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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0496, EPA-HQ-OPP-2012-0841; FRL-9954-37]

Dicamba; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dicamba in or on cotton, gin byproducts; cotton, undelinted seed; soybean, forage; and soybean, hay. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the

instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY**

INFORMATION).

ADDRESSES: The dockets for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0496 for soybeans and EPA-HQ-OPP-2012-0841 for cotton respectively are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0496 and EPA-HQ-OPP-2012-0841 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0496 and EPA-HQ-OPP-2012-0841, by one of the following methods:

- *Federal e-Rulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 4, 2010 (75 FR 46924) (FRL-8834-9) and December 19, 2012 (77 FR 75082) (FRL-9372-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0F7725 and 2F8067, respectively) by Monsanto Company, 1300 I St., NW, Suite 450 East, Washington, DC 20052. The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide dicamba, 3,6-dichloro-*o*-anisic acid and its metabolites 3,6-dichloro-5-hydroxy-*o*-anisic acid (5-OH dicamba) and 3,6-dichloro-2-hydroxybenzoic acid (DCSA), as follows: PP 0F7725 requested tolerances for residues in or on soybean, forage at 45 parts per million (ppm) and soybean, hay at 70 ppm and PP 2F8067 requested tolerances for residues in or on cotton, undelinted seed at 3 ppm and cotton, gin byproducts at 70 ppm. Those documents referenced summaries of the petitions prepared by Monsanto Company, the registrant, which are available in the dockets, <http://www.regulations.gov>. Comments were received, and EPA's responses to these comments are discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances for soybean, forage and soybean, hay that are higher than requested. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCFA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dicamba, including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dicamba follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability, as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable sub-groups of consumers, including infants and children.

For dicamba, toxicology studies for dicamba acid; its salts (isopropylamine (IPA), diglycolamine (DGA), and N, N-Bis-(3-aminopropyl) methylamine (BAPMA)); and its plant metabolites (DCSA (3, 6-dichlorosalicylic acid) and DCGA (3, 6-dichlorogentisic acid)) were all considered for risk assessment. The dicamba BAPMA salt is the BAPMA base added to the dicamba acid form. The DCSA exposure is primarily from dietary exposures (food + water) from uses on transgenic crops, and the dicamba acid exposure is relevant for the incidental oral exposure. In scenarios where co-exposure to the various forms could occur, the most protective point of departure (POD) was utilized for regulation.

Neurotoxic signs (e.g., ataxia, decreased motor activity, impaired righting reflex and gait) were observed in dicamba acid studies in rats and rabbits at doses over 150 mg/kg/day. The DCSA metabolite is less neurotoxic than dicamba acid, although a rat developmental study involving the BAPMA salt indicated neurotoxic effects (e.g., unsteady gait, ataxia, and convulsions) at lower doses (86 mg/kg/day).

The rat reproduction study and the developmental studies in rats and rabbits showed no evidence (qualitative or quantitative) for increased susceptibility following *in utero* or postnatal exposure of dicamba acid or its salts. In the rabbit developmental toxicity study, a single incidence of abortion (1/20 does) was seen at doses that also caused maternal toxicity, as evidenced by clinical signs of neurotoxicity. In a 2-generation reproductive toxicity study involving dicamba acid, offspring toxicity was manifested as decreases in pup weight at a dose where parental toxicity was also observed. There was however, an indication of potential increased quantitative susceptibility from exposure to the metabolite DCSA (decreased pup body weight was observed at 37 mg/kg/day, where no parental toxic effects were noted).

