emergence treatments to GE cotton, applications must be made with a minimum application rate of 22 fluid ounces (0.5 lb a.e. dicamba) per acre. The total for all preplant, at-planting, and pre-emergence applications must not exceed 44 fluid ounces (1.0 lb a.e. dicamba) per acre per season.

The combined total per year for all applications (preplant, at-planting, pre-emergence and post-emergence (in-crop) must not exceed 88 fluid ounces (2.0 lb a.e. dicamba) per acre. For example, if a preplant application of 44 fluid ounces (1.0 lb a.e. dicamba) per acre is made, then the combined total post-emergence (in-crop) annual applications must not exceed 44 fluid ounces (1.0 lb a.e. dicamba) per acre for GE cotton.

The minimum retreatment interval is 7 days; the pre-harvest interval for cottonseed including the livestock feeding of cotton gin by-products is 7 days.

Soybeans

Dicamba products that are currently registered on conventional soybeans are used for preplant, at-planting and/or pre-emergent treatments at application rates that range from 0.125 to 0.5 pounds acid equivalent (lb a.e.) dicamba per acre and for preharvest burndown treatments at 0.25 to 1.0 lb a.e. dicamba per acre. The maximum annual application for all preplant, at planting, pre-emergence, and preharvest burndown applications combined on conventional soybeans is 1.0 lb a.e. dicamba per acre per season.

For the new use for post-emergence (in-crop) application of this product to GE soybeans, the maximum single in-crop application rate is 22 fluid ounces (0.5 lb a.e. dicamba) per acre. This rate is also the minimum single application in order to reduce the selection for resistant weeds. The total for all in-crop applications for GE soybeans is 44 fluid ounces (1.0 lb a.e. dicamba) per acre per season.

For preplant, at-planting, pre-emergence, and preharvest burndown treatments to GE soybeans, applications must be made with a minimum application rate of 22 fluid ounces (0.5 lb a.e. dicamba) per acre. The total for all preplant, at-planting, pre-emergence, and preharvest applications must not exceed 44 fluid ounces (1.0 lb a.e. dicamba) per acre per season.

The combined total per year for all applications must not exceed 88 fluid ounces (2.0 lb a.e dicamba) per acre. The minimum retreatment interval is 7 days; the pre-harvest interval, including feeding of soybean hay, is 14 days (R1 Growth stage).

II. Human Health Risk

A summary of the human health risk assessment, *Dicamba and Dicamba BAPMA Salt: Human-Health Risk Assessment for Proposed Section 3 New Uses on Dicamba-tolerant Cotton and Soybean*, is provided below.

As stated earlier in this document, the data associated with the BAPMA salt were considered to be the most appropriate form to use for assessing the potential for risks to human health. In the human

health risk assessment for dicamba, risks were assessed in a manner that protects human health from exposure to all forms of the chemical. This is a complex analysis because (1) there are a variety of different forms of dicamba that must be considered (e.g., dicamba acid, dicamba BAPMA salt, other dicamba salts such as DGA), (2) the data show greater toxicity for a major metabolite in foods (DCSA) relative to the parent compound, and (3) the different types of toxicity and potency with different routes of exposure (specifically, portal of entry effects observed in inhalation toxicity studies for BAPMA vs. other forms of dicamba).

When determining the safety of a pesticide, the EPA evaluates the available toxicity data and considers its validity, completeness, and reliability, as well as the relationship of the results of the studies to human risk. the EPA also considers available information concerning the variability of the sensitivities of major identifiable sub-groups of consumers, including infants and children. Once a pesticide's toxicological profile is determined, the EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks (e.g., cancer), the agency assumes that any amount of exposure will lead to some degree of risk. Thus, the agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime (dicamba has been determined to be "not likely" to be carcinogenic and therefore a non-threshold approach does not apply in this case). For more information on the general principles the EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

The following risk assessment endpoints were selected for dicamba to be protective to all forms of the chemical.

- For the acute dietary assessment, the most sensitive, single-day toxic effect seen across the entire dicamba database was chosen for quantifying risks, i.e., maternal neurotoxic effects seen in a developmental toxicity study in which animals were dosed with the BAPMA salt. Although dietary exposure could occur from agricultural use of other salts of dicamba resulting in lower risk estimates, the assessment quantified risks assuming everyone exposed to dicamba would be exposed to the more toxic BAPMA salt to assure protection from all forms of the chemical.
- For the chronic dietary assessment, the endpoint was selected from a reproduction study in which animals were dosed with the DCSA metabolite (a plant metabolite), a compound much more chronically toxic than any of the parent dicamba acid or salts pesticides. Although chronic dietary exposure could occur from exposure to various salts of dicamba rather than just this metabolite, risks were estimated assuming all residues in foods were the more toxic metabolite, thus assuring protection from all forms of the chemical.
- For the inhalation exposure assessment, risks were quantified separately for the BAPMA salt vs. other forms of dicamba since the BAPMA salt is (1) only used in agricultural settings and residential inhalation exposures would therefore not be expected, and (2)

more toxic than other forms of dicamba with regard to portal of entry inhalation toxicity.

- Finally, we assessed the toxicity specific to the counter-ion of the BAPMA salt, i.e., BAPMA itself. Since the BAPMA salt shows increased toxicity via inhalation, the BAPMA was included in the aggregate risk assessment. The potential for increased risk resulting from this chemical was assessed and determined to be low relative to the toxicity from the parent compounds and DCSA; therefore, protecting for exposures to the parent compounds and DCSA will also protect for exposures to BAPMA itself.

A. Summary of Toxicological Effects

The toxicology database for dicamba is complete and sufficient for assessing the toxicity and characterizing the hazard of dicamba. Toxicology studies for dicamba acid, its salts [isopropylamine (IPA), diglycolamine (DGA), and N, N-Bis-(3-aminopropyl) methylamine (BAPMA)], and the plant metabolites [DCSA (3, 6-dichlorosalicylic acid) and DCGA (3, 6-dichlorogentisic acid] were all considered for risk assessment for these new uses. In scenarios where co-exposure to the various forms could occur, the most protective point of departure (POD) was utilized.

Dicamba acid has been classified as having a low acute toxicity via oral, dermal and inhalation routes (Acute Toxicity Categories III or IV). It is both an eye and dermal irritant (Toxicity Category II), but it is not a skin sensitizer.

Dicamba is classified as "not likely to be carcinogenic to humans" based upon the lack of evidence of carcinogenicity in mice and rats in the acid form when tested at adequate dose levels. The agency determined, based on review of epidemiological data (see Elizabeth Evans and Shanna Recore, *Dicamba: Tier I (Scoping) Review of Human Incidents and* Epidemiology, 11/10/15), that the existing data did not support a conclusion that links human cancer to dicamba exposure.

B. Toxicological Endpoints and Doses Used in the Human Health Risk Assessment

Once a pesticide's toxicological profile is determined, the EPA identifies toxicological Points of Departure (POD) and Levels of Concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the No Observed Adverse Effect Level (NOAEL)) and the lowest dose at which adverse effects of concern are identified (the Lowest Observed Adverse Effect Level (LOAEL)). Uncertainty factors (UF)/safety factors (SF) are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a Population-adjusted Dose (PAD) or a Reference Dose (RfD) – and a safe Margin of Exposure (MOE). For non-threshold risks, the EPA assumes that any amount of exposure will lead to some degree of risk. Thus, the EPA estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime.

1. Acute Dietary

The acute dietary endpoint was selected from the dicamba BAPMA salt rat developmental toxicity

study, which represents the most sensitive endpoint in the dicamba toxicology database resulting from a single-dose dietary exposure. The NOAEL is 29 mg/kg/day, and the LOAEL is 86 mg/kg/day based on ataxia, unsteady gait, and convulsions in female rats. This NOAEL POD is protective of acute effects of dicamba via the oral route of exposure to the general population, including infants and children. A separate acute dietary endpoint for reproductive females ages 13-49 is not required since no acute developmental toxicity effects were observed in the dicamba database. An uncertainly factor of 100X was applied with 10X for interspecies extrapolation from animal to human, and 10X for intraspecies variation in sensitivity amongst the human population. As discussed in Section C below, the Food Quality and Protection Act (FQPA) safety factor was reduced to 1X, resulting in an aRfD/aPAD of 0.29 mg/kg/day.

2. Chronic Dietary

The chronic dietary endpoint was selected from the DCSA plant metabolite reproduction toxicity study, which represents the most sensitive endpoint in the toxicology database resulting from repeated-dose dietary exposure. The NOAEL is 4 mg/kg/day, and the LOAEL is 37 mg/kg/day based on decreased pup weights. The NOAEL POD is protective of chronic effects of dicamba via the oral route of exposure to the general population, including infants and children. A 100X UF was applied (10X interspecies and 10X intraspecies), and as discussed in Section C below, the FQPA SF was reduced to 1X resulting in a cRfD/cPAD of 0.04 mg/kg/day.

3. Incidental Oral (Short- and Intermediate-Term)

The incidental oral endpoint was selected from the dicamba acid rat multi-generation reproductive toxicity study, which represents the most appropriate endpoint in the toxicology database for assessing short- (1 to 30 days) and intermediate-term (1 to 6 months) incidental oral (hand-to-mouth) exposure. The NOAEL is 136 mg/kg/day, with a LOAEL of 450 mg/kg/day based on impaired pup growth. A 100X UF was applied (10X interspecies and 10X intraspecies), and as discussed in Section C below, the FQPA SF was reduced to 1X resulting in a level of concern of 100.

4. Inhalation (All Durations)

For dicamba acid and the DGA salt inhalation risk assessment for short and intermediate term durations, the POD was based on the route-specific dicamba acid inhalation toxicity study in Wistar rats with a LOAEL of 0.050 mg/L based on local effects of hyperplasia in the lungs and lymph nodes (NOAEL = 0.005 mg/L, non-systemic, pulmonary regional deposited dose ratio (RDDR) = 0.590).

