

adopted, EPA-approved water quality standards.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule removes federally-promulgated water quality standards addressing nutrient pollution in Florida in order to allow Florida to implement its state-adopted, EPA-approved water quality standards. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rule imposes no regulatory requirements or costs on any tribal government. It does not have substantial direct effects on tribal governments, the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)

This rule is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866 and because the environmental health or safety risks addressed by this action do not present a disproportionate risk to children.

H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus

standards in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898—Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because: (1) Florida's WQS apply to waters across the state, and thus this action will not disproportionately affect any one group over another, and (2) EPA has previously determined, based on the most current science, that Florida's adopted and EPA-approved criteria are protective of human health and aquatic life.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The 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. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on October 27, 2014.

List of Subjects in 40 CFR Part 131

Environmental protection, Florida, Nitrogen and phosphorus pollution, Numeric nutrient criteria, Nutrients, Water quality standards.

Dated: September 17, 2014.

Gina McCarthy,
Administrator.

For the reasons set out in the preamble, 40 CFR part 131 is amended as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

Subpart D—Federally Promulgated Water Quality Standards

§ 131.43 [Removed]

■ 2. Remove § 131.43.

[FR Doc. 2014-22835 Filed 9-24-14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0268; FRL-9915-78]

Thiabendazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiabendazole in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 25, 2014. Objections and requests for hearings must be received on or before November 24, 2014, 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-2013-0268, 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: Lois Rossi, 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: RDfRNtices@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-2013-0268 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 November 24, 2014. 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-2013-0268, 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 August 1, 2014 (79 FR 44729) (FRL-9911-67), 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 3F8166) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR 180.242 be amended by establishing tolerances for residues of the fungicide thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite benzimidazole, in or on vegetable, root (except sugar beet), subgroup 1B at 0.02 ppm; radish, tops at 0.02 ppm; onion, bulb, subgroup 3-07A at 0.02 ppm; *Brassica*, head and stem, subgroup 5-A at 0.02 ppm; vegetable, cucurbit group 9 at 0.02 ppm; barley, grain at 0.05 ppm; barley, hay at 0.30 ppm; barley, straw at 0.30 ppm;

wheat, grain at 0.05 ppm; wheat, straw at 0.30 ppm; wheat, hay at 0.30 ppm; wheat, forage 0.30 ppm; oats, grain at 0.05 ppm; oats, hay at 0.30 ppm; oats, straw at 0.30 ppm; oats, forage at 0.30 ppm; rye, grain at 0.05 ppm; rye, straw at 0.30 ppm; rye, forage at 0.30 ppm; triticale, grain at 0.05 ppm; triticale, hay at 0.30 ppm; triticale, straw at 0.30 ppm; triticale, forage at 0.30 ppm; alfalfa, forage at 0.02 ppm; alfalfa, hay at 0.02 ppm; and spinach at 0.02 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

The Notice of Filing (NOF) published on August 1, 2014 (79 FR 44729) supersedes an earlier NOF for the same petition for thiabendazole that was issued in the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL-9386-2).

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 thiabendazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiabendazole 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 thyroid and liver (centrilobular hypertrophy) are the primary target organs of thiabendazole toxicity. Thiabendazole produced a treatment-related increase in absolute and relative liver weights in both sexes in a chronic dog study. Other treatment related effects reported were histopathological changes in kidneys (hyperplasia of transitional epithelium, tubular degeneration) and spleen (congested and pigmented) in rats. Additional toxic effects observed in these studies included decreases in body weight and/or food consumption. The available database indicates that thiabendazole is not neurotoxic. In an acute neurotoxicity rat study (ACN), decreases in the Functional Observation Battery (FOB) (reduced body temperature in males, reduced rearing in females, and reduced locomotor activity in males and females at time of peak effect (approximately 3 hours post-dose) were seen without morphological or histopathological effects on the brain. Thiabendazole was not neurotoxic in rats in a subchronic neurotoxicity study. In a 21-day dermal toxicity study in rats, no systemic or dermal effects were seen at the limit dose (1,000 milligram/kilogram/day (mg/kg/day)). In prenatal developmental toxicity studies in rats, rabbits, and mice and in the 2-generation reproduction study in rats, effects in the fetuses or neonates occurred at or above doses that caused maternal or parental toxicity.