Dicamba is classified as “not likely to be carcinogenic to humans”. Mutagenicity studies did not demonstrate mutagenic concern for dicamba. There was no evidence of dermal or systemic toxicity following repeated dermal application of dicamba acid or the salts at the limit dose (1,000 mg/kg/day). There is no concern for immunotoxicity following exposure to dicamba. Following oral administration, dicamba is rapidly absorbed and rapidly excreted in urine and feces without significant metabolism. Dicamba has a low acute toxicity via the oral, dermal or inhalation route (Acute Toxicity Categories III or IV). It is an eye and dermal irritant but it is not a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by dicamba as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-

adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document Dicamba and Dicamba BAPMA salt: Human-Health risk Assessment for Proposed Section 3 New Uses on dicamba-tolerant Cotton and Soybean in docket ID number EPA-HQ-OPP-2016-0187.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern 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, 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. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for dicamba used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Dicamba Acid and Dicamba BAPMA Salt for use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety	RfD, PAD, LOC for Risk	Study and Toxicological Effects
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	Factors	Assessment	
Acute dietary (Females 13 to 50 years of age)	Not Applicable (NA)	NA	No developmental toxicity attributed to acute exposure in the toxicity database
Acute dietary (General population including infants and children)	NOAEL = 29 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.29 mg/kg/day aPAD = 0.29 mg/kg/day	Developmental Rat Study Dicamba BAPMA LOAEL = 86 mg/kg/day in dams based on ataxia, unsteady gait and convulsions observed shortly after dosing
Chronic dietary (All populations)	Offspring NOAEL= 4 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.04 mg/kg/day cPAD = 0.04 mg/kg/day	Reproductive Rat Study with Metabolite DCSA Offspring LOAEL = 37 mg/kg/day based on decreased pup weights in F ₁ generation PND 14 and 21 (both sexes) and week 18 (females)
Incidental oral short-(1 to 30 days) and intermediate- (1 to 6 months) term	Offspring NOAEL= 136 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Reproductive Study in Rats with Dicamba Acid Offspring LOAEL = 450 mg/kg/day based on decreased pup weights
No endpoints for assessing dermal risk were identified since the dermal toxicology studies for dicamba acid, IPA and DGA salts all had NOAELs of 1,000 mg/kg/day			
Inhalation short-, intermediate-, and long-term	Inhalation study NOAEL= 0.005 mg/L UF _A = 3x	Residential LOC for MOE = 30	Aerosol Inhalation Rat Study with Dicamba Acid LOAEL = 0.050 mg/L

	$UF_H = 10x$ FQPA SF = 1x		based on minimal multifocal bronchiole-alveolar hyperplasia in males, multiple microscopic findings in the lung and associated lymph nodes in females
Cancer (Oral, dermal, inhalation)	Dicamba is classified as "not likely to be carcinogenic to humans"		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. PND = postnatal day

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dicamba, EPA considered exposure under the petitioned-for tolerances as well as all existing dicamba tolerances in 40 CFR 180.227. EPA assessed dietary exposures from dicamba in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for dicamba. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance levels and 100 percent crop treated (PCT) for the acute dietary exposure assessment.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used average residues based on field trial studies for crops, tolerance levels for livestock commodities and relevant PCT data for several existing uses to assess chronic dietary exposure.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that dicamba does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses as follows: Asparagus: 5%; barley: 5%; corn: 10%; oats: 2.5%; sorghum: 15%; sugarcane: 20%; sweet corn: 1%; and wheat: 10%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations

is taken into account through EPA's computer-based model for evaluating the exposure of significant sub-populations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which dicamba may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dicamba in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dicamba. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of dicamba for acute exposures are calculated to be 53.37 parts per billion (ppb) for surface water and 329 ppb parent plus 0.041 ppb DCSA for ground water. For chronic exposures for non-cancer assessments are estimated to be 44.5 ppb for surface water and 187 ppb parent plus 0.041 ppb DCSA for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The combined estimated drinking water residues (parent + DCSA) for peak concentration used in the acute assessment and chronic were 329 and 187 ug/L (ppb), respectively.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

There are no residential uses being proposed in connection with this action for either dicamba or the dicamba BAPMA salt; however, there are existing residential turf uses of dicamba that have been reassessed to reflect updates to the Agency’s 2012 Residential Standard Operating Procedures (SOPs).

There is no potential hazard *via* the dermal route for dicamba; therefore, the handler assessment includes only the inhalation route of exposure, and the post-application assessment includes only the incidental oral routes of exposure.