The standard interspecies extrapolation UF can be reduced from 10X to 3X for dicamba acid due to the calculation of human equivalent concentrations (HECs) accounting for pharmacokinetic (not pharmacodynamic) interspecies differences. Therefore, the LOC for dicamba acid inhalation exposures is for MOEs less than 30 (3X for interspecies extrapolation, 10X for intraspecies variation, and as discussed in Section C below, 1X for FQPA SF when applicable). The inhalation HEC results are listed in Appendix A.5.

5. Dermal (All Durations)

No dermal endpoint was selected since no adverse effects were observed in the subchronic dermal studies for dicamba acid, IPA salt, and DGA salt up to the limit dose.

6. Cancer

Dicamba is classified as "Not Likely to be Carcinogenic to Humans." This decision was based on the lack of findings in the cancer studies in rats and mice, which were tested at adequate dose levels to assess the carcinogenicity of dicamba. Mutagenicity studies generally did not demonstrate evidence of mutagenic potential for dicamba and the concern for genotoxicity in the acid form is low. Epidemiology studies were also examined, and no links were found to dicamba exposure and cancer. Additionally, the DCSA metabolite lacked findings of carcinogenicity in a chronic/carcinogenicity study in rats.

C. FQPA Safety Factor

The EPA has determined that the 10X FQPA Safety Factor for protection of infants and children, mentioned above, can be reduced to 1X for the acute and chronic dietary risk assessment for the following reasons and discussed in more detail below: (1) The toxicity database for dicamba is complete with respect to the required 870 guideline studies. (2) There is no evidence of increased susceptibility following *in utero* exposures to rats and rabbits and following pre and/or post-natal exposure to rats in a two-generation reproduction study. For the dicamba acid and BAPMA salt, no developmental toxicity was seen at the highest doses tested in the prenatal developmental studies with rats. (3) Consistent neurotoxic signs (e.g., ataxia, decreased motor activity, impaired righting reflex and gait) were observed in multiple studies in rats and rabbits. However, after considering the available toxicity data, the EPA determined that there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity due to the following: (i) although clinical signs of neurotoxicity were seen in pregnant animals, no evidence of developmental anomalies of the fetal nervous system were observed in the prenatal developmental toxicity studies, in either rats or rabbits, at maternally toxic doses up to 300 or 400 mg/kg/day, respectively; (ii) there was no evidence of behavioral or neurological effects on the offspring in the two-generation reproduction study in rats; (iii) the ventricular dilation of the brain in the combined chronic toxicity and carcinogenicity study in rats was only observed in females at the high dose after two years of exposure at doses of 127 mg/kg/day, but the significance of this observation is questionable, since no similar histopathological findings were seen in two sub-chronic neurotoxicity studies at the limit dose or other chronic studies.

There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed using tolerance level residues and 100% crop treated assumptions. The chronic dietary food exposure assessment used average residues for crops, tolerances levels for livestock commodities, and percent crop treated assumptions for several registered uses. Conservative ground and surface water estimates calculated using the latest models were used. Similarly, conservative residential Standard Operating Procedure (SOPs) were used to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by dicamba.

1. Completeness of the Toxicology Database

The toxicity database for dicamba is adequate to characterize the potential for prenatal or postnatal risk to infants and children. Acceptable rat and rabbit developmental toxicity studies, two rat 2-generation reproduction studies, and acute/subchronic neurotoxicity studies in rats are available.

2. Evidence of Neurotoxicity

There is evidence of neurotoxicity resulting from exposure to dicamba throughout the toxicology database (i.e., impaired gait, impaired righting reflex, ataxia, decreased motor activity, rigidity upon handling, etc). These signs of neurotoxicity were observed in multiple studies in rats and rabbits. However, after considering the available toxicity data, the agency determined that a developmental neurotoxicity study (DNT) is not required for the following reasons: (1) although clinical signs of neurotoxicity were seen in pregnant animals, no evidence of developmental anomalies of the fetal nervous system were observed in the prenatal developmental toxicity studies, in either rats or rabbits, at maternally toxic doses up to 300 or 400 mg/kg/day, respectively; (2) there was no evidence of behavioral or neurological effects on the offspring in the two-generation reproduction study in rats; (3) the ventricular dilation of the brain in the combined chronic toxicity and carcinogenicity study in rats was only observed in females at the high dose after two years of exposure at doses of 127 mg/kg/day, but the significance of this observation is questionable, since no similar histopathological finding was seen in two sub- chronic neurotoxicity study at the limit dose or other chronic studies.

3. Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

There is no evidence of susceptibility to the young following *in utero* exposure to dicamba acid, dicamba BAPMA or DCSA. Quantitative offspring susceptibility was observed in the 2- generation reproduction study for the DCSA metabolite based on decreased pup weights, which occurred at a dose at which no parental effects were observed. However, the degree of concern for the susceptibility is low, because there is a well-established NOAEL for offspring toxicity in that study and DCSA has rapid clearance. Additionally, the current points of departure are health protective and therefore address the concern for offspring toxicity observed in the reproduction studies.

4. Residual Uncertainty in the Exposure Database

The residential exposure assessment assumes maximum label use rate as well as other conservative assumptions. The acute dietary exposure assessment is based on an exaggerated exposure scenario which assumes that all commodities being consumed retain tolerance level residues, and the chronic dietary exposure assessment assumes field trial residues in which the crops were treated using the use patterns likely to lead to maximum residues. Additionally, the drinking water estimates utilized conservative models (e.g., models using screening level assumptions). Therefore, the agency does not believe that exposure to dicamba will be underestimated.

D. Cumulative effects

The EPA has not made a common mechanism of toxicity finding for dicamba and any other substance, and dicamba does not appear to produce a toxic metabolite produced by other

substances. Therefore, the EPA finds for this decision that dicamba does not have a common mechanism of toxicity with other substances. For information regarding the EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on the EPA's website at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.

E. Dietary (Food + Drinking Water) Risk

Dicamba is a selective systemic herbicide used to control a variety of broadleaf weeds and registered for a variety of food/feed uses. Permanent tolerances for dicamba are established under 40 CFR § 180.227 for a wide variety of crops and livestock commodities. Acute and chronic aggregate dietary food and drinking water exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

1. Acute Dietary Risk

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item are multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user basis (i.e., only those who reported eating relevant commodities/food forms) and a per-capita basis (i.e., those who reported eating the relevant commodities as well as those who did not). In accordance with the EPA policy, per capita exposure and risk are reported for analyses.

Risks are considered to be of no concern when they are less than 100% of the aPAD or cPAD, a value determined by dividing the POD for the most sensitive and pertinent toxicological effect for each exposure scenario by required uncertainty factors. The acute analysis was an unrefined determination which used tolerance level residues and assumed 100 percent crop treated (%CT) for all existing and new uses. The dietary exposure analyses that were performed result in acute dietary risk estimates that are below the agency's LOC for both food and water. For the U.S. population, the exposure was 0.042760 mg/kg/day, which utilized 15% of the acute population adjusted dose (aPAD) at the 95th percentile. The highest exposure and risk estimates were for all infants (<1 year old). At the 95th percentile, the exposure for all infants (<1 year old) was 0.089 mg/kg/day, which utilized 31% of the aPAD.

2. Chronic Dietary Risk

For chronic dietary exposure assessment, an estimate of the residue level in each food or food form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting

residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

The chronic analysis was a partially refined determination which used average residues based on field trial studies for crops, tolerance levels for livestock commodities, and relevant % crop treated (CT) data for several existing uses. The chronic risk estimates for dicamba are below the agency's LOC for the general U.S. population and all population subgroups. The highest exposure and risk estimates were for the population subgroup of children ages 1-2 with a risk estimate for dicamba for food and water of 42% of the cPAD.

F. Residential (Non-Occupational) Exposure/Risk Characterization

There are no residential uses being established for dicamba with this current registration; however, there are existing residential uses of dicamba that have been reassessed in this document to reflect updates to the agency's 2012 Residential SOPs along with policy changes for body weight assumptions. The revision of residential exposures will impact the human health aggregate risk assessment for dicamba. Registered uses of dicamba include solid and liquid products in concentrates or ready-to-use sprays for use as spot and broadcast treatments on turf.

1. Residential Handler Exposure

Based on the currently registered uses, residential handlers may receive exposure to dicamba when mixing, loading and applying the pesticide to lawns and turf. Since there was no dermal hazard identified for dicamba, only inhalation risk estimates were quantitatively assessed. The inhalation risk estimates were based on the following application scenarios:

- Mix/Load/Apply Liquid with Hand-held Equipment
- Apply Ready-To-Use Sprays with Hand-held Equipment
- Load/Apply Granules with Hand-held Equipment

The MOEs for the exposure scenarios assessed range from 190 to 220,000. Since there is potential risk concern only when inhalation MOEs are less than a LOC of 30, residential handler exposures are not a concern.

2. Post-application Exposure

There is the potential for post-application exposure for individuals exposed as a result of being in an environment that has been previously treated with dicamba. Since no dermal hazard was identified for dicamba, the quantitative exposure/risk assessment for residential post-application exposures is based on the following scenarios:

- Children (1 to < 2 years old) incidental oral exposure to treated turf.
- Children (1 to < 2 years old) episodic granular ingestion exposure.

Since dicamba products registered for use on residential turf come in both liquid and granular

formulations, both are accounted for in this assessment. The assessment of post-application exposure to liquid formulations is protective of exposure to solid formulations, except for the episodic granular ingestion scenario which was quantitatively assessed. The life stages selected for assessment are health protective for the exposures and risk estimates for any other potentially exposed life stages.

