the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 2, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (*see* section 307(b)(2)).

**List of Subjects**

*40 CFR Part 52*

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements.

*40 CFR Part 81*

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: July 29, 2010.

**Jeff Scott,**

*Acting Regional Administrator, Region 9.*

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

## PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

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

### Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(380) to read as follows:

**§ 52.220 Identification of plan.**

* * * * *

(c) * * *

(380) The following plan was submitted on July 14, 2010, by the Governor's Designee.

(i) Incorporation by reference.

(A) Great Basin Unified Air Pollution Control District.

(*1*) "Board Order #080128–01 Requiring the City of Los Angeles to Undertake Measures to Control PM–10 Emissions from the Dried Bed of Owens Lake," including Attachments A–D, adopted February 1, 2008, and included as Appendix C to the "2010 PM–10 Maintenance Plan and Redesignation Request for the Coso Junction Planning Area," adopted May 17, 2010.

(ii) Additional materials.

(A) Great Basin Unified Air Pollution Control District (GBUAPCD).

(*1*) Non-regulatory portions of "The 2010 PM–10 Maintenance Plan and Redesignation Request for the Coso Junction Planning Area" (the 2010 Plan), including Appendices A, B, and D, adopted May 17, 2010.

(*2*) Letter dated June 10, 2010 from Theodore D. Schade, GBUAPCD, to Deborah Jordan, United States Environmental Protection Agency Region 9, regarding Coso Junction PM–10 Contingency Measures.

(*3*) GBUAPCD Board Resolution 2010–01, dated May 17, 2010, adopting the 2010 Plan.

(B) California Air Resources Board (CARB).

(*1*) CARB Resolution 10–25, dated June 24, 2010, adopting the 2010 Plan.

## PART 81—[AMENDED]

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

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

### Subpart C—[Amended]

■ 4. Section 81.305 is amended in the table for "California–PM–10" by revising the entry under Inyo County for the "Coso Junction planning area" to read as follows:

**§ 81.305 California.**

* * * * *

CALIFORNIA—PM–10

| Designated area | Designation | | Classification | |
|---|---|---|---|---|
| | Date | Type | Date | Type |
| Inyo County | | | | |
| Coso Junction planning area ..... That portion of Inyo County contained within Hydrologic Unit #18090205. | October 4, 2010 ..... | Attainment. | | |
| * * | * | * * | * | * |

* * * * *

[FR Doc. 2010–21960 Filed 9–2–10; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[EPA–HQ–OPP–2009–0910; FRL–8842–7]**

## Thiabendazole; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of thiabendazole, and its metabolites, benzimidazole (free and conjugated), [2-(4-thiazolyl) benzimidazole], in or on corn. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective September 3, 2010. Objections and requests for hearings must be received on or before November 2, 2010, 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:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0910. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are

available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Janet Whitehurst, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6129; e-mail address: *whitehurst.janet@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr*.

### *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–2009–0910 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 2, 2010. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0910, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 6, 2010 (75 FR 35804) (FRL–8831–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7730) by Syngenta Crop Science. The petition requested that 40 CFR 180.242 be amended by establishing tolerances for residues of the fungicide thiabendazole, and its metabolites, benzimidazole (free and conjugated), [2-(4-thiazolyl) benzimidazole], in or on corn grain and other corn commodities at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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

### *A. Toxicological Profile*

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

The target organs for thiabendazole toxicity are the liver and thyroid. Effects to these organs were observed in multiple studies and across species. Thiabendazole causes thyroid tumors in male rats through an established non-linear mode of action involving perturbation of thyroid hormone synthesis. Accordingly, thiabendazole is classified as "not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." There is no evidence of neurotoxicity in the existing database,

and in developmental and reproductive studies, effects to offspring are observed only at doses toxic to the parents. There are no effects seen in the toxicity database that would be attributable to a single exposure of thiabendazole. The Agency is regulating chronic dietary risk with a chronic RfD at a dose below which thyroid hormone balance is not impacted and consequently is protective of potential carcinogenic effects.

