Subpart AA—Missouri

■ 2. Section 52.1342 is amended by adding paragraph (c) to read as follows:

§ 52.1342 Control strategy: Ozone.

* * * * *

(c) On November 3, 2011 and April 29, 2014, Missouri submitted requests to redesignate the Missouri portion of the St. Louis MO–IL area to attainment of the 1997 8-hour ozone standard. The Missouri portion of the St. Louis MO–IL area includes Jefferson, Franklin, St. Charles, and St. Louis Counties along with the City of St. Louis. As part of the redesignation request, the State submitted a plan for maintaining the 1997 8-hour ozone standard through 2025 in the area as required by Section 175A of the Clean Air Act.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart C—Section 107 Attainment Status Designations

■ 4. Section 81.326 is amended by revising the entry for ''St. Louis MO–IL'' in the table entitled ''Missouri—1997 8-Hour Ozone NAAQS (Primary and Secondary)'' to read as follows:

§ 81.326 Missouri.

* * * * *

MISSOURI—1997 8-HOUR OZONE NAAQS

[Primary and Secondary]

Designated area	Designation [a]		Category/Classification	
	Date [1]	Type	Date [1]	Type
* *	*	* *	*	*
St. Louis, MO–IL				
Franklin County	February 20, 2015	Attainment.		
Jefferson County	February 20, 2015	Attainment.		
St. Charles County	February 20, 2015	Attainment.		
St. Louis City	February 20, 2015	Attainment.		
St. Louis County	February 20, 2015	Attainment.		
* *	*	* *	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is June 15, 2004, unless otherwise noted.

* * * * *

[FR Doc. 2015–03287 Filed 2–19–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0670; FRL–9922–08]

Dimethenamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dimethenamid in or on cottonseed subgroup 20C and cotton, gin byproducts. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 20, 2015. Objections and requests for hearings must be received on or before April 21, 2015, 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 docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0670, is 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: Susan Lewis, 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 Publishing 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–2013–0670 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 April 21, 2015. 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–2013–0670, by one of the following methods:

- *Federal eRulemaking 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 October 25, 2013 (78 FR 63938) (FRL–9901–96), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8197) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. The petition requested that 40 CFR 180.464 be amended by establishing tolerances for residues of the herbicide dimethenamid (1(*RS*)-2-chloro-*N*-[(1-methyl-2-methoxy)ethyl]-*N*-(2,4-dimethylthien-3-yl)acetamide) in or on cottonseed, subgroup 20C at 0.01 parts per million (ppm); cotton, gin byproducts at 1.5 ppm; and cotton, seed, refined oil at 0.02 ppm. Compliance with the tolerance levels is to be determined by measuring only parent. Tolerances would apply to either dimethenamid-P (a 90:10 mixture of S- and R-isomers, a mixture enriched in S-isomer) or dimethenamid (a 50:50 racemic mixture of S- and R-isomers). The enforcement method is not enantiomer specific. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that a separate tolerance in cotton, seed, and refined oil is not needed. The reason for these changes are explained in Unit IV.C.

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 FFDCA 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 FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 dimethenamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dimethenamid 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 subgroups of consumers, including infants and children.

The existing toxicological database is comprised of studies conducted with both dimethenamid, which is a racemic mixture of S- and R-isomers (50:50, S:R), and dimethenamid-P, which is mixture of S- and R-isomers enriched in the S-isomer (90:10, S:R). Both sets of data for dimethenamid and dimethenamid-P show similar toxicity and together are adequate for risk assessment. Because of the similarity of the two mixtures, EPA relies on data for both to assess the hazard of each mixture.

The primary target organ is the liver. The toxicity in 90-day feeding studies in rats showed decreased body weights, increased cholesterol and changes in liver weights along with histopathology showing microscopic effects (centrilobular hypertrophy, periportal eosinophilic inclusions and necrosis) in the liver. Chronic studies in the rat, mouse, and dog showed decreases in body weight and food efficiency as accompanying effects over time. At higher dose levels, liver pathology (hepatic lesions, bile duct hyperplasia, and tumors), stomach hyperplasia, and some indications of kidney effects were noted. Two 21-day dermal toxicity studies in rabbits were conducted and in one of those studies minor skin irritation was observed at all doses tested and a decrease in body weight (bw) gain was also seen at the lowest effect level.