The post-application assessment for turf includes only the incidental oral routes of exposure. The series of assumptions and exposure factors that served as the basis for completing the residential post-application risk assessment are detailed in the 2012 Residential SOPs (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide). In addition, chemical-specific residue data were used in the assessment. The residential post-application risk estimates are not of concern for dicamba since all MOEs are greater than the LOC of 100 (the lowest MOE = 6600 for use of liquids on lawns).

3. Residential Bystander Post-application Inhalation Exposure

The potential exposure to bystanders from vapor phase dicamba residues emitted from treated fields has been evaluated for the new uses of dicamba on GE corn and GE soybean. Bystander exposure to dicamba emitted from treated fields depends on two main factors: 1) the rate at which these chemicals volatilize from a treated field (described as the off-gassing, emission or flux), and 2) how those vapors are dispersed in the air over and around the treated field. In general, volatilization can occur during the application process or thereafter. It can result from aerosols evaporating during application, while deposited sprays are still drying (possibly via co-distillation), or after as dried deposited residues volatilize.

Volatilization modeling for a single day was completed using the Probabilistic Exposure and Risk model for Fumigants (PERFUM). There are a variety of factors that potentially affect the emission rates of dicamba and subsequent offsite transport including: field condition (bare soil, growing or mature crop canopy), field parameters (soil type, moisture, etc.), formulation type, meteorological conditions, and application scenario (rate, method).

A chemical-specific flux study was used to estimate a flux rate of 0.0004 $ug/m^2/s$ for dicamba. This flux rate, along with an assumption of a single 40-acre field, and using Bradenton, FL meteorological data from Bradenton, FL were used with PERFUM to estimate risk.

The field volatility study suggests that volatilization of dicamba from treated crops does occur, which could result in bystander exposure. Although a more recent volatility study conducted using the M1768 formulation was submitted and reviewed, which demonstrated comparable potential for volatility as described in greater detail in the document entitled *Review of EFED Actions and Recent Data Submissions Associated with Spray and Vapor Drift of the Proposed Section 3 New Uses on Dicamba-Tolerant Soybean and Cotton* available in the docket for this action, that study was not available at the time this Human Health assessment was developed. Results of PERFUM modeling using the Bradenton, FL study however, indicate that airborne concentrations are negligible, and even at the edge of the treated fields risk estimates for potential human bystander exposure are not of concern.

4. Spray Drift

Without considering mitigation measures, it is reasonable to assume that spray drift may be a potential source of exposure to residents nearby to spraying operations. Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (*e.g.*, children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues are calculated using drift modeling coupled with methods employed for residential risk assessments for turf products.

The approach to be used for quantitatively incorporating spray drift into risk assessments is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them. Direct exposures would include inhalation of the spray plume or being sprayed directly. Rather, the exposures addressed here occur indirectly through contact with impacted areas, such as residential lawns, when compliant applications are conducted. Given this premise, exposures for children (1 to 2 years old) and adults who have contact with turf where residues are assumed to have deposited via spray drift thus resulting in an indirect exposure are the focus of this analysis, analogous to how exposures to turf products are considered in risk assessment.

Several dicamba products have existing labels for use on turf, thus it was considered whether the risk assessment for that use would be considered protective of any type of exposure that would be associated with spray drift. Because the registered residential uses on turf result in exposure greater than potential exposure from spray drift, no new residential assessment needs to be completed. If the maximum application rate on crops adjusted by the amount of drift expected is less than or equal to existing turf application rates, the existing turf assessment is considered protective of spray drift exposure. The maximum single application rate of dicamba for this new use is 1 lb a.e./A. The highest degree of spray drift noted for any application method immediately adjacent to a treated field (Tier 1 output from the aerial application using fine to medium spray quality) results in a deposition fraction of 0.26 of the application rate. This spray drift fraction estimation differs from that used for environmental exposures because, unlike environmental risk assessment that uses estimations to determine exposures at the edge of the treated field, estimations for human health risk assessment are used to assess the average deposition over a wide area of lawn. For the purposes of the new uses on dicamba, this is considered a screening level assumption since the new use is for groundboom applications only. A quantitative spray drift assessment for dicamba is not required because the maximum application rate to a crop/target site multiplied by the adjustment factor for drift of 0.26 is less than the maximum direct spray residential turf application rate of 1 lb a.e./A for any dicamba products. The turf post-application MOEs have been previously assessed, are based on the revised SOPs for Residential Exposure Assessment, and were not found to be of concern, as noted above.

5. Aggregate Risk Assessment

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), the EPA must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard, or the risks themselves can be

aggregated. When aggregating exposures and risks from various sources, the EPA considers both the route and duration of exposure. Since residential exposure is expected, aggregate exposure consists of exposure from residential, food and drinking water sources.

Acute and chronic aggregate risks include only dietary exposure from food and drinking water sources. Since there are residential uses, short-term aggregate risks were assessed which include contributions from food, drinking water, and residential exposure. Intermediate-term aggregate risks were not considered as residential exposure is not expected to occur for more than 30 days. Cancer aggregate risk was not quantified since dicamba is not a carcinogen. A common oxicological endpoint of concern was not identified for short-, intermediate- or long-term durations via the oral, dermal, or inhalation routes. Therefore, the aggregate exposure risk assessment should include exposure across the oral routes only, as appropriate for the populations of concern (i.e., food and water for adults; and food, water and incidental oral for children).

a. Acute Aggregate Risk

The acute aggregate risk assessment includes only food and water exposure; therefore, the acute dietary (food and drinking water) assessment represents acute aggregate risk. The acute dietary exposure assessment was conducted using tolerance-level residues, DEEM default processing factors and 100% crop-treated information for all registered and new use sites. Drinking water values were incorporated directly into the assessment. The most highly exposed population subgroup is all infants (<1 year old; 31% of the aPAD). The acute dietary exposure estimates are not of concern for the general U.S. population or any population subgroup.

b. Short-term Aggregate Risk

The short-term aggregate risk assessment includes food, water and residential exposure. The resulting short-term aggregate risks are not of concern for children (MOEs > LOC 100). For adults, since there was no dermal hazard identified in the route-specific dermal studies and the inhalation effects were not systemic, the chronic dietary assessment is protective for short-term aggregate risks.

c. Long-term Aggregate Risk

The chronic (long-term) aggregate risk assessment includes only food and water exposure. The chronic dietary analysis was a partially refined determination which used average residues based on field trial studies for crops, tolerance levels for livestock commodities, and relevant percent crop treated (CT) data for several existing uses. The chronic risk estimates for dicamba are below the agency's LOC for the general U.S. population and all population subgroups. The highest exposure and risk estimates were for the population subgroup of children ages 1-2 with a risk estimate for dicamba for food and water of 42% of the cPAD.

6. Occupational Risk Assessment

a. Short- and Intermediate-term Handler Risk

The EPA uses the term occupational handler to describe people who mix, load and/or apply pesticides professionally (e.g., farmers, professional pesticide applicators). Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used (e.g., mixing/loading liquids for ground boom application, and applying sprays by ground boom equipment), occupational handler exposure is expected from the new uses.

The occupational handler risk estimates are not of concern (i.e., MOEs > LOC of 30) for all of the scenarios for the use of dicamba on GE cotton and GE soybean. At baseline personal protective equipment (PPE) (i.e., no respirator), the occupational handler inhalation MOEs are 380 for mixer/loaders and 250 for applicators using ground boom equipment.

b. Short- and Intermediate-term Post-application Risk

The EPA uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

i. Dermal Post-application Risk

There is no potential hazard via the dermal route for dicamba; therefore, a quantitative occupational post-application dermal risk assessment was not completed.

ii. Inhalation Post Application Risk

There are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037. The agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0219-0002). During Registration Review, the agency will utilize this analysis to determine if additional data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for the active ingredient dicamba, generically.

In addition, the agency is continuing to evaluate the available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. Given these two efforts, the agency will continue to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the agency's risk assessments.

III. Environmental Risk

A summary of the environmental fate and ecological effects, and potential environmental risks from the use of dicamba on GE soybean and GE cotton is provided below. More detailed discussions can be found in the agency documents titled:

- *Ecological Risk Assessment for Dicamba and its Degradate, 3,6-dichlorosalicylic acid (DCSA), for the Proposed New Use on Dicamba-Tolerant Soybean (MON87708)* and
- *Ecological Risk Assessment for Dicamba DGA Salt and its Degradate, 3,6-dichlorosalicylic acid (DCSA), for the Proposed Post-Emergence New Use on Dicamba-Tolerant Cotton (MON 87701),* and its addendums entitled,
- *Addendum to the Environmental Fate and Ecological Risk Assessment for the Section 3 New Use of Dicamba on Dicamba-Tolerant Soybean* and
- *Dicamba DGA; Second Addendum to the Environmental Fate and Ecological Risk Assessment for Dicamba DGA salt and its Degradate, 3,6-dichlorosalicylic acid (DCSA) for the Section 3 New Use on Dicamba-Tolerant Soybean* and
- *M-1691 Herbicide, EPA Reg. No. 524-582 (Active Ingredient: Dicamba Diglycolamine Salt) and M-1768 herbicide, EPA Reg. No. 524-617 (AI: Diglycolamine Salt with VaporGrip™) – Review of EFED Actions and Recent Data Submissions Associated with Spray and Vapor Drift of the Proposed Section 3 New Uses on Dicamba-Tolerant Soybean and Cotton.*

These documents are in docket number EPA-HQ-OPP-2016-0187, available at regulation.gov. A fuller description of how these potential risks are assessed can be found at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical.

A. Environmental Fate

1. Degradation

Dicamba is generally stable to abiotic processes, and is more persistent under anaerobic conditions. It is stable to abiotic hydrolysis at all pH levels and photodegrades slowly in water and soil. Under anaerobic soil conditions, the dicamba parent molecule has a half-life of 141 days. It is not persistent under aerobic conditions; aerobic soil metabolism is the main degradative process for dicamba, with a half-life of 6 days. Dicamba was found in two acceptable field dissipation studies in soil segments deeper than 10 cm with half-lives ranging from 4.4 to 19.8 days. In aquatic systems, dicamba degrades more rapidly when sediment is present and has an aerobic soil metabolism half-life in sediment-water system of ~24 days.