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 entitled "Thiabendazole Human Health Risk Assessment for Seed Treatment Use on Corn," pages 6–11 in docket ID number EPA–HQ–OPP–2007–0546.

*B. Toxicological Points of Departure/Levels of Concern*

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

A summary of the toxicological endpoints for thiabendazole used for human risk assessment is shown in the following Table 1.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAZBENDAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

| Exposure/Scenario | Point of Departure | Uncertainty/FQPA Factors | Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|---|
| Acute dietary (general population including females 13–49 years) | No effect attributable to a single dose seen in the database | | | |
| Chronic dietary | NOAEL = 10 mg/kg/day | $UF_A$ = 3x<br>$UF_H$ = 10x<br>FQPA = $UF_{DB}$ = 10x | cRfD = 0.033 mg/kg/day<br>cPAD = 0.033 mg/kg/day | 2-Year Feed/Chronic Carcinogenicity in the Rat<br>LOAEL = 30 mg/kg/day based on decreased body weight gains and histopathological changes in liver and thyroid |
| Incidental oral (ST/IT) | NOAEL = 10 mg/kg/day | $UF_A$ = 3x<br>$UF_H$ = 10x<br>FQPA = $UF_{DB}$ = 10x | LOC for MOE = 300 | Subchronic oral toxicity study - rat<br>LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid |
| Dermal short-term (1-30 days) DAF = 0.5% | NOAEL= 10 mg/kg/day | $UF_A$ = 3x<br>$UF_H$ = 10<br>FQPA = $UF_{DB}$ = 10x | Occupational and residential LOC for MOE = 300 | Subchronic oral toxicity study - rat<br>LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid |
| Inhalation short-term (1–30 days) | NOAEL = 10 mg/kg/day | $UF_A$ = 3x<br>$UF_H$ =10x<br>FQPA = $UF_{DB}$ = 10x | Occupational LOC for MOE = 300 | Subchronic oral toxicity study - rat<br>LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid |

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIAZBENDAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

| Exposure/Scenario | Point of Departure | Uncertainty/FQPA Factors | Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|---|
| Dermal intermediate-term (1-6 mos) DAF = 0.5%* | NOAEL = 10 mg/kg/day | $UF_A$ = 3x<br>$UF_H$ = 10x<br>FQPA = $UF_{DB}$ = 10x | Occupational LOC for MOE = 300 | Subchronic oral toxicity study - rat<br>LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid |
| Inhalation intermediate-term (1-6 mos) | NOAEL = 10 mg/kg/day | $UF_A$ = 3x<br>$UF_H$ = 10x<br>FQPA = $UF_{DB}$ = 10x | Occupational LOC for MOE = 300 | Subchronic oral toxicity study - rat<br>LOAEL = 40 mg/kg/day based on reduced body weight gains and histopathological changes in the bone marrow, liver and thyroid |
| Cancer (all routes) | Not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis | | | |

$UF_A$ = extrapolation from animal to human (interspecies).
$UF_H$ = potential variation in sensitivity among members of the human population (intraspecies).
$UF_{DB}$ = to account for the absence of data or other data deficiency.
FQPA SF = Food Quality Protection Act Safety Factor.
PAD = population adjusted dose (a = acute, c = chronic).
RfD = reference dose. MOE = margin of exposure.
LOC = level of concern.