The acute neurotoxicity study resulted in effects such as partially closed eyelids, lacrimation, and slight salivation at the highest dose tested of (600 milligrams/kilograms/body weight (mg/kg/bw)). There were no treatment-related or toxicologically significant findings during the gross examination of rats or in the microscopic examination of neurological tissues. In the subchronic neurotoxicity study, there were no clinical signs seen and no adverse effects seen up to 323/390 mg/kg/bw day. Systemic effects seen were renal pelvic dilation in males (considered incidental) and a trend of higher liver weights in females was found at the lowest dose tested and

were not considered adverse nor were they corroborated with any other guideline studies submitted. There were no liver histopathology or clinical chemistry measurements in the subchronic neurotoxicity study; however, the adversity of this finding is supported by the observation of multiple liver effects (increased cholesterol, increased total serum protein, increased liver weights, and enlarged centrilobular hepatocytes) in the 90-day rat study at doses of 98/119 (Male/Female) milligrams/kilograms/day (mg/kg/day) and above. There was no neurotoxicity observed at higher doses nor in other guideline studies.

Developmental toxicity studies show increased post-implantation loss and minor skeletal variations in the rat, and late resorptions and minor skeletal variations in the rabbit at the highest dose tested (lowest observed adverse effect level: LOAEL, 425 mg/kg/day). In the rabbit, the developmental effects occurred at the same dose as maternal toxicity (LOAEL, 150 mg/kg/day), whereas in the rat, the developmental toxicity occurred at much higher doses than in the dams (LOAEL, 215 mg/kg/day). The chosen no observed adverse effect level (NOAEL) of 75 mg/kg/day is considered protective for effects seen in both studies. The reproduction study resulted in decreases in body weight in both pups and parental animals at the same dose levels. The only other effects noted at the LOAEL of 150 mg/kg/day were increases in liver weights in both male and female parental animals.

A review of the immunotoxicity study resulted in no immunotoxicity effects at the limit dose of 1,167 milligrams/kilograms (mg/kg), although increased absolute and relative liver weights were seen at this dose level. Dimethenamid-P is classified as group ''C'' possible human carcinogen, based on weak evidence for carcinogenicity.

The agency concluded that quantification of cancer risk using a non-linear approach would adequately account for all chronic toxicity (including carcinogenicity) that could result from exposure to dimethenamid based on the following weight of evidence considerations:

1. No statistically significant increase in liver tumors (only an increasing trend for liver tumors in one sex (male) and one species (rat)).
2. No evidence of carcinogenicity in male or female mice.
3. Equivocal evidence for mutagenicity.
4. The POD of 5 mg/kg/day used for human health risk assessment is 15-fold lower than the dose (75 mg/kg/day) that caused the liver tumors and thus considered protective for cancer.

Specific information on the studies received and the nature of the adverse effects caused as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document titled, ''Dimethenamid/Dimethenamid-P. Human Health Risk Assessment for Proposed New Use on Cottonseed Subgroup 20C.,'' on pg. 42–48, in docket ID number EPA–HQ–OPP–2013–0670.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological 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 the NOAEL and the LOAEL are identified. 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 Dimethenamid/Dimethenamid-P used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DIMETHENAMID/DIMETHENAMID-P FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day. aPAD = 2.0 mg/kg/day.	Acute Neurotoxicity. LOAEL = 600 mg/kg/day based on lacrimation, salivation, irregular and accelerated respiration, slight tremors, reduced exploration, unsteady gait, and significantly reduced rearing.
Acute dietary (Females 13–49 years of age).	NOAEL = 75 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.75 mg/kg/day. aPAD = 0.75 mg/kg/day.	Developmental Rabbit Study Maternal. LOAEL = 150 mg/kg/day based on abortions (not considered acute effect). Developmental; LOAEL = 150 mg/kg/day based on post-implantation loss.
Chronic dietary (All populations)	NOAEL = 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day. cPAD = 0.05 mg/kg/day.	Chronic/Carcinogenicity Rat Study. LOAEL = Male/Female; 36/49 mg/kg/day based on decreased body weight and body weight gain in both sexes, increased food conversion ratios in females, and increased microscopic hepatic lesions in both sexes.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DIMETHENAMID/DIMETHENAMID-P FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term and intermediate-term (1 to 6 months).	NOAEL = 10 mg/kg/ day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic/Chronic Oral Dog Studies. Chronic NOAEL = 10 mg/kg/day. Chronic LOAEL = 48.7 mg/kg/day. Subchronic NOAEL = 4.72 mg/kg/day. Subchronic LOAEL = 33.6 mg/kg/day based on decreased body weight in females, increased relative to body liver weight in both sexes, increased periportal cytoplasmic vacuolation in liver in both sexes, and dilation of liver sinusoids in females.
Dermal short-term (1 to 30 days) and intermediate-term (1–6 months).	NOAEL = 300 mg/ kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	21-Day Dermal Rabbit Study. LOAEL = 500 mg/kg/day based on decreased body weight gain only (non-specific).
Inhalation short-term (1 to 30 days).	NOAEL = 10 mg/kg/ day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE= 100	Subchronic/Chronic Oral Dog Studies. Chronic NOAEL = 10 mg/kg/day. Chronic LOAEL = 48.7 mg/kg/day. Subchronic NOAEL = 4.72 mg/kg/day. Subchronic LOAEL = 33.6 mg/kg/day based on decreased body weight in females, increased relative to body liver weight in both sexes, increased periportal cytoplasmic vacuolation in liver in both sexes, and dilation of liver sinusoids in females.
Cancer (Oral, dermal, inhalation).	''C'' Possible human carcinogen. The chronic RfD is considered protective of the cancer effects.		

