D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only three hours and 30 minutes that will prohibit entry within 250-yard radius of where the fireworks display will be conducted. It is categorically excluded from further review under paragraph L[60] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0576 to read as follows:

§ 165.T09–0576 Safety Zone; Maumee River; Toledo, OH

(a) *Location.* The following area is a safety zone: All U.S. navigable waters of the Maumee River within a within a 250-yard radius of the fireworks launch site located at position 41°38′54″ N 83°31′54″ W. All geographic coordinates are North American Datum of 1983 (NAD 83).

(b) *Enforcement period.* This regulation will be enforced from 7:30 p.m. through 11 p.m. on September 3, 2021. The Captain of the Port Detroit, or a designated representative may suspend enforcement of the safety zone at any time.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Detroit, or his designated representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Detroit or his designated representative.

(3) The ''designated representative'' of the Captain of the Port Detroit is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port Detroit to act on their behalf. The designated representative of the Captain of the Port Detroit will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port Detroit or a designated representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Detroit or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Detroit or a designated representative.

Dated: August 25, 2021.

Brad W. Kelly,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2021–18642 Filed 8–27–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0054; FRL–8750–02–OCSPP]

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 that are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 30, 2021. Objections and requests for hearings must be received on or before October 29, 2021, 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–2020–0054, 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.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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–2020–0054 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 October 29, 2021. 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–2020–0054, 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 June 28, 2021 (86 FR 33922) (FRL–10025–08), 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 9E8812) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested EPA to establish tolerances in 40 CFR 180.242 for residues of thiabendazole (2-(4-thiazolyl)benzimidazole), including its metabolites and degradates, in or on the following raw agricultural commodities: Animal feed, nongrass, group 18 at 0.01 parts per million (ppm); Beet, garden, leaves at 0.01 ppm; *Brassica,* leafy greens, subgroup 4–16B at 0.01 ppm; Burdock, edible, leaves at 0.01 ppm; Carrot, leaves at 0.01 ppm; Carrot, roots at 10 ppm; Celeriac, leaves at 0.01 ppm; Chervil, turnip rooted, leaves at 0.01 ppm; Chicory, leaves at 0.01 ppm; Fruit, citrus, group 10–10 at 10 ppm; Fruit, pome, group 11–10 at 10 ppm; Kohlrabi at 0.01 ppm; Radish, oriental, leaves at 0.01 ppm; Rutabaga, leaves at 0.01 ppm; Salsify, black, leaves at 0.01 ppm; Sweet potato, tuber at 3 ppm; Vegetable, *Brassica,* head and stem, group 5–16 at 0.01 ppm; Vegetable, root, except sugar beet, subgroup 1B at 0.01 ppm; Vegetable, tuberous and corm, subgroup 1C, except sweet potato at 10 ppm.

The petition also proposed to remove the established tolerances for residues of thiabendazole (2-(4-thiazolyl)benzimidazole), including its metabolites and degradates, in or on the following raw agricultural commodities: Potato, postharvest at 10.0 ppm; Sweet potato (postharvest to sweet potato intended only for use as seed) at 0.05 ppm; Alfalfa, forage at 0.02 ppm; Alfalfa, hay at 0.02 ppm; Radish, tops at 0.02 ppm; *Brassica,* head and stem, subgroup 5A at 0.02 ppm; Fruit, citrus, group 10, postharvest at 10.0 ppm; Fruit, pome, group 11, postharvest at 5.0 ppm; Vegetable, root (except sugarbeet), subgroup 1B at 0.02 ppm; Carrot, roots, postharvest at 10.0 ppm; and in paragraph (b) Sweet potato at 10 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.* No comments were received in response to the notice of filing.

A previous notice of filing was published in the **Federal Register** of April 15, 2020 (85 FR 20910) (FRL–10006–54). The April 15, 2020 notice is superseded by the June 28, 2021 notice.

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.