The overall composite uncertainty factor for assessing thiabendazole risk is 300X. That is based on a 10X for intraspecies variability among humans, 3X for interspecies pharmacokinetic differences between humans and rats, and 10X for FQPA safety factor for database uncertainty. The 3X interspecies factor was chosen because the endpoint used for the Point of Departure is a thyroid effect and adult rats are known to be more sensitive pharmacodynamically to thyroid toxicants than humans. Focusing on the thyroid effects will produce the most protective PAD despite the fact that a reduced interspecies factor is appropriate as to this effect.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiabendazole, EPA considered exposure under the petitioned-for tolerances as well as all existing thiabendazole tolerances in 40 CFR 180.242. EPA assessed dietary exposures from thiabendazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No such effects were identified in the toxicological studies for thiabendazole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* Thiabendazole chronic dietary exposure assessments were conducted using the DEEM-FCID™ (ver. 2.03) which incorporates consumption data from the United States Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII) (1994–1996 and 1998). In estimating residue levels on food, EPA assumed residues in corn were at tolerances levels. For other commodities, EPA estimated residue levels based on residue monitoring data. EPA also used percent crop treated (PCT) data on some commodities.

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

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

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The following PCT were used in the assessment:

- Apple 30%.
- Orange 20%.
- Pear 45%.
- Potato 1%.
- Soybeans 1%.
- Strawberry 6.3% imported.
- Sweet potato 1%.
- Wheat 1%.

In most cases, EPA uses available data from USDA/National Agricultural

Statistics Service (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 above 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.

iv. *Cancer*. EPA has concluded that thiabendazole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

A Tier 2 drinking water assessment was conducted for thiabendazole in surface water and Tier 1 in ground water for the proposed new seed treatment product on corn. The annual mean concentration of 0.0000048 ppm was used in the chronic dietary exposure analysis. Drinking water concentrations from ground water sources were estimated, but were lower than that estimated concentration from surface water, so the estimated concentration from surface water sources was used in the dietary exposure analysis.

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 the following uses that could result in residential exposures: paint and sponges. These residential uses have been assessed and aggregated with the food and water exposures. EPA assumed that 5% of the thiabendazole on sponges is transferred to the surface being wiped (such as counters, tables, floors) each day. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

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

*D. Safety Factor for Infants and Children*

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

2. *Prenatal and postnatal sensitivity*. 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.

3. *Conclusion*. EPA is retaining a FQPA factor of 10X based on the following findings:

i. The database for thiabendazole is complete except for a developmental thyroid study and data needed for the new data requirements including an immunotoxicity study and the neurotoxicity screening battery. Pending the outcome of the developmental thyroid toxicity study, there is uncertainty with respect to the effect of thiabendazole in developing offspring. 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, the absence of the developmental thyroid study raises concern whether infants and children are sufficiently protected from developmental effects. The developmental thyroid toxicity study will better address this concern than a developmental neurotoxicity study. The absence of neurotoxicity studies (acute, subchronic, and developmental) raise relatively low concern because: (1) Thiabendazole has shown no indication of neurotoxicity in relevant studies, and; (2) to the extent that thiabendazole's thyroid effects may have neurological effects on the young, the nature of the thyroid effects (and the potential for any resulting neurological effects on the young) will be addressed by the developmental thyroid study. The

absence of the immunotoxicity study raises relatively low concern because there are no indications in the available studies that organs associated with immune function, such as the thymus and spleen, are affected by thiabendazole.

ii. There is no evidence that thiabendazole results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on PCT and anticipated residues primarily from Pesticide Data Program (PDP) data and some tolerance-level residues. These data are reliable and will not underestimate the exposure and risk. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to thiabendazole in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. 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 population adjusted dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, 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. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, thiabendazole is not expected to pose an acute risk.

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 1.4% of the cPAD occupied for the U.S. population. The most highly exposed subpopulation was all infants at 4.6% cPAD.

3. *Short- and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). To assess short-term and intermediate-term aggregate risk likely to result from the new and existing thiabendazole uses, EPA combined average food and water exposures with estimates of residential exposure for both adult painters and adult females and small children exposed to surfaces cleaned with treated sponges.