In the adult animal, effects on the thyroid following thiabendazole exposure were observed at a dose lower than the neurotoxicity dose observed in the ACN. There are no thiabendazole data with which to determine whether

this is also the case in the fetus/postnatal animal. Based on a weight of evidence (WOE) approach considering all the available hazard and exposure information for thiabendazole, the Agency concluded that a developmental thyroid toxicity study is required since there is clear evidence of thyroid toxicity in adult animals and thus a concern for potential toxicity during pregnancy, infancy and childhood. The developmental thyroid toxicity study will better address this concern than a developmental neurotoxicity study.

In an immunotoxicity study, thiabendazole produced significant decreased spleen activity at the highest dose tested (5,000 ppm equivalent to 1,027 mg/kg/day) which also produced significant increased liver weight.

The genetic toxicology studies on thiabendazole indicate that it is not genotoxic in *in vivo* and *in vitro* assays. Review of literature studies indicated that thiabendazole has weak aneugenic activity in both somatic and germinal cells. In a chronic rat study, thiabendazole induced thyroid tumors in males only. Thiabendazole did not induce tumors in mice. Thiabendazole has been classified by the Agency as “likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormonal balance but not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance.” Taking into account all of this information, the Agency has determined that quantification of risk using a non-linear approach (i.e., chronic population adjusted dose (cPAD)) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to thiabendazole.

Specific information on the studies received and the nature of the adverse effects caused by thiabendazole 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 the document titled “Thiabendazole: Human Health Risk Assessment for the Requested Increase in the Currently Registered

Seed Treatment Use Rate on Soybeans and the New Section 3 Uses of Thiabendazole for Seed Treatment on Assorted Vegetables and Small Grains Including: Vegetable, Root (Except Sugar Beet), Subgroup 1B; Radish Tops; Onion, Bulb, Subgroup 3-07A; *Brassica*, Head and Stem, Subgroup 5A; Vegetable, Cucurbit Group 9; Alfalfa; Spinach; and a Number of Small Grains (Barley, Oats, Rye, and Triticale)” on pages 45–53 in docket ID number EPA–HQ–OPP–2013–0268.

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 (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, 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 thiabendazole used for human risk assessment is shown in the following table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIABENDAZOLE 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 females 13–49 years of age and children).	NOAEL = 50 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = UF _{DB} 10x	Acute RfD = 0.05 mg/kg/day. aPAD = 0.05 mg/kg/day	Acute neurotoxicity study. LOAEL = 200 mg/kg based decreases in the FOB (reduced body temperature in males, and reduced rearing in females, reduced locomotor activity in males and females, at time of peak effect (approximately 3 hours post-dose). Reduced body weight gain and food consumption occurred on day 1.
Chronic dietary (all populations)	NOAEL = 10 mg/kg/day UF _A = 3x UF _H = 10x FQPA SF = UF _{DB} 10x	Chronic RfD = 0.033 mg/kg/day. cPAD = 0.033 mg/kg/day	2-year chronic carcinogenicity in the rat. Chronic LOAEL = 30 mg/kg/day based on decreased body weight gains and liver hypertrophy. Thiabendazole induced thyroid adenomas in male rats at dosages of ≥30 mg/kg/day. Supported by subchronic toxicity rat study. Subchronic LOAEL = 40 mg/kg/day based on reduced body weight and body weight gains and histopathological changes in the bone marrow (erythroid hyperplasia), liver (centrilobular hypertrophy), thyroid (follicular cell hypertrophy) and spleen (pigmented).
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 10 mg/kg/day UF _A = 3x UF _H = 10x FQPA SF = 10x UF _{DB}	LOC for MOE = 300	Subchronic oral toxicity study—rat. LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Dermal (or oral) study ... NOAEL = 10 mg/kg/day (dermal absorption rate = 0.5%. UF _A = 3x UF _H = 10x FQPA SF = 10x UF _{DB}	LOC for MOE = 300	Subchronic oral toxicity study—rat. LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 10 mg/kg/day UF _A = 3x UF _H = 10x FQPA SF = 10x UF _{DB}	LOC for MOE = 300	Subchronic oral toxicity study—rat. LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid.
Cancer (oral, dermal, inhalation)	Likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormonal balance but not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance. Quantification of risk using a non-linear approach (i.e., cPAD) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to thiabendazole.		