Decreased body weight is the most sensitive effect of exposure to thiabendazole observed even in young rat pups during lactation. Histopathological changes in the spleen (congestion and pigmentation) and kidney (calculus and hyperplasia of transitional epithelium) were noted in a subchronic rat study, and splenic erythropoiesis and hemosiderosis were reported in a chronic dog study. Other target organs of thiabendazole toxicity are the liver and thyroid. Increased quantitative susceptibility was observed in the rat and rabbit developmental toxicity studies, in which developmental effects occurred in the absence of maternal toxicity. Increased quantitative susceptibility was not observed in the prenatal developmental toxicity study in mice and in the 2-generation reproduction study in rats. In an acute neurotoxicity rat study (ACN), reduced locomotor activity was identified, although no morphological or histopathological effects were noted in the brain. No signs of neurotoxicity were seen in the subchronic neurotoxicity study. Thiabendazole is classified as ''Likely to be carcinogenic to humans at doses high enough to cause a disturbance of the thyroid hormonal balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance''.

Additional information on the toxicological profile can be found at *http://www.regulations.gov* in the document titled ''Thiabendazole: Human Health Risk Assessment for the Establishment of Permanent Tolerances and Registration for Use on Animal feed, nongrass, group 18; *Brassica,* leafy greens, subgroup 4–16B; and Sweet Potato; and Crop Group Conversions/Expansions to Fruit, citrus, group 10–10; Fruit, pome, group 11–10; Kohlrabi; Vegetable, *Brassica,* head and stem, group 5–16; Vegetable, root, except sugar beet, subgroup 1B; and Vegetable, tuberous and corm, subgroup 1C, except sweet potato'' (hereinafter ''Thiabendazole Human Health Risk Assessment'') in docket ID number EPA–HQ–OPP–2020–0054.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide.*

A summary of the toxicological endpoints for thiabendazole used for human risk assessment can be found in the Thiabendazole Human Health Risk Assessment.

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. 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.

In conducting the acute dietary exposure assessment, EPA used the 2003–2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is partially refined and incorporated established and recommended tolerance-level residues for some commodities, maximum field trial residues for the remaining commodities according to blending classification, 100 percent crop treated (PCT), and default processing factors (except for apple juice, grapefruit juice, lemon juice, lime juice, orange juice, pear juice, potato granules/flakes, and tangerine juice).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the 2003–2008 food consumption data from the USDA's NHANES/WWEIA. The chronic dietary exposure assessment is partially refined and incorporated established and recommended tolerance-level residues for some commodities, average field trial residues for the remaining commodities according to blending classification, 100 PCT, and default processing factors (except for apple juice, grapefruit juice, lemon juice, lime juice, orange juice, pear juice, potato granules/flakes, and tangerine juice).

iii. *Cancer.* 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.'' EPA is regulating chronic exposure based on a reference dose that is lower than (and thus protective of) the level that would cause a disturbance in the thyroid hormonal balance, making tumor formation highly unlikely; therefore, a cancer dietary exposure assessment is not required. The current partially refined chronic dietary risk assessment is conservative and is protective for cancer effects.

iv. *Anticipated residue and PCT information.* EPA used some tolerance-level residues and some anticipated residue data for assessing tolerances. 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.

EPA did not use PCT estimates in the dietary assessment for thiabendazole; 100 PCT was 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 thiabendazole in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the FQPA Index Reservoir Screening Tool (FIRST; surface water) model and the Pesticide Root Zone Model for Ground Water (PRZM–GW; groundwater), EPA used an estimated drinking water concentration (EDWC) of 3.80 ppb for the acute dietary risk assessment and a value of 0.47 ppb for the chronic dietary risk assessment.

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 uses that may result in residential handler and post-application exposures, including use in paints and textiles. As an initial matter in assessing aggregate risk of the pesticide chemical residues, the Agency takes into consideration those residential exposure scenarios that provide the most conservative estimate of residential exposures, including handler exposure and post-application exposure or both.

The residential handler exposure scenario used in the aggregate assessment is for adult handler inhalation exposures from applying thiabendazole-treated paint using airless sprayers. For this scenario, the Aggregate Risk Index (ARI) approach was used since the PODs/endpoints were similar, but the levels of concern (LOCs) were different. An ARI greater than or equal to 1 is not of concern.

The residential exposure scenario used for the post-application assessment is incidental oral exposures from children 1 to <2 years old mouthing preserved textiles (clothing) treated with thiabendazole.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to thiabendazole and 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 not assumed that thiabendazole has a common mechanism of toxicity with other substances.