No risks of concern were seen for adult painters. A potential risk of concern would be the use of thiabendazole treated sponges, if the Agency assumes that 100% of the thiabendazole on a treated sponge is transferred to surfaces each day. It is very unlikely that a sponge would release all of the thiabendazole used to treat it in a single day, and the user would use a new sponge every day. Since this is a very unrealistic assumption, a second aggregate assessment was conducted 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. This assumption is still conservative because: (1) Sponges will generally be used much longer than 20 days; (2) it is very unlikely that 100% of the thiabendazole would be released from the sponge in such a short period given that environmental fate data show thiabendazole to have low water solubility indicating that thiabendazole will bind strongly to the sponge; and (3) it is very unlikely that 100% of any released thiabendazole would be transferred to countertops because this assumption does not account for any thiabendazole that is washed down the sink or that normally degrades. With this assumption, none of the aggregate exposures represent risks of concern, as all MOEs are greater than the target MOE of 300.

A summary of the short-term and intermediate-term aggregate risk for thiabendazole used in the human risk assessment is shown in Tables 2 and 3 of this unit.

TABLE 2.—SHORT-TERM AND INTERMEDIATE-TERM AGGREGATE RISK FOR RESIDENTIAL PAINTER

| Population Subgroup | Average Food and Water Exposure (mg/kg/day) | Residential Exposure[1] (mg/kg/day) | Aggregate MOE (food and residential)[2] |
|---|---|---|---|
| U.S. Population | 0.000451 | 0.0046 | 2000 |
| Youth (13–19 yrs) | 0.000289 | 0.0046 | 2000 |
| Adults (20–49 yrs) | 0.000308 | 0.0046 | 2000 |
| Adults (50 + yrs) | 0.000331 | 0.0046 | 2000 |
| Females (13–49 yrs) | 0.000333 | 0.0046 | 2000 |

[1] Residential Exposure = Dermal exposure + Inhalation Exposure.
[2] (Avg Food Aggregate MOE = NOAEL (10 mg/kg/day and Water Exposure + Residential Exposure).

TABLE 3.–SHORT-TERM AND INTERMEDIATE-TERM AGGREGATE RISK CALCULATIONS FOR SPONGE USAGE

| Population Subgroup | Average Food and Water Exposure (mg/kg/day) | Residential Exposure[1] (mg/kg/day) | Aggregate MOE (food and residential)[2] |
|---|---|---|---|
| Fraction of Thiabendazole Transferred Daily From Sponge to Surface = 100% | | | |
| Children (3–5 yrs) | 0.001252 | 0.08 | 120 |
| Females (13–49 yrs) | 0.000333 | 0.02 | 500 |
| Fraction of Thiabendazole Transferred From Sponge to Surface = 5% | | | |
| Children (3–5 yrs) | 0.001252 | 0.004 | 2300 |
| Females (13–49 yrs) | 0.000333 | 0.001 | 4500 |

[1] Residential Exposure = Dermal exposure + Inhalation Exposure.
[2] Aggregate MOE = NOAEL (10 mg/kg/day) ÷ (Average Food & Water Exposure plus Residential Exposure).

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

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

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (spectrophotofluorometric, Methods I, A, B and C) is available to enforce the tolerance expression. In all of the methods, residues are extracted with ethyl acetate, and the extracts are purified by washing with dilute NaOH and/or HCl.

An high-performance liquid chromatography (HPLC) method with fluorescence detection (FLD) is available for the enforcement of tolerances for residues of free and conjugated benzimidazole. This method is listed in the U.S. EPA Index of Residue Analytical Methods under thiabendazole as Study No. 93020 (MRID 43328302).

In addition, the analytical method used in this petition may be used for enforcement. This sample is extracted and hydrolized and analyzed by liquid chromatography/mass spectrometry (LC/MS/MS). The method limit of quantation (LOQ) is 0.01 ppm, and the limit of detection (LOD) is 0.004 ppm. The method was adequately validated using samples of field corn forage, grain, and stover, and sweet corn forage and K+CWHR fortified with each analyte at 0.01, 0.05, and 0.1 ppm. Acceptable concurrent recovery data for the method were also submitted and achieved.

### *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 U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for thiabendazole.