The major degradate of dicamba is 3,6-dichlorosalicylic acid (DCSA). It is persistent when formed under anaerobic conditions, comprising more than 60% of the applied dose after 365 days of anaerobic incubation in sediment-pond water system. DCSA is not persistent when formed under aerobic conditions and degrades roughly at the same rate as the parent dicamba with a half-life of 8.2 days. Like the parent molecule, DCSA is mobile and was also found in the two acceptable field studies in soil segments deeper than 10 cm. If it were to reach anaerobic groundwater, it would

likely persist; however, the EPA does not expect DCSA to reach groundwater at levels that would be of concern. DCSA is formed in aerobic soil under laboratory conditions at the maximum of 17.4 % of the applied parent dose. Other minor dicamba degradates of concern are DCGA and 5-OH-dicamba, and both are less toxic than the parent molecule and DCSA. The formation of DCGA in the laboratory studies did not exceed 3.64%, and the formation of 5-OH dicamba did not exceed 1.9 % in soil-water system during anaerobic aquatic degradation of dicamba under laboratory conditions. DCSA was also a major metabolite in plant metabolism and magnitude of residue studies for GE soybean and cotton, comprising approximately 80% and 20%, respectively, of dicamba-related residues in plant tissues for these crops.

2. Mobility

Dicamba is very soluble and mobile. Without considering mitigation measures on the product label, possible pathways for reaching surface water include field/site runoff, spray drift during application, and vapor drift from volatilization. It is not expected to bioaccumulate in aquatic organisms as it is an anion at environmental pHs. Since dicamba is not persistent under aerobic conditions, very little dicamba is expected to reach groundwater. The major degradate of dicamba, DCSA, is persistent under anaerobic conditions; however, the EPA does not expect DCSA to reach groundwater at levels that would be of concern. Without considering mitigation measures, the major route of exposure to non-target organisms is likely spray drift and runoff. While multiple literature studies show that there is potential for high vapor drift for certain dicamba salts and formulations from soybean fields resulting in non-target plant injury, the available dicamba M1768 formulation volatility research the agency has reviewed indicates that non-target plant biomass and yield will not be affected by use of the M1768 formulation. The assessments, which can be found in the docket for this action, related to these routes of exposure are described in the sections below.

3. Runoff

The agency considered the potential effects due to runoff and developed mitigation to limit off-site runoff that is reflected in the approved labeling for these new uses (e.g., Do not make application of this product if rain is expected in the next 24 hours.). A component of the model used to assess terrestrial risk assumes that the mass of pesticide running off the treated field is directly related to the pesticide's solubility in water. In the case of dicamba DGA salt, the dissociated salt yields highly soluble dicamba acid. The model assumes that the high solubility of the acid results in a runoff mass of 5 percent of the field-applied mass, which is considered to be a highly conservative estimate because the model does not account for loss of chemical from degradation, partitioning, or the temporal aspects of runoff (e.g., a rain event following application that exceeds soil's field capacity).

4. Spray Drift

Without consideration of mitigation measures on the approved label, the agency considers spray drift exposure to be the principal risk issue to be considered with these new uses, owing to a variety of lines of evidence, including past experience with other dicamba formulations. In addition, visual observations of off-field plant damage have been reported following applications of currently registered dicamba products (not containing the same labeling restrictions), likely the result of subsequent spray drift and/or volatilization of dicamba residues.

The agency used a weight of evidence approach incorporating spray drift modeling, a spray drift droplet deposition study, and raw data from field trials to determine an appropriate in-field buffer to avoid dicamba exposure to non-target organisms (e.g., endangered plants). The EPA determined that the label must specify that nozzles must be used that produce extra-course and ultra-course droplet spectra for application to reduce the potential for spray drift. The approved labeling for this action contains these restrictions. Based on the weight of evidence approach, the EPA also determined that labels must include language to maintain an in-field buffer (downwind at the time of application) of 110 feet when applying at the 0.5 lb a.e./A application rate and 220 feet when applying at the 1.0 lb a.e./A application rate in order to restrict the movement of residues to the field. Using these buffers, expected residues at the field's edge from spray drift would be below apical endpoints for the most sensitive tested species (i.e., NOAEC for soybean plant height). The approved labeling for this action includes these restrictions.

5. Volatilization

After reviewing submitted data relating to the volatility of dicamba, and at the time the EPA proposed these new uses, the agency had concerns regarding the volatility of dicamba and possible post-application, vapor-phase off-site transport that might damage non-target plants. Monsanto responded to these concerns with an additional submission post-proposal that acknowledged the long-recognized volatility of dicamba acid and described measurements of the volatilization in the different formulations.

Based on field volatility (flux) studies (conducted in accordance with the label conditions such as nozzle and ground speed limitations) and laboratory vapor-phase toxicity and exposure (humidome) studies, the 110-foot omnidirectional buffer for volatilization is no longer warranted for the dicamba DGA plus VaporGrip™ (M1768) formulation, because the expected exposure at field's edge is less than the NOAEC for plant risk.

The EPA's buffer is determined by evaluation of plant toxicity data required under FIFRA and conducted under GLP conditions where apical endpoints (plant height and yield) are used as measures of plant growth and reproduction. Once the no observed adverse effect concentration (NOAEC) was determined for the most sensitive endpoint (i.e., plant height) for the most sensitive plant species tested (i.e., soybeans), the EPA uses field studies and modeling to determine the distance from site of application to where the NOAEC is not expected to be exceeded. It is further noted that the labels for the new uses will specify a spray nozzle and pressure combination that is expected to reduce drift of the herbicide, which are drift reduction measures not on the previously registered dicamba formulations and could also influence the size of a protective buffer.

B. Ecological Risk

Ecological risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The process of integrating the results of exposure with the ecotoxicity data is called the risk quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and

chronic (RQ = Exposure/Toxicity). RQs are then compared to the EPA's levels of concern (LOCs). The LOCs are criteria used by the agency to indicate potential risk to non-target organisms. The criteria indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms.

For terrestrial animals, the agency's acute risk LOCs are set at 0.5 for non-listed species and 0.1 for listed species. For aquatic animals, acute risk LOCs are also set at 0.5 for non-listed species but for listed species, they are set at 0.05. The chronic risk LOC is set at 1.0 for both terrestrial and aquatic animals. For plants, acute risk LOCs are set at 1 for both non-listed and listed species. The potential difference in sensitivity for listed plant species compared to non-listed plant species is addressed through the use of different toxicity endpoints in the RQ equation [the concentration causing effects to 25% of the test population (EC25) for non-listed plants vs the NOAEC or concentration causing effects to 5% of the test population (EC05) for listed species]. Chronic risk is not assessed for plants.

Dicamba is currently registered for use on several food and non-food use sites, including conventional cotton and soybean. The new uses on GE soybeans and GE cotton expand the timing of applications from only pre-emergence and pre-harvest for soybeans and only pre-emergence and post-harvest for cotton to allowing post-emergence over-the-top applications on these GE crops. The maximum yearly application rates would remain 2.0 lb a.e./A for both cotton and soybeans. However, as detailed in section I of this document, the applicator could now split the 2.0 lb a.e./A between pre-emergence and post-emergence applications.

The EPA has a specific process based on sound science that it follows when assessing risks to listed species for pesticides like dicamba that will be used on seeds that have been genetically modified to be tolerant to the pesticide. The agency begins with a screening-level assessment that includes a basic ecological risk assessment based on its 2004 Overview of the Ecological Risk Assessment Process document. [USEPA, 2004, available at http://www.epa.gov/oppfead1/endanger/litstatus/riskasses.htm]. That assessment uses broad default assumptions to establish estimated environmental concentrations of particular pesticides. If the screening - level assessment results in a determination that no levels of concern are exceeded, the EPA concludes its analysis. On the other hand, where the screening-level assessment does not rule out potential effects (exceedances of the level of concern) based on the broad default assumptions, the EPA then uses increasingly specific methods and exposure models to refine its estimated environmental concentrations at the species-specific level.

The results of the screening-level risk assessments indicate that the RQs do not exceed the agency's LOC for terrestrial invertebrates (including pollinators), freshwater fish, aquatic-phase amphibians, estuarine/marine fish, freshwater invertebrates, or estuarine/marine invertebrates for either acute or chronic exposures. Acute RQs for aquatic plants and mammals, and chronic RQs for birds, reptiles, and terrestrial-phase amphibians also do not exceed the agency's LOC. The screening-level assessment uses broad default assumptions to establish estimated environmental concentrations of particular pesticides. It does not make effects determinations related to any particular listed species. Instead, species-specific assessments are conducted for effects determinations. A more detailed description can be found in Section IV below.

For both GE cotton and GE soybeans, based on the new maximum application rates, the screening-

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level analysis indicates that risks for acute exposure to listed and non-listed birds, and listed and non-listed terrestrial dicot plant species, result in RQs that exceed the agency's LOCs. For soybeans, there is also a potential for direct adverse effects to birds and mammals from chronic exposure to the dicamba degradate DCSA. Though the rates are similar to those in currently registered dicamba pesticide products, the potential for ecological concerns is related to the potential increase in acres treated with dicamba products, resulting in additional acres with residues of DCSA in GE soybeans. Before considering mitigation measures, the EPA also found a potential for increased susceptibility of direct adverse effects to late season plants from spray drift.

While concern levels are exceeded in the screening-level assessment, further refinement, as discussed below, suggest that risks are lower and confined to the treated field under the mitigations imposed on the registration. Risks above the level of concern remain for terrestrial plants and animals on the treated field; comparison of the risk to benefits associated with the new use are described in Section VIII.