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.* The data submitted to the Agency, as well as those from published literature, demonstrated increased quantitative susceptibility in the rat and rabbit developmental toxicity studies, in which developmental effects (decreased fetal weights in rat and rabbit pups) were observed while maternal toxicity was not observed up to the highest doses tested. No increased susceptibility was observed in mice *in utero* and/or to rats following early postnatal exposure to thiabendazole.

3. *Conclusion.* EPA has determined there is reliable data to support a conclusion that a FQPA Safety Factor (SF) of 1X will be protective for infants and children for all scenarios, with the exception of the assessment of inhalation exposure. The default FQPA 10X SF remains in place for assessing the non-occupational inhalation exposure due to the lack of a subchronic inhalation study with thyroid measurements. That decision is based on the following findings:

i. The toxicology database for thiabendazole is complete with the exception of a subchronic inhalation toxicity study with thyroid measurements. Based on a weight of evidence approach considering all the available hazard and exposure information for thiabendazole, the Agency determined that a developmental thyroid toxicity study is not required at this time. Acceptable studies are available for developmental, reproduction, chronic, subchronic, subchronic neurotoxicity and immunotoxicity.

ii. In an acute neurotoxicity rat study (ACN), 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 at the highest dose tested (1,500 ppm equivalent to 95 mg/kg/day).

iii. As noted above, there is some evidence of increased susceptibility in the developmental fetus from exposure to thiabendazole. Nevertheless, the Agency has sufficient data to understand and protect against the potential developmental effects. The data indicating the potential for developmental toxicity presented well-defined NOAELs and LOAELs, which the Agency took into account when identifying endpoints. The selected points of departure for regulating exposure are protective of both the potential for neurotoxicity and the increased susceptibility of infants and children. There is no residual uncertainty concerning the potential for prenatal or post-natal toxicity that precludes the reduction of the FPQA 10X SF.

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 were slightly refined analyses. The assessments utilized tolerance-level residues, maximum residue or average

residue values from field-trial data, empirical or EPA's 2018 default processing factors, and 100 PCT. The analysis also used Tier 1 drinking water estimates. For these reasons, it can be concluded that the analysis does not underestimate risk from acute or chronic exposure to thiabendazole. Similarly, EPA does not believe that the non-dietary exposures are underestimated because they are also based on conservative assumptions.

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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to thiabendazole from food and water will utilize 50% of the aPAD for children 1 to 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 64% of the cPAD for children 1 to 2 years old, 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). Thiabendazole is 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 thiabendazole.

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 ARI of 1.88 for adults and an MOE of 200 for children 1 to 2 years old. Because EPA's level of concern for thiabendazole is an ARI of less than or equal to 1 or an MOE of 100 or below, these ARIs/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, thiabendazole 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 thiabendazole.

5. *Aggregate cancer risk for U.S. population.* As the risks estimated based on the chronic reference dose are protective of cancer effects, no separate cancer risk assessment is necessary. The chronic dietary aggregate risk assessment is below the Agency's level of concern; therefore, the Agency concludes that aggregate exposure to thiabendazole is not likely to pose a cancer risk.

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 thiabendazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate spectrophotofluorometric methods are available in the Pesticide Analytical Manual, Volume II (PAM II) for enforcement of thiabendazole tolerances.

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.

Codex has established more restrictive (*i.e.,* lower) MRLs for residues in/on citrus fruits and pome fruits (7 ppm and 3 ppm respectively, versus the existing U.S. tolerances for the old crop groups, which are 10.0 ppm for citrus and 5.0 ppm for pome fruit.) Therefore, harmonization with the Codex MRLs are not possible because U.S. growers would be at risk of violative residues of thiabendazole despite legal use according to the label. Instead, EPA is harmonizing the tolerance for fruit, pome, group 11–10 with the Canadian MRL of 10 ppm in/on apples and pears. Additionally, Codex has established an MRL for residues in/on potato at 15 ppm, which is higher than the revised U.S. tolerance of 10 ppm. Per the registrant's request, the Agency is not harmonizing with the established Codex MRL for residues in/on potato. Instead, the U.S. tolerance is harmonized with the Canadian MRL for potatoes at 10 ppm because Canada is a major trading partner with the United States for potatoes.