## V. Conclusion

Therefore, tolerances are established for residues of thiabendazole, and its metabolites, benzimidazole (free and conjugated), [2-(4-thiazolyl) benzimidazole], in or on corn grain and other corn commodities at 0.01 ppm.

## VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply

to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

### VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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 20, 2010.

**Lois Rossi,**

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

■ Therefore, 40 CFR chapter I is amended as follows:

## PART 180—[AMENDED]

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

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

■ 2. Section 180.242 is amended by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

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

(a) * * * (1) * * *

| Commodity | Parts per million | Expiration/ Revocation Date |
|---|---|---|
| * * | * * | * |
| Corn, field, forage | 0.01 | None |
| Corn, field, grain | 0.01 | None |
| Corn, field, stover | 0.01 | None |
| Corn, pop, forage | 0.01 | None |
| Corn, pop, grain | 0.01 | None |
| Corn, pop, stover | 0.01 | None |
| Corn, sweet, forage | 0.01 | None |
| Corn, sweet, kernels plus cop with husks removed | 0.01 | None |
| Corn, sweet, stover | 0.01 | None |
| * * | * * | * |

* * * * *

[FR Doc. 2010–22121 Filed 9–2–10; 8:45 am]

**BILLING CODE 6560–50–S**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 64

**[CG Docket No. 03–123; DA 10–1235]**

### Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; extension of waiver.

**SUMMARY:** In this document, the Commission extends for an additional year current waivers of certain Telecommunications Relay Services (TRS) mandatory minimum standards for Video Relay Service (VRS) and Internet Protocol Relay (IP Relay). The waived TRS mandatory minimum standards are: One-line voice carry over (VCO); VCO-to-teletypewriter (TTY); VCO-to-VCO; one-line hearing carry over (HCO); HCO-to-TTY; HCO-to-HCO; call release; speech-to-speech (STS); pay-per-call (900) calls; types of calls; and equal access to interexchange carriers requirements. The Commission also extends for one year a requirement for default Internet-based TRS providers that are unable to meet such standards for newly-registered Internet-based TRS users who port their customer premises equipment (CPE) from a former default provider. The Commission extends the waivers for one year because the record demonstrates that it is technologically infeasible for VRS and IP Relay providers to offer these services at this time. All of these waivers are conditioned on the filing of a report, due April 16, 2011, addressing whether it is necessary for the waivers to remain in effect.

**DATES:** DA 10–1235 became effective on June 30, 2010. The waivers of certain TRS mandatory minimum standards for VRS and IP Relay will expire on July 1, 2011, or until the Commission addresses pending petitions regarding CPE portability, which ever comes first.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554. Parties may submit documentation related to the waivers, identified by [CG Docket No. 03–123 and/or DA 10–1235], by mail, to Dana Wilson, Consumer and Governmental Affairs Bureau, Disability Rights Office, Room 3–C418.

**FOR FURTHER INFORMATION CONTACT:** Gregory Hlibok, (202) 559–5158 (voice/videophone), or e-mail *Gregory.Hlibok@fcc.gov*.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's document DA 10–1235, adopted June 30, 2010, released June 30, 2010 extending certain waivers for TRS mandatory minimum standards to July 1, 2011. The full text of document DA 10–1235, and copies of any subsequently filed documents in this matter, will be available for public inspection and copies during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. DA 10–1235, and copies of subsequently filed documents in this matter also may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Customers may contact the Commission's duplicating contractor at its Web site, *http://www.bcpiweb.com* or by calling 1–800–378–3160.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY). The Commission's document DA 10–1235 can also be downloaded in Word and Portable Document Format (PDF) at *http://www.fcc.gov/cgb/dro.trs.html*.

### Synopsis

*One-line VCO, VCO-to-TTY, and VCO-to-VCO.* One-line VCO is a type of traditional TTY-based TRS that can be used by persons with a hearing disability who can speak. The VCO user speaks directly to the other party to the call, and the CA types the response back