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_{DB} = to account for the absence of data or other data deficiency. 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 thiabendazole, EPA considered exposure under the petitioned-for tolerances as well as all existing thiabendazole tolerances in 40 CFR 180.242. EPA assessed dietary exposures from thiabendazole 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 thiabendazole. In estimating acute dietary exposure, EPA used 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). As to residue levels in food, EPA used a refined acute probabilistic dietary exposure assessment for thiabendazole using both anticipated residue estimates based on USDA Pesticide Data Program (PDP) monitoring data and percent crop treated (PCT) information for soybean and wheat and assumed 100 PCT for all other commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA used a refined chronic probabilistic dietary

exposure assessment for thiabendazole using both anticipated residue estimates based on USDA PDP monitoring data and PCT information for soybean and wheat and assumed 100 PCT for all other commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action

data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to thiabendazole. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and 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 PCT for existing uses as follows:

Acute dietary risk assessment:
soybeans 2.5%; wheat 2.5%.

Chronic dietary risk assessment:
soybeans 1%; wheat 1%.

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 6–7 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 subpopulations 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 thiabendazole 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 thiabendazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiabendazole. 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 FQPA Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of thiabendazole for acute exposures are estimated to be 3.80 parts per billion

(ppb) for surface water and 0.62 ppb for ground water and for chronic exposures are estimated to be 0.47 ppb for surface water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 3.80 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.47 ppb was used to assess the contribution to drinking water.

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). Thiabendazole is currently registered for use as antimicrobial ingredient in paint, sponges, carpet backing, canvas textiles, wallboard and ceiling tiles, polyurethane foam, plastics and rubber, paper, and coatings and filters used in HVAC systems. There are two antimicrobial exposure scenarios that were assessed for residential exposures: Treated paint and impregnated sponges. The other antimicrobial uses of thiabendazole (carpet backing, canvas textiles, wallboard and ceiling tiles, polyurethane foam, plastics and rubber, paper, and coatings and filters used in HVAC systems) are not expected to cause exposure in residential settings because there is no direct contact to the treated articles, the vapor pressure of thiabendazole is very low, and the unlikelihood that the treated plastics and rubbers would be used in toys.

EPA assessed residential exposure to treated paint and impregnated sponges using the following assumptions: For treated paint, residential short-term dermal and inhalation exposure to residential handlers using brush/roller application and airless sprayer application; for the impregnated sponge use, short- and intermediate-term incidental oral exposure. Thiabendazole treated sponges are limited to 600 ppm thiabendazole on a sponge. Various residue amounts may be transferred from the sponge to food contact surfaces, such as countertops and utensils/glassware, and then to food and subsequently ingested. An assessment was conducted for incidental oral exposure assuming that 100% of the thiabendazole on a treated sponge is transferred to surfaces over 20 days and that each 20 days the user would use a new sponge (5% released per day). This assumption is considered conservative because (1) sponges will generally be used much longer than 20 days; (2) it is