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_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dimethenamid-P and/or dimethenamid, EPA considered exposure under the petitioned-for tolerances as well as all existing dimethenamid tolerances in 40 CFR 180.464 which are established for either of the herbicides dimethenamid-P (an enriched S-isomer with 90:10 mixture of the S- and R-isomers) or dimethenamid (a 50:50 racemic mixture of the S- and R-isomers). Therefore, EPA assessed dietary exposures from dimethenamid-P and/or dimethenamid 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 dimethenamid and dimethenamid-P. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The acute dietary analysis was conducted for dimethenamid and/or dimethenamid-P assuming tolerance level residues, default processing factors, and 100% crop treated (CT) information.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 CSFII. The chronic dietary exposure assessment was conducted for dimethenamid and/or dimethenamid-P assuming tolerance level residues, default processing factors, and 100% CT information.

iii. *Cancer.* As discussed in Unit III.A, EPA has concluded that cancer dietary risk concerns due to long-term consumption of dimethenamid residues are adequately addressed by the chronic dietary exposure analysis using the reference dose; therefore, a separate cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information.* Tolerance level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dimethenamid-P and/or dimethenamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dimethenamid-P and/or dimethenamid. 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 Surface Water Concentration Calculator (SWCC) and the Pesticide Root Zone Model for Ground Water (PRZM–GW), estimated drinking water concentrations (EDWCs) were calculated for the parent compound plus its ethanesulfonic acid and oxanilic acid degradates, which are residues of concern in drinking water as follows: For acute exposures, EDWCs are estimated to be 73 parts per billion (ppb) for surface water and 153 ppb for ground water; for chronic exposures, EDWCs for non-cancer assessments are estimated to be 27 ppb for surface water and 140 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

Because there was little difference between the maximum EDWCs for acute and chronic exposures, the maximum water concentration value of 153 ppb was used to assess the contribution to drinking water for both the acute and chronic dietary risk assessments.

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). Although there are no currently registered uses of dimethenamid that could result in residential exposures, dimethenamid-P is currently registered for the following uses that could result in residential exposures: Turf grass, ornamentals, and tree plantations. Only short-term residential exposures to dimethenamid-P are expected based on the 2012 Residential Standard Operating Procedures (SOPs). Potential exposure/risk scenarios identified for residential handlers include:

- Mixing/loading/applying liquid formulations to lawns/turf with a hose-end and/or backpack sprayer, and a manually-pressurized hand wand.
- Mixing/loading/applying liquid formulations to garden/trees with a sprinkler can and a hose-end sprayer.
- Mixing/loading/applying granular formulations to lawns/turf with a push-type rotary sprayer and a belly grinder.
- Mixing/loading/applying granular formulations to garden/trees with a shaker can/cup, a spoon or by hand dispersal.

The scenarios, routes of exposure, and lifestages of potential post-application exposure include:

- Physical activities on turf: Adults (dermal) and children 1 to <2 years old (dermal and incidental oral).
- Mowing: Adults (dermal) and children 11 to <16 years old (dermal).
- Golfing: Adults (dermal), children 11 to <16 years old (dermal), and children 6 to <11 years old (dermal).
- Contact with Treated Gardens and Trees: Adults (dermal) and children 6 to <11 years old (dermal). The values used for aggregate assessment are based on the worst-case residential exposure estimates via the inhalation (adult male) and oral (child 1 < 2 years old) routes.

