



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2015-0554; FRL-9950-05]**

### **Thiabendazole; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of thiabendazole in or on the legume vegetable group 6 and foliage of legume vegetable group 7. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also assigns an expiration date to existing tolerances for bean, dry, seed at 0.1 part per million (ppm) and soybean at 0.1 ppm as well as removes a threshold of regulation determination for seed treatment use of thiabendazole on dry pea (including field pea, pigeon pea, chickpea or lentil). Lastly, this regulation establishes a time-limited tolerance on sweet potato. The time-limited tolerance is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The time-limited tolerance will expire and be revoked on December 31, 2019.

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

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0554, 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:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## **I. General Information**

*A. Does this Action Apply to Me?*

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](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-2015-0554 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of*

*publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0554, 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 Agency's Action**

### *A. Petitioned-For Tolerances*

In the **Federal Register** of September 9, 2015 (80 FR 54257) (FRL-9933-26), 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 5F8368) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.242 be amended by establishing tolerances for residues of the fungicide thiabendazole in or on legume vegetables (succulent or dried), crop group 6 at 0.01 parts per million (ppm); foliage of legume vegetables, crop group 7, except pea, field, hay and vines at 0.01 ppm; pea, field, hay at 0.15 ppm; and pea, field, vines at 0.03 ppm. The petition also requested to amend the tolerances in 40 CFR 180.242 for residues of thiabendazole by removing the tolerances in or on bean, dry, seed at 0.1 ppm and soybean at 0.1 ppm. That document referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified levels at which the tolerances are being established by this document. The reason for these changes are explained in Unit IV.D.

*B. Thiabendazole Threshold of Regulation Determination*

In 2008, EPA established a rule codifying its determination that the use of thiabendazole as a seed treatment for dry pea using a maximum application rate of 0.075 pound of active ingredient per 100 pounds of seed did not require a tolerance because residues were below the Agency's threshold of regulation. (73 FR 1976 (Jan. 11, 2008);

see 40 CFR 180.2010). The new tolerances for residues of thiabendazole on crop group 6 legume vegetable commodities, including dry pea, and on crop group 7, foliage of legume vegetable commodities, which includes vines and hay from the legume vegetables that the Agency is establishing make the existing threshold of regulation determination unnecessary. The new tolerances cover residues on these commodities resulting from new seed treatment uses that allow for higher application rates and thus residues associated uses covered by the threshold of regulation determination are covered by the new tolerances. As a result, the Agency is removing this determination from section 180.2010.

*C. Tolerance for Use of Pesticide under Emergency Exemption*

In response to a crisis exemption request and authorization of a specific exemption request filed under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) on behalf of the North Carolina Department of Agriculture and Consumer Services for the emergency use of thiabendazole to control black rot disease on sweet potato, EPA is establishing pursuant to FFDCA section 408(l)(6) time-limited tolerances for the use of thiabendazole on sweet potato at 10 ppm with an expiration date of December 31, 2019.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of thiabendazole on sweet potato. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and the Agency decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need

to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2019, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on sweet potato after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by the time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions whether thiabendazole meets FIFRA's registration requirements for use in or on sweet potato or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance serves as a basis for registration of thiabendazole by a State for Special Local Needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than North Carolina to use this pesticide on sweet potato under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for thiabendazole, contact the Agency's Registration Division at the address provided under "FOR FURTHER INFORMATION CONTACT".

### **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 assessment 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, including the time-limited tolerance, 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.” This conclusion is based on the observation that thiabendazole was not mutagenic, but above a threshold dose it interfered with thyroid-pituitary homeostasis leading to increased thyroid stimulating hormone (TSH) stimulation of the thyroid and thyroid tumors. The chronic NOAEL (10 mg/kg/day) for non-cancer risk assessment is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation; therefore, 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: ID#16NC02 – Section 18 Specific Emergency Exemption for the Postharvest Use of Thiabendazole on Sweet Potatoes in North Carolina*” on page 32 in docket ID number EPA-HQ-OPP-2015-0554.

*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-pesticides>.

A summary of the toxicological endpoints for thiabendazole used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 25, 2014 (79 FR 57450) (FRL-9915-78).

### *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 and the tolerance being established in response to the Agency issuing a section 18 emergency exemption, 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 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). 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 2003-2008 food consumption data from the USDA's 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.* 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., *chronic exposure.*

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data calls 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 FFDCFA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute assessment, the Agency estimated the PCT for existing uses as follows:

Soybeans, 2.5%; wheat, 2.5%.

For the chronic assessment, the Agency estimated the PCT for existing uses as follows:

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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the FQPA Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model GroundWater (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 the acute dietary risk assessment, the water concentration value of 3.80 ppb was used to assess the contribution to drinking water.

For the 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 which are expected to result in the highest exposures from these antimicrobial uses: 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://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.”

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 website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is

commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* 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.

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 (UFDB). 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 at the 99.9<sup>th</sup>

percentile of exposure will occupy 68% 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 5.1% 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 or greater for all population subgroups and aggregate MOEs from the sponge use of 1,400 for children 1–2 years old and 7,000 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.* As discussed in Unit III.A., EPA is regulating chronic dietary risk, including cancer risk, with a chronic RfD that reflects a dose level below those levels at which thyroid hormone balance is impacted, which is protective of potential carcinogenic effects. Based on the lack of chronic risk, EPA concludes there is not a cancer risk from exposure to thiabendazole.