unlikely that 100% of the thiabendazole would be released from the sponge in such a short period; and (3) it is very unlikely that 100% of any released thiabendazole would be transferred to countertops because this assumption does not account any thiabendazole that is washed down the sink or that normally degrades. 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 thiabendazole to share a common mechanism of toxicity with any other substances, and thiabendazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiabendazole 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 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 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.* No evidence of increased quantitative or qualitative susceptibility was seen following *in utero* exposure to thiabendazole with rats or rabbits in the prenatal developmental studies or in

young rats in the 2-generation reproduction study. There is no evidence for neurotoxicity following oral exposures to thiabendazole. Thyroid toxicity was seen following subchronic and chronic exposures to adult rats in multiple studies. There is, however, no data regarding the potential effects of thiabendazole on thyroid homeostasis in the young animals. This lack of characterization creates uncertainty with regards to potential life stage sensitivities due to exposure to thiabendazole. Therefore, the Agency is requiring a developmental thyroid assay in rats with thiabendazole. This study will better address the concern for potential thyroid toxicity in the young. Although the Agency is asking for the developmental thyroid study, EPA does not expect it to result in a lower point of departure than what the Agency is regulating from and therefore the 10X is protective. There are no residual uncertainties in the thiabendazole residue database with regards to dietary or occupational exposure. Therefore, the FQPA SF is retained at 10X in the form of a database uncertainty factor (UF_{DB}). For the acute dietary endpoint the total UF is 1,000 (an interspecies scaling factor of 10X, an intraspecies variability factor of 10X, a FQPA database uncertainty factor of 10X for lack of a developmental thyroid study). For the remaining endpoints, the combined total UF is 300 (an interspecies scaling factor of 3X, lowered from 10X for toxicodynamic reasons (rats eliminate thyroxine (a thyroid hormone) at a higher rate than humans), an intraspecies variability factor of 10X, an FQPA database uncertainty factor of 10X for lack of a developmental thyroid study was applied).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF is retained at 10X in the form of a database uncertainty factor (UF_{DB}). That decision is based on the following findings:

i. The toxicology database for thiabendazole is complete with the exception of a developmental thyroid toxicity study. Based on a WOE approach considering all the available hazard and exposure information for thiabendazole, the Agency concluded that a developmental thyroid toxicity study is required since there is clear evidence of thyroid toxicity in adult animals and thus a concern for potential toxicity during pregnancy, infancy and childhood. The developmental thyroid toxicity study will better address this concern than a developmental neurotoxicity study. Acceptable studies are available for developmental,

reproduction, chronic, subchronic, subchronic neurotoxicity and immunotoxicity.

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

iii. The data submitted to the Agency, as well as those from published literature, demonstrate no increased susceptibility in rats, rabbits, or mice to *in utero* and/or early postnatal exposure to thiabendazole. In the prenatal developmental toxicity studies in rats, rabbits, and mice and in the 2-generations reproduction study in rats, developmental effects in the fetuses or neonates occurred at or above doses that caused maternal or parental toxicity. A developmental neurotoxicity study with thiabendazole was deemed not required by the Agency.

There is evidence of thyroid toxicity following subchronic and chronic exposures to rats characterized as histopathological changes in the thyroid in multiple studies in rats. Disruption of thyroid homeostasis is the initial, critical effect that may lead to adverse effects on the developing nervous system. Thus, as noted above, a developmental thyroid study is required.

iv. There are no residual uncertainties in the exposure database. The dietary risk assessment is conservative and will not underestimate dietary and/or non-dietary occupational exposure to thiabendazole. The acute and chronic dietary assessments conducted with the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) were refined analyses. The assessments utilized anticipated residues, default processing factors, and available percent crop treated data. The DEEM analysis also used Tier 1 drinking water estimates. For these reasons it can be concluded that the DEEM-FCID analysis does not underestimate risk from acute or chronic exposure to thiabendazole. Similarly, EPA does not believe that the non-dietary occupational exposures are underestimated because they are also based on conservative assumptions, including maximum application rates, and standard values for unit exposures and acreage treated/amount handled. These assessments will not underestimate the exposure and risks posed by thiabendazole.