1. Risk to Birds

For birds, the screening-level assessment (which assumed that 100% of diet is from the treated field) indicated that the RQs exceeded the agency's LOCs on an acute basis for both GE soybean and GE cotton. More specifically, the screening-level assessment found that the acute LOCs are exceeded for listed and non-listed birds, with a maximum acute dose-based RQ of 2.21 for small birds consuming short grass. Chronic LOCs were also exceeded for birds feeding on DCSA residues in GE soybeans, with a maximum chronic dietary RQ of 1.7 for small birds consuming GE soybean forage/hay.

The agency's screening-level assessment employed residue estimates based on reasonable upper bound modeling assumptions for dicamba DGA residues on food items consumed by birds. These residue estimates have been developed for a variety of wildlife food items, and are based on measured residues from a large number of field trials on many pesticides. The agency's assessment also used the maximum labeled rate of the pesticide and the empirical maximum measured concentrations for DCSA residues in GE soybeans and cotton plants to determine the RQ values. To represent a maximum, or "worst-case" estimate of risk, these high-end exposure estimates for a variety of food items were compared, across a variety of body weights and sizes, to the most sensitive oral dose toxicity endpoint in order to generate RQs. Some of these RQs exceeded the LOC. While the LOCs were exceeded, further consideration of all lines of evidence shows that risks under more realistic use scenarios are expected to be lower. For example, high-end dicamba residues compared to endpoints from toxicity studies using chemicals incorporated in the animal's diet do not trigger concerns. This suggests that dicamba consumed in the diet may be less available than assumed using dose-based exposures. Expected field exposure is more likely to be accounted for by the dietary studies that did not indicate risk exceeding levels of concern rather than the acute oral dose studies where risk exceeding thresholds of concern was indicated. As mentioned above, the screening-level analysis assumes that 100% of the diet comes from the treated field which may overestimate total dicamba ingestion.

Further, more frequently expected residues levels, such as mean or median estimates of exposure, would be lower by a factor of two or more, suggesting that residues are often not likely to trigger

concerns for many food items. In addition, estimates of exposure in screening-level assessments are the maximum levels expected, and represent residues at the actual point of application, right on the field. The exposure analysis in this screening-level risk assessment indicates that the transport of dicamba off-field by spray drift decreases with distance, suggesting that exposures to dicamba, and therefore associated risks, can be substantially lower for organisms that are off the treated field. With this last line of evidence in mind, the pesticide label requires an in-field 110 to 220-foot downwind buffer to eliminate off-site exposure above threshold levels that would trigger risk concern for birds (buffer is discussed in more detail in the "Risk to Plants" section, below). Exposures to DCSA residues are only expected for birds feeding on GE plants on the field, and are not expected off the field (since DCSA formation is only a result of dicamba tolerant-plant metabolism).

2.Risk to Mammals

For parent dicamba, none of the RQs for mammals exceed any of the agency's LOCs. Acute RQs range from <0.01 to 0.04 and chronic RQs range from 0.01 to 0.84. However, the screening-level assessment using the maximum exposure values from empirical datasets for DCSA residues in GE soybean resulted in exceedances of the chronic LOC for all size classes of mammals consuming soybean forage and hay, or consuming insects that had consumed soybean tissues with DCSA residues. These RQs range from 1.1 to 3.3. The screening-level assessment using the maximum exposure values from empirical data for DCSA residues in GE cotton did not result in exceedances of the chronic LOC for any mammal (chronic RQs ranged from <0.01 to 0.34).

The agency's screening-level assessment employed residue estimates based on reasonable upper bound modeling assumptions for dicamba residues, the maximum labeled rate of the pesticide, and the empirical maximum measured concentrations for DCSA residues in GE soybeans and GE cotton plants to determine the RQ values. the EPA further considered more realistic residue estimates and other lines of evidence, such as food preferences and foraging ranges relative to distance from the site of application. This analysis showed reduced concerns for adverse effects because larger mammals have more varied diets and larger home ranges where feeding is more likely to occur well away from treatment areas. As described in the section for risk to birds, the screening-level assessment assumes that 100% of the diet comes from the treated field.

Consideration of these lines of evidence also produces reduced risk estimates for small herbivorous mammals, due to reduced exposure, but does not reduce risk estimates for these organisms to the point that concern levels are not exceeded. As in the case for birds, the pesticide label requires an in-field 110 to 220-foot downwind buffer eliminate off-site exposure above threshold levels that would trigger risk concern for mammals (buffer is discussed in more detail in the "Risk to Plants" section, below). Exposures to DCSA residues are only expected for mammals feeding on GE plants on the field, and are not expected off the field.

3. Risk to Plants

For aquatic plants, the only RQ that would exceed an agency LOC of 1.0 is for any listed non-vascular aquatic plants for the parent dicamba, with an RQ of 8.5. However, there are currently no listed non-vascular aquatic plants.

Dicamba exposure to terrestrial and semi-aquatic plants was estimated through modeling for plants residing near a use area that may be exposed via runoff and/or spray drift. Only a single application at the maximum rate for a particular use and compound-specific solubility information is considered, because it is assumed that for plants, toxic effects are likely to manifest shortly after the initial exposure, and that subsequent exposures do not contribute to the response. Hence, estimates are based on application rate, the solubility factor, and default assumptions of drift.

For a single application of dicamba at the maximum label rate for the new uses, the RQs exceeded the LOC (1.0) for terrestrial dicots due to spray drift (without mitigation measures), and for dicots in semi-aquatic areas due to runoff and spray drift (without mitigation measures). The RQs for dicots in semi-aquatic areas were 4.15 for non-listed species and 7.58 for listed species. The RQs for spray drift were 19.49 for non-listed species of dicots and 38.31 for listed species of dicots. The RQs for dicots in dry areas were 0.49 for non-listed species and 0.89 for listed species which are both less than the LOC for plants of 1.0.

Although the RQ analysis indicated there may be risks to plants from runoff and spray drift, studies conducted on the dicamba DGA formulation demonstrates that the approved labeling restrictions will keep the product on the field, thereby reducing spray drift off field. These determinations were made after reviewing additional registrant submitted studies for a refined spray drift analysis using the specific Tee Jet® TT11004 nozzles and a change in the formulation to be registered. The analysis indicates that the dicamba product applied through the specific Tee Jet® TT11004 nozzle is protective of plants from exposures of the M1768 Herbicide when an in-field 110 to 220-foot downwind buffer is incorporated between the application equipment and the edges of the treated field. Therefore, potential risks to plants from spray drift is mitigated by requiring a 110-220 foot (depending on application rate) buffer downwind at the time of application.

4. Synergism

The agency views synergism to be a rare event and intends to follow the National Research Council's recommendation for government agencies to proceed with estimating effects of pesticide mixtures with the assumption that the components have additive effects[1] in the absence of any data to support the hypothesis of a synergistic interaction between pesticide active ingredients. However, data is being cited in connection with patent claims submitted to the U.S. Patent and Trademark Office (USPTO) for claims of synergism for specific combinations of dicamba with other herbicides.

The EPA is aware that a common agricultural practice involves tank mixing of pesticides, resulting in the co-occurrence of chemical stressors to non-target plants including endangered species. This phenomenon has been described in academic research as well as patent application filings with the USPTO where the combined mixture is sometimes claimed to have enhanced activity or synergistic effects. The endpoints in these patent application studies were based on visual observations of weed control and injury, and so were not directly applicable to the EPA's quantitative risk assessment process for plants, in which measures of sub-lethal effects (plant height and weight) serve as sensitive effects thresholds for risk estimation purposes. The EPA believes this quantitative

[1] The phrase 'additive effects' is used when the effect of the combination of chemicals can be estimated directly from the sum of the scaled exposure levels (dose addition) or of the responses (response addition) of the individual components.

approach is very reliable for the purpose of potential toxicity to plants.

The agency is continuing its work with that information in order to better understand the scope of these uncertainties for these specific combinations and to develop an approach that best manages the potential risks while still maintaining the important benefits derived from tank mixing. While evaluation of these data are still in progress, the agency is requiring that the end-use product label allow only tank mixing with other herbicides in combinations that have not been granted patents for synergistic behavior at the time of this registration. For prohibited combinations, if the EPA determines that sufficient data do not exist to support synergistic effects with a particular active ingredient, or if the agency has evaluated data that is more directly applicable to the agency's quantitative risk assessment process for plants that demonstrates that no increased toxicity to plants exists and are therefore not of concern, that ingredient may then be allowed in tank mix combinations. A list of acceptable tank mixes will be maintained by Monsanto on their already established website, www.xtendimaxapplicationrequirements.com

IV. Endangered Species for Dicamba Diglycolamine Salt (DGA)

Below is a summary of the endangered species assessments for dicamba (DGA). More detailed discussions can be found in the EPA documents titled, *Addendum to Dicamba Diglycolamine Salt (DGA) Section 3 Risk Assessment: Refined Endangered Species Assessment for Proposed New Uses on Herbicide-Tolerant Soybean and Cotton in 16 states (Arkansas, Illinois, Iowa, Indiana, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, Ohio, Oklahoma, South Dakota, Tennessee, and Wisconsin); Addendum to Dicamba Diglycolamine (DGA) Salt Section 3 Risk Assessment: Endangered Species Effects Determinations for Dicamba DGA on Herbicide-Tolerant Cotton and Soybean in 7 U.S. States: AL, GA, KY, MI, NC, SC, and TX;* and *Addendum to Dicamba Diglycolamine (DGA) Salt Section 3 Risk Assessment: Endangered Species Effects Determinations for Dicamba DGA on Herbicide-Tolerant Cotton and Soy in 11 U.S. States: AZ, CO, DE, FL, MD, NM, NJ, NY, PA, VA and WV.* These documents are in the docket for this final decision.