C. Revisions to Petitioned-For Tolerances

As mentioned in Unit II., the petitioner requested that the time-limited tolerance in § 180.242(b) at 10 ppm for residues of thiabendazole in/on sweet potato be removed upon the establishment of a permanent tolerance for residues of thiabendazole in/on sweet potato in § 180.242(a). EPA is not removing the time-limited tolerance on sweet potato in § 180.242(b) due to a difference between the section 18 use pattern and the proposed use pattern for the section 3 registration. There is a potential that use under the current section 18 could result in exceedances if this tolerance was revoked.

D. International Trade Considerations

In this rule, EPA is establishing tolerances for thiabendazole residues in or on the Animal feed, nongrass, group 18; Vegetable, *Brassica,* head and stem, group 5–16; and the Vegetable, root, except sugar beet, subgroup 1B (all at 0.01 ppm) that are lower than the current tolerances of Alfalfa forage, Alfalfa hay, *Brassica* head and stem

subgroup 5A, and Vegetable, root (except sugarbeet), subgroup 1B (all 0.02 ppm). For the reasons explained in the Thiabendazole Human Health Risk Assessment, the Agency believes these revised, lower tolerances are appropriate.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a ''reasonable interval'' between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is establishing an expiration date for the existing tolerances to allow these tolerances to remain in effect for a period of six months after the effective date of this final rule. After the six-month period expires, these tolerances will be reduced or revoked, as indicated in the regulatory text, and allowable residues on alfalfa forage, alfalfa hay, *Brassica* head and stem subgroup 5A, and vegetable, root (except sugarbeet), subgroup 1B must conform to the tolerances for Animal feed, nongrass, group 18; Vegetable, *Brassica,* head and stem, group 5–16; and Vegetable, root, except sugar beet, subgroup 1B. This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of thiabendazole in or on Animal feed, nongrass, group 18 at 0.01 ppm; Beet, garden, leaves at 0.01 ppm; *Brassica,* leafy greens, subgroup 4–16B at 0.01 ppm; Burdock, edible, leaves at 0.01 ppm; Carrot, leaves at 0.01 ppm; Carrot, roots at 10 ppm; Celeriac, leaves at 0.01 ppm; Chervil, turnip rooted, leaves at 0.01 ppm; Chicory, leaves at 0.01 ppm; Fruit, citrus, group 10–10 at 10 ppm; Fruit, pome, group 11–10 at 10 ppm; Kohlrabi at 0.01 ppm; Radish, oriental, leaves at 0.01 ppm; Rutabaga, leaves at 0.01 ppm; Salsify, black, leaves at 0.01 ppm; Sweet potato, tuber at 3 ppm; Vegetable, *Brassica,* head and stem, group 5–16 at 0.01 ppm; Vegetable, root, except sugar beet, subgroup 1B at 0.01 ppm; and Vegetable, tuberous and corm, subgroup 1C, except sweet potato at 10 ppm.

Additionally, the following tolerances are removed as unnecessary due to the establishment of the above tolerances: Alfalfa, forage; Alfalfa, hay; *Brassica,* head and stem, subgroup 5A; Carrot, roots, postharvest; Fruit, citrus, group 10, postharvest; Fruit, pome, group 11, postharvest; Potato, postharvest; Radish, tops; Sweet potato (postharvest to sweet potato intended only for use as seed); and Vegetable, root (except sugarbeet), subgroup 1B.

Finally, EPA is revising the tolerance expression for thiabendazole in 40 CFR 180.242(a)(1) and (2) 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. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

VI. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 18, 2021.