The quantitative exposure/risk assessment developed for residential handlers to adults is based on the following lawn/turf application scenarios:

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

The quantitative exposure/risk assessment for residential post-application exposures to children 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.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA requires that, when considering whether to establish, modify, or

revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found dicamba to share a common mechanism of toxicity with any other substances, and dicamba does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dicamba does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of susceptibility to the young following *in utero* exposure to dicamba acid or its salts. Although quantitative offspring susceptibility was observed in the 2-generation reproduction study for the DCSA metabolite based on decreased pup weights, 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 this reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for dicamba is complete for purposes of assessing the safety of existing and petitioned-for tolerances under the FFDCa.

ii. Although consistent neurotoxic signs (e.g., ataxia, decreased motor activity, impaired righting reflex and gait) were observed in multiple studies in rats and rabbits, there is no need for a developmental neurotoxicity study to account for neurotoxicity 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; and (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. The significance of this dilation observation is questionable, since no similar histopathological finding was seen in two sub-chronic neurotoxicity studies at the limit dose or other chronic studies. Endpoints and points of departure chosen to quantify chronic risks are well below the dose level at which these effects were observed, and are therefore protective.

iii. As indicated in Unit III.D.2., the degree of concern for potential susceptibility is low; therefore, there is no need to retain the 10X FQPA safety factor to address any concern for prenatal or postnatal exposure.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues for the acute dietary, and average field trial data and percent crop treated information for the chronic dietary. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dicamba in drinking water. EPA used similarly conservative assumptions 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.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dicamba will occupy 31% of the aPAD for all infants (<1 year old), the population sub-group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dicamba from food and water will utilize 42% of the cPAD for children 1 to 2 years old the population sub-group receiving the greatest

exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of dicamba is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential post-application exposures to children (1 to 2 years old) on turf result in an aggregate MOE of 3,600. Because EPA's level of concern for dicamba is a MOE of 100 or below, this MOE is not of concern.

EPA has determined that it is not appropriate to aggregate short-term exposures for adults, since there was no dermal hazard identified in the route-specific dermal studies and the inhalation effects were not systemic.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, dicamba is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for dicamba.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies on dicamba acid and one on DCSA, dicamba is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to dicamba residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology liquid chromatography/mass spectrometer/mass spectrometer (LC/MS/MS) method, BASF Method D0902 is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL;

however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for dicamba in or on soybean, forage; soybean, hay; and cotton, gin byproducts.

The Codex has established a MRL for dicamba in or on cotton seed at 0.04 ppm. This MRL is different than the tolerance being established for dicamba in or on cotton, undelinted seed at 3.0 ppm in the United States. Since the use pattern of dicamba on dicamba-tolerant cotton has been changed to late season, the currently established international tolerances are not adequate to cover residues likely from the new use in the United States. In addition, the dicamba residues of concern for dicamba-tolerant cotton also include the DCSA metabolite, which is not found nor regulated in the other common varieties of cotton. Therefore, harmonization with respect to the tolerance expression is not possible at this time for cotton seed.

C. Response to Comments

Several comments were received in both dockets EPA-HQ-OPP-2010-0496 and EPA-HQ-OPP-2012-0841, objecting to any approval of new dicamba uses on cotton and soybeans under the Federal Insecticide, Fungicide, and Rodenticide Act. Several comments raised concerns about a sharp increase of dicamba use due to a longer application season, the possible spread of weed resistance, off-site drift to non-targets, volatility, negative environmental effects, possible threat to endangered species, and the negative impact the new uses may have on the U.S. agricultural business as a whole. These comments do not appear to be concerned with the issuance of the tolerances under the FFDCA, but rather the approval of the uses under FIFRA. In any event, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated

that the pesticide meets the safety standard imposed by the statute, taking into consideration human health impacts from aggregate exposure (including dietary and other non-occupational exposure) from the pesticide and other related chemicals. The scope of review under the FFDC does not extend to other environmental considerations. Therefore, the Agency is not addressing these comments here. Where appropriate, the Agency may address them in connection with the associated pending pesticide registration action.