In the screening-level risk assessment performed for the new application timing of dicamba (DGA) on GE cotton and GE soybean to be resistant to dicamba, the EPA determined that levels of concern were not exceeded for mammals (acute) and (chronic- for cotton use only), birds, reptiles, and terrestrial-phase amphibians (chronic from parent dicamba or DCSA degradate from use on cotton), terrestrial insects, freshwater fish, aquatic-phase amphibians (acute and chronic), estuarine/marine fish (acute and chronic), freshwater invertebrates (acute and chronic), estuarine/marine invertebrates (acute and chronic), and aquatic plants (vascular and non-vascular). However, potential indirect effect risk concerns were identified for any species that have dependencies (e.g., food, shelter, and habitat) on mammals, birds, reptiles, terrestrial-phase amphibians, or terrestrial plants that are directly affected.

The EPA has a specific process based on sound science that it follows when assessing risks to listed species for pesticides like dicamba that will be used on GE seeds to be resistant to the pesticide. The agency begins with a screening-level assessment that includes a basic ecological risk assessment consistent with its 2004 Overview of the Ecological Risk Assessment Process document. [USEPA, 2004, available at species/ecological-risk-assessment-process-under-endangered-species-act]. That assessment uses broad default assumptions to establish estimated

environmental concentrations of particular pesticides. If the screening-level assessment results in a determination that no levels of concern are exceeded, the EPA concludes its analysis. On the other hand, where the screening-level assessment does not rule out potential effects (exceedances of the level of concern) based on the broad default assumptions, the EPA then uses increasingly specific methods and exposure models to refine its estimated environmental exposures. At each step, the EPA compares the more refined exposures to the toxicity of the pesticide active ingredient to determine whether the pesticide exceeds levels of concern established for listed aquatic and terrestrial species. The EPA determines that there is "no effect" on listed species if, at any step in the screening-level assessment, no levels of concern are exceeded. If, after performing all of the steps in the screening-level assessment, a pesticide still exceeds the agency's levels of concern for listed species, the EPA then conducts a species-specific refined assessment to make effects determinations for individual listed species. The refined assessment, unlike the screening-level assessment, takes account of species' habitats and behaviors to determine whether any listed species may be affected by use of the pesticide.

The screening-level risk assessment generates a series of taxonomic (e.g., mammals, birds, fish, etc.) risk quotients (RQs) that are the ratio of estimated exposures to acute and chronic effects endpoints. These RQs are then compared to the EPA established levels of concern (LOCs) to determine if risks to any taxonomic group are of concern. The LOCs address risks for both acute and chronic effects. Acute effects LOCs range from 0.05 for aquatic animals that are federally-listed threatened or endangered species (listed species) to 0.5 for aquatic non-listed animal species and 0.1 to 0.5 for terrestrial animals for listed and non-listed species. The LOC for chronic effects for all animal taxa (listed and non-listed) is 1. Plant risks are handled in a similar manner, but with different toxicity thresholds (NOAEC/EC_{05} and EC_{25}, respectively) used in RQ calculation for listed and non-listed species and an LOC of 1 used to interpret the RQ. As described above, if the screening-level assessment shows that an RQ exceeds either the acute or chronic LOC, a concern for direct toxic effects is identified for that particular taxon and a species-specific assessment is necessary to make an effects determination. On the other hand, if RQs fall below the LOC, a No Effect determination is identified for the corresponding taxon.

This registration for dicamba has been finalized for registration for use in the states of Alabama, Arkansas, Arizona, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, West Virginia, and Wisconsin. Additional states may be added to the labeling once an acceptable assessment of listed species is completed for any such state.

Based on the EPA's LOCATES v.2.4.0 database and information from the U.S. Fish and Wildlife Service (USFWS), the EPA identified the listed species that are inside the "action area" (area of concern where use of pesticide may result in exposure to endangered species) associated with the new cotton and soybean uses within a total of 34 states.

The following criteria are used to make a species-specific effects determination:

- For listed individuals inside the action area but not part of an affected taxa nor relying on the affected taxa for services involving food, shelter, biological mediated resources necessary for survival and reproduction, use of a pesticide would be determined to have NO EFFECT.
- For listed individuals outside the action area, use of a pesticide would be determined to have NO EFFECT.
- Listed individuals inside the action area may either fall into the NO EFFECT or MAY EFFECT categories depending upon their specific biological needs and circumstances of exposure.
- Those that fall under the MAY EFFECT category are found to be either LIKELY or NOT LIKELY TO ADVERSELY AFFECT the listed species.
  A NOT LIKELY TO ADVERSELY AFFECT determination is made using criteria that categorizes the effect as insignificant, highly uncertain, or wholly beneficial
- A NOT LIKELY TO ADVERSELY AFFECT determination is made using criteria that categorizes the effect as insignificant, highly uncertain, or wholly beneficial.

Spray drift label mitigation language including an in-field spray drift buffer of 110 feet (for the 0.5 lb/A rate) and 220 feet (for the 1.0 lb/A rate) downwind at the time of application is expected to limit off site transport of dicamba DGA through spray drift. Therefore, the EPA expects that exposure will remain confined to the dicamba (DGA) treated field. Consequently, the EPA concluded a NO EFFECT determination for all but 24 species originally identified as potentially at-risk (in the screening-level assessment) because they are not expected to occur on cotton and soybean fields.

The 24 remaining listed species that were not ruled out because their range contains areas that include treated fields were considered in more depth in the EPA's refined endangered species assessments. Species-specific biological information along with dicamba (DGA) use patterns were also considered. After utilizing processes such as refined modeling incorporating species-specific information and migration habits, the EPA made a determination that exposure occurring on the field would have "may affects" (either "unlikely to adversely affect" or "likely to adversely affect" on 3 species (the Eskimo Curlew, the Spring Creek Bladderpod in Wilson county, TN, and the Audubon Crested Caracara in Palm Beach county, FL) within the States covered by this final decision. The EPA initiated informal consultation with the U.S. Fish and Wildlife Service (FWS) for the Eskimo curlew. The FWS concurred with the "unlikely to adversely affect" determination and no further action need be taken relative to this species. Furthermore, to address the remaining effects, the registrant submitted revised labeling and the EPA approved the labeling that prohibits application in both Wilson county, TN and Palm Beach county, FL. Therefore, the EPA makes no effect determinations for all listed species that are expected to be on the treated fields.

Additionally, the agency considered the potential effects attributed to runoff. As refined modeling predictions indicate that expected exposures from runoff (sheet flow) are below the most sensitive toxicological endpoint thresholds, the EPA's analysis also supports a no effects determination for runoff exposure for off-field listed plants for the new labeled use of dicamba DGA. To further protect species off the treated field against runoff, rainfast mitigation is required on the label ("Do not irrigate treated fields for at least 24 hours after application of this product. Do not make application of this product if rain is expected in the next 24 hours.").

V. Resistance Management

The emergence of herbicide resistant weeds is an increasing problem that has become a significant issue to growers. This has led to a concern that the use of dicamba on GE crops may result in over-reliance on dicamba and result in a larger number of resistant weeds. Currently, in certain areas of the United States there are populations of Kochia and prickly lettuce known to be resistant to dicamba. Kochia infests millions of acres of soybean and cotton and, in addition, glyphosate-resistant biotypes have been identified in Kansas and Nebraska.

In an effort to address these issues, the EPA is requiring, as a term of registration, that Monsanto develop an Herbicide Resistance Management (HRM) plan that will promote herbicide resistance management efforts by growers, the registrant, and others. The plan mandates that Monsanto must investigate any reports of lack of performance. Dicamba users who experience a lack of performance can obtain direct support from Monsanto through a toll free telephone number that is identified on the label to get advice on how to resolve any uncontrolled weeds.

"Lack of performance" refers to inadequate weed control with various possible causes, including, but not limited to: application rate, stage of weed growth, environmental conditions, herbicide resistance, plugged nozzle, boom shut off, tank dilution, post-application weed flush, unexpected rainfall event, weed misidentification, etc. It can be challenging to distinguish emerging weed resistance from other causes at an early stage. Therefore, the EPA has identified criteria that should be used to evaluate instances of "lack of performance" to determine if they do in fact constitute "likely herbicide resistance." These "likely herbicide resistance" criteria are: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; or (2) a spreading patch of uncontrolled plants of a particular weed species; or (3) surviving plants mixed with controlled individuals of the same species (Norsworthy, et al., 2012). The identification of any of these criteria in the field indicates that "likely herbicide resistance" is present. The responsibilities of the registrant if "likely herbicide resistance" is found are discussed below.

Researchers, extension specialists, growers, USDA, and other leaders involved with pest management all acknowledge the importance of scouting (e.g., monitoring the fields) in herbicide resistance management. For the new uses, the labeling states that fields should be scouted before application of dicamba to identify the weed species present as well as their stage of growth. Fields also should be scouted after each application to identify lack of performance that may be the early signs of resistance. Additionally, the labeling states that in the event that a user encounters lack of performance they should report this to Monsanto or its representative using the toll-free number identified on the label.

When a lack of performance is identified and reported to the registrant, Monsanto or its representative must investigate and conduct a site visit if needed to evaluate the lack of performance using decision criteria identified by leading weed science experts in order to determine if "likely herbicide resistance" is present (also termed "possible resistance" by Norsworthy et al., 2012). A report of lack of herbicide performance to Monsanto will be the trigger to start this investigation.

When Monsanto or its representative applies the Norsworthy, et al., criteria cited above, and likely herbicide resistance is identified, Monsanto must proactively engage with the grower to control and

contain likely resistant weeds in the infested area. This may be accomplished by re-treating with an herbicide or using mechanical control methods. After implementing these measures, Monsanto must follow-up with the growers, with the growers' permission, to determine if the likely resistant weeds have been controlled. Monsanto must also annually report to the EPA findings of likely herbicide resistance. In addition, prior to implementing control measures, Monsanto must make best efforts to obtain samples of the likely herbicide resistant weeds and/or seeds, and as soon as practicable, laboratory or greenhouse testing must be initiated in order to confirm whether resistance is the reason for the lack of herbicide efficacy.