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 thiabendazole will occupy 69% of the aPAD for children 1–2 years old, 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 thiabendazole from food and water will utilize 4.7% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of thiabendazole is not expected.

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

Thiabendazole is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to thiabendazole.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in aggregate MOEs from the paint use of 2,000 for all population subgroups and aggregate MOEs from the sponge use of 1,400 for children 1–2 years old and 7,300 for the general population. Because EPA's level of concern for thiabendazole is a MOE of 300 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Since thiabendazole is classified as likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormonal balance but not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal

balance, a cancer dietary exposure assessment is not required. EPA is currently regulating chronic dietary risk with a chronic RfD that reflects a dose level below dose levels at which thyroid hormone balance is impacted and consequently is also being protective of potential carcinogenic effects.

5. *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 thiabendazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Acceptable enforcement analytical methods are available for thiabendazole and benzimidazole in plant commodities. Four spectrophotofluorometric methods for the determination of thiabendazole are published in the Pesticide Analytical Manual (PAM) Vol. II, and a high performance liquid chromatography (HPLC) method with fluorescence detection (FLD) for the determination of benzimidazole (free and conjugated) is identified in the U.S. EPA Index of Residue Analytical Methods under thiabendazole as Study No. 93020.

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 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 thiabendazole on any of the commodities cited in this document.

C. Revisions to Petitioned-For Tolerances

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of thiabendazole not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of thiabendazole, [2-(4-thiazolyl) benzimidazole] and its metabolite benzimidazole (free and conjugated), in or on alfalfa, forage at 0.02 ppm; alfalfa, hay at 0.02 ppm; barley, grain at 0.05 ppm; barley, hay at 0.30 ppm; barley, straw at 0.30 ppm; *Brassica*, head and stem, subgroup 5A at 0.02 ppm; oat, forage at 0.30 ppm; oat, grain at 0.05 ppm; oat, hay at 0.30 ppm; oat, straw at 0.30 ppm; onion, bulb, subgroup 3–07A at 0.02 ppm; radish, tops at 0.02 ppm; rye, forage at 0.30 ppm; rye, grain at 0.05 ppm; rye, straw at 0.30 ppm; spinach at 0.02 ppm; triticale, forage at 0.30 ppm; triticale, grain at 0.05 ppm; triticale, hay at 0.30 ppm; triticale, straw at 0.30 ppm; vegetable, cucurbit, group 9 at 0.02 ppm; vegetable, root (except sugarbeet), subgroup 1B at 0.02 ppm; wheat, forage at 0.30 ppm; and wheat, hay at 0.30 ppm. In addition, the following existing tolerances are modified: wheat, grain from 1.0 ppm to 0.05 ppm; and wheat straw from 1.0 ppm to 0.30 ppm.

Also, the time-limited tolerances for beet, sugar, dried pulp; beet, sugar, roots; and beet, sugar, tops, are removed because they expired on 12/25/10.

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: September 18, 2014.

Lois Rossi,

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 § 180.242, revise paragraph (a)(1) and the introductory text of paragraph (a)(2) to read as follows:

§ 180.242 Thiabendazole; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of thiabendazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolite benzimidazole (free and conjugated), calculated as the stoichiometric equivalent of thiabendazole, in or on the commodity.

Commodity	Parts per million
Alfalfa, forage	0.02
Alfalfa, hay	0.02
Apple, wet pomace	12.0
Avocado ¹	10.0
Banana, postharvest	3.0
Barley, grain	0.05
Barley, hay	0.30
Barley, straw	0.30
Bean, dry, seed	0.1
Brassica, head and stem, subgroup 5A	0.02
Cantaloupe ¹	15.0
Carrot, roots, postharvest	10.0
Citrus, oil	15.0
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Corn, pop, forage	0.01
Corn, pop, grain	0.01
Corn, pop, stover	0.01
Corn, sweet, forage	0.01
Corn, sweet, kernels plus cop with husks removed	0.01
Corn, sweet, stover	0.01
Fruit, citrus, group 10, postharvest	10.0
Fruit, pome, group 11, postharvest	5.0
Mango	10.0
Mushroom	40.0
Oats, forage	0.30
Oats, grain	0.05
Oats, hay	0.30
Oats, straw	0.30
Onion, bulb, subgroup 3–07A	0.02
Papaya, postharvest	5.0