Comments were submitted in both docket EPA-HQ-OPP-2010-0496 and EPA-HQ-OPP-2012-0841 raising issues about the establishment of tolerances for dicamba on cotton and soybeans. Commenters raised concerns about the potential toxicity of dicamba, questioned the Agency's endpoint selection, and alleged that increased use of the pesticide would increase exposure to farmers and workers and dietary exposure. The Agency considered all the available toxicity and exposure data for dicamba and its sales and metabolites and determined that these tolerances are safe for the reasons spelled out in detail within the risk assessment Dicamba and Dicamba Salt: Human-Health Risk Assessment for Proposed Section 3 New Uses on Dicamba-tolerant Cotton and Soybean located in Docket ID number EPA-HQ-OPP-2016-0187 on [regulations.gov](https://www.regulations.gov). Although many of the commenters' concerns are about toxicity that may occur or be associated with occupational exposure to dicamba and even though occupational exposure is outside the scope of the Agency's FFDC safety analysis, the Agency did consider the available toxicity information and has concluded that dicamba does not pose risks of carcinogenicity or developmental toxicity. In addition, to take into account new toxicology received since the last risk assessment, the Agency has updated the chronic endpoint and is no longer relying on the endpoint about which the commenters expressed concern in their comments. The updated chronic reference dose takes into account all the available information, which has been updated since the 1987 Health Advisory that the commenters

mention. The Agency also reviewed comments and requests for evaluating residue tolerances for dicamba tolerant crops and the tolerances proposed by a SOCC petition concurrently due to the potential dangers of dicamba drift and volatilization. After completing our final assessments of the new dicamba uses (which can be found in Docket ID # EPA-HQ-OPP-2016-0187) it has been determined that through proper label mitigations and restrictions, the Agency does not expect use of dicamba on cotton or soybeans to result in any inadvertent residues on neighboring crops. As a result, the Agency believes there is no need to establish tolerances for inadvertent residues on food crops as a result of the new uses for dicamba on cotton and soybean.

Finally, the commenters expressed concern that approval of new uses would increase exposure to workers and urged the Agency to take into account the likely increased dietary exposure, including any residues of dicamba that are in cattle diets and livestock commodities from treated cotton plants, from increased use of dicamba from approval of these tolerances. Because the FFDCa directs EPA to aggregate non-occupational exposure with dietary exposure, the Agency's assessment under the FFDCa does not assess the levels of occupational exposure to farmers and other workers. As to the dietary exposure, as noted in Unit III.C.1., the Agency considers exposure under the petitioned-for tolerances (including residues ingested by livestock diets that may result in residues livestock commodities) as well as all existing dicamba tolerances. Upon assessing those levels of exposure, the Agency has determined that these tolerances will be safe.

D. Revisions to Petitioned-For Tolerances

Tolerances for soybean forage and hay requested by the petitioner were estimated using the North American Free Trade Agreement (NAFTA) MRL calculator. EPA is establishing tolerances, which differ from the proposed tolerances, based on the Organization for Economic

Co-operation Development (OECD) MRL calculation procedures, which is the Agency's current standard for determination of tolerances.

V. Conclusion

Therefore, tolerances are established for residues of dicamba, 3,6-dichloro-2-methoxybenzoic acid, in or on cotton, gin byproducts at 70 ppm; cotton, undelinted seed at 3.0 ppm; soybean, forage at 60 ppm; and soybean, hay at 100 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDC section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 9, 2016.

Michael Goodis,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.227:

a. Remove from the table in paragraph (a)(1), the entry “Cotton, undelinted seed”.

b. Add alphabetically the following entries to the table in paragraph (a)(3) “Cotton, gin byproducts”; “Cotton, undelinted seed”; “Soybean, forage”; and “Soybean, hay”.

The additions read as follows:

§ 180.227 Dicamba; tolerances for residues.

(a) * * *

(3) * * *

Commodity	Parts per million
Cotton, gin byproducts	70
Cotton, undelinted seed	3.0
* * *	* * *
Soybean, forage	60
Soybean, hay	100
* * *	* * *

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