Beginning January 15, 2018, on or before January 15th of each year thereafter, Monsanto must submit annual summary reports to the EPA. These reports must include a summary of the number of instances of likely and confirmed resistance by weed species, crop, and state. These reports will also summarize the status of laboratory or greenhouse testing for resistance. The annual reports will also address the disposition of incidents of likely or confirmed resistance reported in previous years.

Monsanto must report annually any inability to control likely resistant weeds to relevant stakeholders. To accomplish this, Monsanto must establish a website to facilitate delivery of resistance information to users.
Several best management practices that are designed to help users avoid initial occurrences of weed resistance appear on the final dicamba product label listed under the Herbicide Resistance Management heading of the label. These practices are discussed in Section VIII.B.3 of this document.

Refer to Section VIII.C below for the EPA's terms of registration to address the issue of weed resistance.

VI. Response to Comments

The agency received 21,710 comments in response to the public participation process (Docket ID: the EPA-HQ-OPP-2016-0187) regarding the EPA's proposed decision for the application to register the use of dicamba on GE cotton and GE soybeans. Comments received were both in favor of and opposed to the decision to register the new uses which will provide growers with additional tools to control broadleaf weeds. The EPA welcomes input from the public during the decision process when registering significant new uses, and is committed to reviewing the comments received and determining whether changes or further mitigation are necessary to meet the applicable statutory standards. the EPA reviewed and evaluated the comments received during the comment period before issuing this final regulatory decision. Since many of the comments covered similar concerns, the comments were grouped into major topic areas. Please see *Response to Public Comments Received Regarding the New Use of Dicamba on Dicamba-Tolerant Cotton and Soybeans* dated November 7, 2016 for the agency's response to these comments.

VII. Benefits

Growers throughout the United States have experienced yield and economic losses due to weeds developing resistance to the herbicide glyphosate and other heavily used herbicides. The need for additional tools to manage these resistant weeds has become important as resistance to both glyphosate and other herbicides has become a significant financial, production and pest

management issue for many cotton and soybean growers. Weeds such as marestail, giant ragweed, common waterhemp, and Palmer amaranth can be difficult to control during the crop growing season. Previously registered uses of dicamba only allow for pre-plant application and post-harvest application in cotton for conventional or conservation tillage systems. Similarly, the previously registered uses of dicamba on soybeans only allows for preplant application along with a pre-harvest broadcast or spot treatment application. New postemergence uses of dicamba will expand weed management options on GE cotton and GE soybeans by providing an additional mechanism of action during the growing season. Dicamba used during the season will target new flushes of weeds, thereby reducing populations of these weeds and particularly will help reduce seed banks. Postemergence use of dicamba will expand options for weed control in cotton and soybeans and enable control of broadleaf weeds, including glyphosate-resistant biotypes.

VIII. Registration Decision

In accordance with FIFRA, the EPA only registers a pesticide when it finds that the use will not cause unreasonable adverse effects on man or the environment, 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 the uncertainties and risks posed by a pesticide against the benefits associated with the use of the pesticide. The EPA must determine if the benefits in light of its use outweigh the risks in order for the agency to register a pesticide.

In the case for the new uses of dicamba on GE soybeans and GE cotton, and in consideration of all best available data and assessment methods, the EPA determines that its decision to register these uses meets the requirements of FIFRA. The database submitted to support the assessment of human health risk is sufficient for a full hazard evaluation and is considered complete and adequate to evaluate risks to infants and children. The agency has not identified any risks of concern in regards to human health, including all population subgroups, or for occupational handlers.

In terms of ecological risk, some LOCs were exceeded for certain birds, reptiles, amphibians, and mammals that may be in the treated fields. These assessments included conservative risk estimates using screening-level (worst case) assumptions that are unlikely to apply to the majority of the birds, reptiles, amphibians, and mammals that are outside of the treatment area. For example, it is assumed that animals would forage for food exclusively in the treated area consuming only the treated crop, neither of which is likely to be true. Additionally, the protections afforded by the labeling, such as the requirement of infield buffers, would reduce the likelihood of spray drift and volatilization that could affect organisms located beyond the treated field. Because of these additional restrictions, the EPA expects these uses to have less environmental impact than other currently registered products that do not require the same buffers. It is also noted that, if further refinements that included more realistic exposure scenarios were conducted, these risks would likely fall below the agency's levels of concern.

On the benefits side of the analysis, use of dicamba on GE soybeans and GE cotton is expected to become an important part of a resistance management strategy for these crops. Soybeans and cotton are extremely important agricultural commodities in the United States and the world. According to the USDA's National Agricultural Statistics Service, soybeans are grown on approximately 85 million acres and cotton is grown on approximately 9 million acres. USDA's Economic Research Service describes soybeans as the world's largest source of animal protein feed

and the second largest source of vegetable oil, and describes cotton as one of the most important textile fibers in the world, accounting for around 35 percent of total world fiber use. The United States is the world's leading soybean producer and exporter, and together with China and India provide two-thirds of the world's cotton. USDA estimates the gross value of soybean production at approximately 48 billion dollars in the United States, and soybean is grown throughout the United States with more than 80 percent of the United States soybean acreage concentrated in the upper Midwest. The gross cotton production is estimated by USDA at over 6 billion dollars in the United States, and is grown in 17 states in the United States. However, resistance to glyphosate, the current market leader in soybeans and cotton, is having severe economic consequences in soybean and cotton production. The Weed Science Society of America and other weed control experts warn that the problem of glyphosate resistance is increasing, and that significant economic consequences will continue to increase without effective alternatives for weed control.

Consequentially, use of dicamba on GE soybeans and GE cotton is beneficial as it provides an effective tool to treat especially noxious weeds, such as marestail, giant ragweed, common waterhemp, and Palmer amaranth, including glyphosate-resistant biotypes that threaten soybean and cotton production today. By adding an effective tool to combat glyphosate-resistant weeds, dicamba can help reduce this difficult weed pressure and aid significantly in production, reducing economic losses to GE soybean and GE cotton growers. In addition, effective treatment of glyphosate-resistant weeds can help control the spread of resistance. And, as stated previously, using dicamba for these uses according to the approved labeling restrictions will include further beneficial protections such as in-field buffers, best practice requirements for drift management and application techniques, and active resistance management stewardship of weed populations.

The EPA finds these benefits important. Furthermore, this regulatory decision includes a number of requirements that are expected to effectively limit concerns for off field risk. This registration action is only for a product confirmed by data to be a lower volatility formulation. In addition, the label requires very specific and rigorous drift mitigation measures, including in-field buffers, aerial application prohibitions, boom height requirements, specific nozzle and spray pressure requirements, and wind and tractor speed limitations. These mitigations are known to profoundly impact any drift potential from pesticide application. In aggregate, these formulations and labeling requirements are expected to eliminate any offsite exposures and effectively prevent risk potential to people and non-target species.

After weighing all the risks of concern against the benefits of the new uses, the EPA finds that when the mitigation measures for these uses are applied, the benefits of the use of the pesticide outweighs any remaining minimal risks, if they exist at all. Therefore, registering these new uses will not generally cause unreasonable adverse effects on human health or the environment. the EPA believes that the available data and scientific assessments as well as the overall considerations for benefits for weed management in these important crops support a FIFRA Section 3(c)(7)(B) registration finding for the new uses. Although the EPA proposed registering dicamba under FIFRA section 3(c)(5), new data requirements have been identified through registration review that will be applicable to all dicamba products (and all uses), therefore the agency is registering these new uses under FIFRA section 3(c)(7)(B).

A. Data Requirements

Although there are currently no outstanding data require to support the final registration of this action, the EPA has identified data that will be required in connection with Registration Review activities for dicamba. Those requirements will be applicable to dicamba uses and products in general and would be handled in accordance with the registration review process.

B. Labeling Requirements

The following labeling is included in the final supplemental labels unless otherwise noted below.

1. Worker Protection

(Although the following Worker Protection labeling applies to the new uses, it is not included in the new supplemental labeling. This labeling can be found in the previously accepted master labeling that was accepted by the agency on May 1, 2014 for this product.)

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your state or tribe, consult the agency responsible for pesticide regulation.

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

PPE required for mixers, loaders, applicators and other handlers is:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves
- Shoes plus socks

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls worn over short sleeved shirt and short pants
- Chemical-resistant footwear plus socks
- Chemical-resistant gloves made of any waterproof material
- Chemical-resistant headgear for overhead exposure
- Protective eyewear

2. Environmental Hazards

(Although the following Environmental Hazards labeling applies to the new uses, it is not included in the new supplemental labeling. This labeling can be found in the previously accepted master labeling that was accepted by the agency on September 18, 2013 for this product.)

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate. Apply this product only as directed on the label.

This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

3. Resistance Management

To aid in the prevention of developing weeds resistant to this product, the following steps should be followed:

- Scout fields before application to ensure herbicides and rates will be appropriate for the weed species and weed sizes present.
- Apply full rates of M1768 Herbicide for the most difficult to control weed in the field at the specified time (correct weed size) to minimize weed escapes.
- Scout fields after application to detect weed escapes or shifts in weed species.
- Report any incidence of non-performance of this product against a particular weed species to your Monsanto retailer, representative or call 1-844-RRXTEND.
- If resistance is suspected, treat weed escapes with an herbicide having a mode of action other than Group 4 and/or use non-chemical methods to remove escapes, as practical, with the goal of preventing further seed production.