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.

Another adequate analytical method, GRM040.05A, is also available for data collection and tolerance enforcement of residues of thiabendazole and benzimidazole (free and conjugated) in/on plant commodities. Method GRM040.05A, developed by Syngenta Crop Protection, LLC, is a high performance liquid chromatography with tandem mass spectrometry detection (LC/MS/MS) method used for data collection in

crop matrices. HED has designated Method GRM040.05A as a new tolerance enforcement method.

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

### *B. International Residue Limits*

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

A comment was submitted by the Center for Food Safety and was primarily concerned about EPA's consideration of the impacts of thiabendazole on the

environment, pollinators, and endangered species. This comment is not relevant to the Agency's evaluation of safety of the thiabendazole tolerances under section 408 of the FFDCA, which requires the Agency to evaluate the potential harms to human health, not effects on the environment.

#### *D. Revisions to Petitioned-For Tolerances*

The petitioned-for tolerances did not include measurement of benzimidazole (free and conjugated) which is a residue of concern for regulatory purposes. Therefore, the petitioned-for tolerance for the vegetable, legume, group 6 at 0.01 ppm for thiabendazole only, is adjusted to 0.02 ppm to account for the combined residues of thiabendazole and benzimidazole (free and conjugated). Also, EPA concluded that the maximum levels of the combined residues of concern in/on the representative crop commodities of vegetable, foliage of legume, group 7 are within 5x, and that a crop group 7 tolerance level of 0.20 ppm is more appropriate than the petitioned-for separate tolerances for pea, field, hay; pea, field, vines; and vegetable, foliage of legume, group 7, except pea, field, hay and vines.

#### *E. International Trade Considerations*

In this rulemaking, EPA is adding an expiration date of [*insert date six months from the publication*] to the existing tolerances for bean, dry, seed at 0.1 ppm and soybean at 0.1 ppm. These tolerances were based on foliar uses of thiabendazole which are no longer registered and Syngenta requested that these tolerances be removed as part of the petition and notice of filing (NOF). The seed treatment uses on dry bean seed and soybean is now covered by the tolerance being established on vegetable, legume, group 6

at 0.02 ppm. This new tolerance is lower than some existing MRLs on these commodities in Europe and other countries.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures Agreement, EPA notified the WTO of the request to revise these tolerances on September 9, 2015, as WTO notification G/SPS/N/USA/2779. In this action, EPA is allowing the existing higher tolerances to remain in effect for 6 months following the publication of this rule in order to allow a reasonable interval for producers in exporting countries to adapt to the requirements of these modified tolerances. On *[insert date 6 months following date of publication in the **Federal Register**]*, those existing higher tolerances will expire, and the new reduced tolerances for vegetable, legume, group 6 at 0.02 ppm will remain to cover residues of thiabendazole on those commodities. Before that date, residues of thiabendazole on those commodities would be permitted up to the higher tolerance levels; after that date, residues of thiabendazole on vegetable, legume, group 6 will need to comply with the new lower tolerance levels. This reduction in tolerance is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods.

## **V. Conclusion**

Therefore, tolerances are established for residues of thiabendazole in or on vegetable, foliage of legume, group 7 at 0.20 ppm and vegetable, legume, group 6 at 0.02 ppm. The Agency is also adding an expiration date of *[insert date six months from the date of publication in the **Federal Register**]* to the existing tolerances for bean, dry, seed at 0.1 ppm and soybean at 0.1 ppm. Residues of thiabendazole will be covered by these

higher tolerances until the expiration date, after which time, they will need to comply with the lower tolerance being established today on the vegetable, legume, group 6 at 0.02 ppm. The tolerance for group 6 without a time limitation supersedes the existing section 18 time-limited tolerance for “pea, succulent shelled”; therefore, the Agency is removing that section 18 tolerance.

The Agency is also removing the threshold of regulation determination for thiabendazole from 180.2010 because it is no longer necessary. Lastly, this regulation additionally establishes a time-limited tolerances for residues of thiabendazole in or on sweet potato at 10 ppm.

## **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 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 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 26, 2016.

Michael Goodis,

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

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

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

2. In § 180.242;

a. Revise the entries “bean, dry, seed” and “soybean” to the table in paragraph (a)(1);

b. Add alphabetically the entries “Vegetable, foliage of legume, group 7” and “Vegetable, legume, group 6” to the table in paragraph (a)(1)

c. Remove the entry for “Pea, succulent shelled” from the table in paragraph (b);

d. Add alphabetically the entry “sweet potato” to the table in paragraph (b).

The additions and revisions read as follows:

**§ 180.242 Thiabendazole; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
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****	***
Bean, dry, seed <sup>2</sup>	0.1
****	***
Soybean <sup>2</sup>	0.1
****	***
Vegetable, foliage of legume, group 7	0.20
Vegetable, legume, group 6	0.02
****	***

<sup>2</sup> This tolerance expires on [*insert date 6 months after date of publication in the **Federal Register***].

(b) \* \* \*

Commodity	Parts per million	Expiration Date
Sweet potato	10	December 31, 2019

\* \* \* \* \*

### **§180.2010 [Removed and Reserved]**

3. Section 180.2010 is removed and reserved.

[FR Doc. 2016-21753 Filed: 9/21/2016 8:45 am; Publication Date: 9/22/2016]