Catherine Aubee,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 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:
■ a. Amend paragraph (a)(1) by:
■ i. Revising the introductory text.
■ ii. In the table:
■ A. Adding the heading ''Table 1 to Paragraph (a)(1)'';
■ B. Removing the entries for ''Alfalfa, forage''; and ''Alfalfa, hay'';
■ C. Adding in alphabetical order the entries ''Animal feed, nongrass, group 18''; and ''Beet, garden, leaves'';
■ D. Removing the entry for ''*Brassica,* head and stem, subgroup 5A'';
■ E. Adding in alphabetical order the entries ''*Brassica,* leafy greens, subgroup 4–16B''; ''Burdock, edible, leaves''; ''Carrot, leaves''; and ''Carrot, roots'';
■ F. Removing the entry for ''Carrot, roots, postharvest'';
■ G. Adding in alphabetical order the entries ''Celeriac, leaves''; ''Chervil, turnip rooted, leaves''; ''Chicory, leaves''; and ''Fruit, citrus, group 10–10'';
■ H. Removing the entry for ''Fruit, citrus, group 10, postharvest'';
■ I. Adding the entry ''Fruit, pome, group 11–10'';
■ K. Removing the entry for ''Fruit, pome, group 11, postharvest'';
■ L. Adding in alphabetical order the entry ''Kohlrabi'';
■ M. Removing the entry for ''Potato, postharvest'';
■ N. Adding in alphabetical order the entry ''Radish, oriental, leaves'';
■ O. Removing the entry for ''Radish, tops'';
■ P. Adding in alphabetical order the entries ''Rutabaga, leaves''; and ''Salsify, black, leaves'';
■ Q. Removing the entry for ''Sweet potato (postharvest to sweet potato intended only for use as seed)'';
■ R. Adding in alphabetical order the entries ''Sweet potato, tuber''; ''Vegetable, *Brassica,* head and stem, group 5–16''; and ''Vegetable, root, except sugar beet, subgroup 1B'';
■ S. Removing the entry for ''Vegetable, root (except sugarbeet), subgroup 1B'';
■ T. Adding in alphabetical order the entry ''Vegetable, tuberous and corm, subgroup 1C, except sweet potato'' and
■ b. Amend paragraph (a)(2) by:
■ i. Revising the introductory text.
■ ii. In the table, adding the heading ''Table 2 to Paragraph (a)(2)''.
■ The additions and revisions 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 table 1 to paragraph (a)(1). Compliance with the tolerance levels specified to table 1 to paragraph (a)(1) is to be determined by measuring only thiabendazole in or on the commodity.

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
Alfalfa, forage [1]	0.02
Alfalfa, hay [1]	0.02
Animal feed, nongrass, group 18	0.01
* * * * * * *	
Beet, garden, leaves	0.01
Brassica, head and stem, subgroup 5A [1]	0.02
Brassica, leafy greens, subgroup 4–16B	0.01
Burdock, edible, leaves	0.01
* * * * * * *	
Carrot, leaves	0.01
Carrot, roots	10
Celeriac, leaves	0.01
Chervil, turnip rooted, leaves	0.01
Chicory, leaves	0.01
* * * * * * *	
Fruit, citrus, group 10–10	10
Fruit, pome, group 11–10	10
Kohlrabi	0.01
* * * * * * *	
Radish, oriental, leaves	0.01
Rutabaga, leaves	0.01
Salsify, black, leaves	0.01
Sweet potato, tuber	3
* * * * * * *	
Vegetable, *Brassica,* head and stem, group 5–16	0.01
* * * * * * *	
Vegetable, root, except sugar beet, subgroup 1B	0.01
Vegetable, root, except sugar beet, subgroup 1B [1]	0.02
Vegetable, tuberous and corm, subgroup 1C, except sweet potato	10
* * * * * * *	

[1] This tolerance expires on February 28, 2022.

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

TABLE 2 TO PARAGRAPH (a)(2)

* * * * *

[FR Doc. 2021–18390 Filed 8–27–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0523; FRL–5993–04–OCSPP]

Chlorpyrifos; Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 29, 2021, the United States Court of Appeals for the Ninth Circuit ordered EPA to issue a final rule concerning the chlorpyrifos tolerances by August 20, 2021. Based on the currently available data and taking into consideration the currently registered uses for chlorpyrifos, EPA is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of the Federal Food, Drug, and Cosmetic Act (FFDCA). Accordingly, EPA is revoking all tolerances for chlorpyrifos.

DATES: This final rule is effective October 29, 2021. The tolerances for all commodities expire on February 28, 2022.

Written objections, requests for hearings, or requests for a stay identified by the docket identification (ID) number EPA–HQ–OPP–2021–0523 must be received on or before October 29, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** unit in this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0523, 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.

Due to public health concerns related to COVID–19, the EPA/DC and Reading Room are closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Elissa Reaves, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 703–347–0206; email address: *OPPChlorpyrifosInquiries@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).

Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the contact listed under **FOR FURTHER INFORMATION CONTACT**.

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 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–2021–0523 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 October 29, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although at this time, EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.* At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges (OALJ) are working remotely and not able to accept filings or correspondence by courier, personal deliver, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA OALJ, a person should utilize the OALJ e-filing system, at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is