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 FFDCA 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 that dimethenamid-P and dimethenamid share a common mechanism of toxicity with any other substances, or that they appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dimethenamid-P and dimethenamid do 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 Web site 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 Food Quality Protection Act Safety Factor (FQPA 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 concern for increased qualitative and/or quantitative susceptibility following *in utero* (rats and rabbits) and pre-and post-natal exposure (rats). The NOAEL and LOAEL values for the fetal/pup effects observed in the developmental study and effects seen in the reproduction studies occurred at the same doses or higher than those which caused maternal toxicity. The rabbit developmental study was used as an acute dietary endpoint for females 13–49 years of age. The POD selected for risk assessment are protective of effects seen in these guideline studies. Therefore, the acute and chronic dietary risk assessments are protective of potential fetal/offspring effects.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 1X. That decision is based on the following findings:

i. The toxicity database for dimethenamid and dimethenamid-P is complete.

ii. There is no indication that dimethenamid or dimethenamid-P is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that dimethenamid or dimethenamid-P results in increased susceptibility *in utero* in rat or rabbit prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues which results in very high-end estimates of dietary exposure. The dietary drinking water assessment, which included parent plus its ethanesulfonic acid and oxanilic acid degradates, utilizes values generated by model and associated modeling parameters which are designed to provide health protective, high-end estimates of water concentrations. These assessments will not underestimate the exposure and risks posed by dimethenamid-P and/or dimethenamid residues of concern.

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 dimethenamid-P and/or dimethenamid residues of concern will occupy 1.3% of the aPAD for infants <1 year of age, the population 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 dimethenamid-P and dimethenamid residues of concern from food and water will utilize 17% of the cPAD for infants <1 year of

age, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dimethenamid-P is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to dimethenamid-P.

Dermal and inhalation exposures to handlers were not aggregated because the toxicity endpoints for these exposure routes are not based on common toxicity effects in/of the liver. Dermal effects (bw gain) were considered to be non-specific. EPA aggregated the worst-case residential exposure estimates via the inhalation (adult male) and oral (child 1 < 2 years old) routes.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOEs of 2,200 for adults and 1,100 for children 1–2 years old. Because EPA's LOC for dimethenamid-P is a MOE of 100 or below, these MOEs are not of concern.

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, dimethenamid-P 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 dimethenamid-P.

5. *Aggregate cancer risk for U.S. population.* As indicated in Unit III.A., EPA has concluded that the chronic RfD would be protective of any cancer effects. Based on the results of the chronic aggregate risk assessment, EPA concludes there is no risk of concern for cancer effects from exposure to dimethenamid and dimethenamid-P.

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 dimethenamid and dimethenamid-P residues of concern.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement method is available for determining residues of dimethenamid in plant commodities. The Gas Chromatography/Nitrogen-Phosphorus Detector (GC/NPD) method (AM–0884–0193–1) has been validated by the Agency and submitted for publication in the Food and Drug Administration (FDA) Pesticide Analytical Manual (PAM), Volume II. The limit of quantitation (LOQ; determined as the lowest level of method validation, LLMV) is 0.01 ppm. This method is not enantiomer specific.

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 FFDCA 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 dimethenamid or dimethenamid-P in/on members of cottonseed subgroup 20C and cotton, gin byproducts.

C. Revisions to Petitioned-For Tolerances

A separate tolerance in cotton, seed, refined oil is not needed since the exaggerated rate processing study demonstrates that the petitioned-for tolerance in/on cottonseed subgroup 20C (0.01 ppm) will be adequate to cover potential residues of dimethenamid in refined oil.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide dimethenamid, 1(*RS*)-2-chloro-*N*-[(1-methyl-2-methoxy) ethyl]-*N*-(2, 4-dimethylthien-3-yl) acetamide, applied as either the 90:10 or 50:50 S:R isomers, in or on cottonseed subgroup 20C at 0.01 ppm and cotton, gin byproducts at 1.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 FFDCA section 408(d), such as the tolerance 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 final rule 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 FFDCA 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: February 10, 2015.

Susan Lewis,

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 § 180.464, add alphabetically the following commodities to the table in paragraph (a) to read as follows:

§ 180.464 Dimethenamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cotton, gin byproducts	1.5
Cottonseed subgroup 20C ...	0.01
* * * * *	

* * * * *

[FR Doc. 2015–03458 Filed 2–19–15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0574; FRL–9920–62]

Bacillus Subtilis Strain IAB/BS03; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the fungicide *Bacillus subtilis* strain IAB/BS03 in or on all food commodities when used in accordance with label directions and good agricultural practices. Investigaciones y Aplicaciones Biotechnologicas (IAB, S.L.) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* strain IAB/BS03.

DATES: This regulation is effective February 20, 2015. Objections and requests for hearings must be received on or before April 21, 2015, 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 docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0574 is 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: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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 40 CFR part 180 through the Government Publishing 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(g), 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–2013–0574 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 April 21, 2015. 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