Commodity	Parts per million
Potato, postharvest	10.0
Radish, tops	0.02
Rye, forage	0.30
Rye, grain	0.05
Rye, straw	0.30
Soybean	0.1
Spinach	0.02
Strawberry ¹	5.0
Sweet potato (postharvest to sweet potato intended only for use as seed)	0.05
Triticale, forage	0.30
Triticale, grain	0.05
Triticale, hay	0.30
Triticale, straw	0.30
Vegetable, cucurbit, group 9	0.02
Vegetable, root (except sugarbeet), subgroup 1B	0.02
Wheat, forage	0.30
Wheat, grain	0.05
Wheat, hay	0.30
Wheat, straw	0.30

¹There are no U.S. registrations on the indicated commodity.

(2) Tolerances are established for residues of thiabendazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of thiabendazole (2-(4-thiazolyl)benzimidazole) and its metabolites 5-hydroxythiabendazole (free and conjugated) and benzimidazole (free and conjugated), calculated as the stoichiometric equivalent of thiabendazole, in or on the commodity.

* * * * *

[FR Doc. 2014-22833 Filed 9-24-14; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA-HQ-SFUND-1990-0011; FRL-9916-83-Region 6]

Withdrawal of Direct Final Rule; National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Direct Deletion of the Monroe Auto Equipment (Paragould Pit) Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Withdrawal of direct final rule.

SUMMARY: On August 14, 2014, Environmental Protection Agency (EPA) published a direct final rule (79 FR 47586) and a proposed rule; notice of intent to delete (79 FR 47610) that deleted the Monroe Auto Equipment Company (Paragould Pit) site from the Superfund National Priorities List

(NPL). EPA stated in the direct final rule that if EPA received adverse comments by September 15, 2014, EPA would publish a timely notice of withdrawal in the **Federal Register**. Subsequently, EPA discovered scribal errors in the supporting documentation of the final direct rule. EPA will correct those errors in a subsequent final action based on the parallel proposal which published on August 14, 2014. EPA will not institute a second comment period on this final action. Unless adverse comments are received by September 15, 2014, the effective date of the final rule will be September 29, 2014.

DATES: *Effective:* The direct final rule published at 79 FR 47586 on August 14, 2014, is withdrawn effective September 25, 2014.

FOR FURTHER INFORMATION CONTACT:

Brian Mueller, Remedial Project Manager; U.S. Environmental Protection Agency, Region 6; Superfund Division (6SF-RL); 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733, telephone (214) 665-7167; email address: mueller.brian@epa.gov,

SUPPLEMENTARY INFORMATION: The EPA Region 6 published a direct final Notice of Deletion of the Monroe Auto Equipment (Paragould Pit) Superfund Site located in Paragould, Greene County, Arkansas, from the National Priorities List (NPL) on August 14, 2014. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The NPL constitutes Appendix B of 40 CFR Part 300 as amended. EPA maintains the

NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 300.425(e)(3) of the NCP, sites deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions. The direct final deletion was published by EPA with the concurrence of the State of Arkansas, through the Arkansas Department of Environmental Quality (ADEQ), because EPA has determined that all appropriate response actions under CERCLA have been completed. EPA subsequently discovered scribal errors in the supporting documentation of the final direct rule. EPA will correct those errors in a subsequent final action based on the parallel proposal which published on August 14, 2014. We will not institute a second comment period on this final action unless adverse comments are received by September 15, 2014. If no adverse comments are received the effective date of the subsequent action will be September 29, 2014.

Dated: September 9, 2014.

Ron Curry,

Regional Administrator, Region 6.

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