Additionally, users should follow as many of the following herbicide resistance management practices as practicable:

- Use a broad spectrum soil-applied herbicide with other modes of action as a foundation in a weed control program.
- Utilize sequential applications of herbicides with alternative modes of action.
- Rotate the use of this product with non-Group 4 herbicides.
- Incorporate non-chemical weed control practices, such as mechanical cultivation, crop rotation, cover crops and weed-free crop seeds, as part of an integrated weed control program.
- Thoroughly clean plant residues from equipment before leaving fields suspected to contain resistant weeds.
- Avoid using more than two applications of dicamba and any other Group 4 herbicides within a single growing season,
- Manage weeds in and around fields, during and after harvest to reduce weed seed production.

4. Spray Drift Management

Nozzle type:

Use only Tee Jet® TTI11004 nozzle with a maximum operating pressure of 63 psi when applying XtendiMax™ With VaporGrip™ Technology or any other approved nozzle found at www.xtendimaxapplicationrequirements.com. Do not use any other nozzle and pressure combination not specifically listed on this website. www.xtendimaxapplicationrequirements.com

Spray Volume:

Apply this product in a minimum of 10 gallons of spray solution per acre. Use a higher spray volume when treating dense vegetation.

Equipment Ground Speed:

Select a ground speed that will deliver the desired spray volume while maintaining the desired spray pressure, but do not exceed a ground speed of 15 miles per hour. Slower speeds generally result in better spray coverage and deposition on the target area.

Spray boom Height:

Spray at the appropriate boom height based on nozzle selection and nozzle spacing, but do not exceed a boom height of 24 inches above target pest or crop canopy. Set boom to lowest effective height over the target pest or crop canopy based on equipment manufacturer's directions. Automated boom height controllers are recommended with large booms to better maintain optimum nozzle to canopy height.

Temperature and Humidity:

When making applications in low relative humidity or temperatures above 91 degrees Fahrenheit, set up equipment to produce larger droplets to compensate for evaporation. Larger droplets have a lower surface to volume ratio and can be impacted less by temperature and humidity. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversions:

Do not apply this product during a temperature inversion. Off-target movement potential can be high during a temperature inversion. During a temperature inversion, the atmosphere is very stable and vertical air mixing is restricted, which can cause 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 evenings and nights with limited cloud cover and light to no wind. Cooling of air at the earth's surface takes place and warmer air is trapped above it. They can 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. The inversion will often dissipate with increased winds (above 3 MPH) or at sunrise when the surface air begins to warm (generally 3°F from morning low).

Wind Speed:

Drift potential is lowest between wind speeds of 3 to 10 miles per hour. Do not apply at wind speeds greater than 15 mph. A chart is included in the product label that lists the appropriate wind speeds and application conditions and restrictions.

5. Protection of Sensitive Areas:

Buffer

Maintain a 110 foot downwind buffer (when applying 22 fluid ounces of this product per acre) or a 220 foot downwind buffer (when applying 44 fluid ounces of this product per acre) between the last treated row and the closest downwind edge (in the direction in which the wind is blowing). If any of the following areas below are directly adjacent to the treated field, the areas listed below can be considered part of the buffer distance.

To maintain this required buffer zone:

- No application swath can be initiated in, or into an area that is within the applicable buffer distance.

The following areas may be included in the buffer distance calculation when adjacent to field edges:

- Roads, paved or gravel surfaces.
- Planted agricultural fields containing: corn, dicamba tolerant cotton, dicamba tolerant soybean, sorghum, proso millet, small grains and sugarcane. If the applicator intends to include such crops as dicamba tolerant cotton and/or dicamba tolerant soybeans in the buffer distance calculation, the applicator must confirm the crops are in fact dicamba tolerant and not conventional cotton and/or soybeans.
- Agricultural fields that have been prepared for planting.
- Areas covered by the footprint of a building, silo, or other man made structure with walls and or roof.

Susceptible Plants:

Do not apply under circumstances where spray drift may occur to food, forage, or other plantings that might be damaged or the crops thereof rendered unfit for sale, use or consumption. Do not allow contact of herbicide with foliage, green stems, exposed non- woody roots of crops, and desirable plants, including beans, cotton, flowers, fruit trees, grapes, ornamentals, peas, potato, soybean, sunflower, tobacco, tomato, and other broadleaf plants, because severe injury or destruction may result, including plants in a greenhouse. Small amounts of spray drift that may not be visible may injure susceptible broadleaf plants.

Applicators are required to ensure that they are aware of the proximity to sensitive areas, and to avoid potential adverse effects from off-target movement of M1768 Herbicide. Before making an application, the applicator must survey the application site for neighboring sensitive areas prior to application. The applicator should also consult sensitive crop registries for locating sensitive areas where available.

Failure to follow the requirements in this label could result in severe injury or destruction to desirable sensitive broadleaf crops and trees when contacting their roots, stems or foliage.

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Specifically, commercially grown tomatoes and other fruiting vegetables (EPA crop group 8), cucurbits (EPA crop group 9), and grapes are sensitive to dicamba. In order to prevent unintended damage from any drift of this product, do not apply this product when the wind is blowing towards adjacent commercially grown sensitive crops.

6. Application Restrictions:

- Do not apply this product aerially.
- Do not tank mix any other herbicides with M1768 Herbicide.
- Do not make an application of the product if rain is expected in the next 24 hours.
- The maximum combined quantity of this product that may be applied for all preplant, at-planting, and preemergence applications is 44 fluid ounces (1.0 lb a.e. dicamba) per acre per season for both cotton and soybeans.
- The maximum application rate for a single, preplant, at-planting, or preemergence application must not exceed 44 fluid ounces (1.0 lb a.e. dicamba) per acre for both cotton and soybeans.
- The combined total application rate from crop emergence up to R1 must not exceed 44 fluid ounces (1.0 lb a.e. dicamba) per acre for soybeans per year.
- The combined total application rate from crop emergence up to 7 days' pre-harvest must not exceed 88 fluid ounce (2.0lb a.e dicamba) per acre for cotton per year.
- All applications for both cotton and soybeans must not exceed 88 fluid ounces (2.0 lb a.e dicamba) per acre per year.

C. Registration Terms

The EPA has determined that certain registration terms are needed to ensure that likely weed resistance as discussed in section V will be adequately addressed. The EPA believes that it is important to address likely weed resistance and not wait until confirmation that resistance has been found. The EPA is basing the final registration terms on a list of criteria, presented in the peer-reviewed publication, Norsworthy, et al., "Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations," *Weed Science* 2012 Special Issue: 31–62 (Norsworthy criteria).

1. Herbicide Resistance Management (HRM) Plan

The EPA is issuing this registration with a term that requires Monsanto to have an Herbicide Resistance Management (HRM) Plan for M1768 Herbicide. The HRM Plan will focus on educating growers on the appropriate use of the M1768 Herbicide and the associated dicamba-tolerant seeds. The EPA is requiring that the HRM plan include the following measures that will reduce the potential for the development of weed resistance.

a. Investigation

The EPA is requiring that Monsanto or its representative investigate reports of lack of herbicide efficacy as reported by users following "scouting." When investigating any reports of lack of herbicide efficacy, Monsanto or its representative must make an effort to evaluate the field for

"likely resistance" by applying the "Norsworthy criteria."

b. Remediation

If "likely resistance" is found, Monsanto must engage with the grower to control and prevent the spread of likely resistant weeds in the affected area. Monsanto must provide the grower with specific information and recommendations to control and contain likely resistant weeds, including retreatment and/or other nonchemical controls, as appropriate, and if requested by the grower, Monsanto will assist the grower in implementing those additional weed control measures. Additionally, Monsanto must routinely collect plant material for further testing.

c. Annual Reporting of Herbicide Resistance to the EPA

Monsanto must submit annual summary reports to the EPA that include a summary of the number of instances of likely and confirmed weed resistance by weed species, crop, and state. The annual reports must include summaries of the status of laboratory or greenhouse testing for resistance. The annual reports will also address the disposition of incidents of likely or confirmed resistance reported in previous years. These reports will not replace or supplement adverse effects reporting required under FIFRA § 6(a)(2).

d. Reporting of Likely Resistance to other Interested Parties

Monsanto must inform growers and other stakeholders of cases of likely resistance that are not resolved by the application of additional weed control measures.

e. Education

Monsanto must develop an education program that will provide growers with the best available information on herbicide resistance management.

D. Registration Expiration

The issue of weed resistance is an extremely important issue to keep under control and can be very fast moving. Also, the EPA is aware of reports of off-site incidents potentially due to the illegal use of dicamba products that do not employ the lower volatility formulation of dicamba DGA plus VaporGrip™ (M-1768) on GE cotton and GE soybean. Although the EPA finds that herbicide resistance is adequately addressed by the required herbicide resistance plan and does not expect off-site incidents to occur due to the specific measures required (described above) to this registration, the agency is requiring expiration dates that will ensure that the EPA retains the ability to easily modify the registration or allow the registration to terminate if necessary.

Specifically, this registration automatically expires on November 9, 2018, unless the EPA determines before that date that off-site incidents are not occurring at unacceptable frequencies or levels. If this automatic expiration date is amended (in whatever way the EPA determines is appropriate at the time), it shall not be amended to a date later than November 9, 2021, by which date this registration will automatically expire unless the EPA determines before that date that

herbicide resistance to dicamba is not occurring at unacceptable frequencies or levels, and that off-site incidents are not occurring at unacceptable frequencies or levels.

E. Geographic Limitation on Use of Dicamba M1768 Herbicide

The EPA is issuing these new uses only to be sold and used in Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, West Virginia, and Wisconsin.

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[i] Norsworthy, J. K., Ward, S. M., Shaw, D. R., Llewellyn, R. S., Nichols, R. L., Webster, T. M., Bradley, K. W., Frisvold, G., Powles, S. B., Burgos, N. R., Witt, W. W., Barrett, M. 2012. Reducing the risks of herbicide resistance: Best Management Practices and Recommendations. Weed Science Special Issue: 31-62. http://wssajournals.org/doi/pdf/10.1614/WS-D-11-00155.1

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