November 29, 2007, November 25, 2008, April 23, 2010 and November 19, 2010, to discontinue the vehicle inspection and maintenance (I/M) program in Clark and Floyd Counties. The submittal also includes Indiana's demonstration that eliminating the I/M programs in Clark and Floyd Counties will not interfere with the attainment and maintenance of the ozone NAAQS and the fine particulate NAAQS and with the attainment and maintenance of other air quality standards and requirements of the CAA. We are further approving Indiana's request to modify the SIP such that I/M is no longer an active program in these areas and is instead a contingency measure in this area's maintenance plan.

[FR Doc. 2011–10323 Filed 4–28–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0308; FRL–8869–1]

Metiram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metiram in or on bananas and wine grapes. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 29, 2011. Objections and requests for hearings must be received on or before June 28, 2011, 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–2005–0308. 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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; e-mail address: *ertman.andrew@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.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–2005–0308 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 June 28, 2011. 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–2005–0308, 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** issue of November 30, 2005 (70 FR 71829) (FRL–7747–2), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E6006) by BASF Corporation, 26 Davis Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide metiram: A mixture of 5.2 parts by weight of ammoniates of ethylenebis(dithiocarbamato) zinc with 1 part by weight ethylenebis(dithiocarbamic acid) bimolecular and trimolecular cyclic anhydrosulfides and disulfides, calculated as zinc ethylenebisdithiocarbamate in or on

imported bananas (whole fruit) at 5.0 parts per million (ppm) and grapes at 7.0 ppm. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. BASF subsequently revised their petition by requesting that the tolerances be set for banana at 3.0 ppm and for grape wine at 5.0 ppm.

In the **Federal Register** issue of September 16, 2009, (74 FR 47507) (FRL–8431–4) in a document titled "Mancozeb, Maneb, Metiram, and Thiram; Proposed Tolerance Actions," EPA proposed:

1. Revising the existing tolerances for apple and potato.

2. Adding a tolerance for apple, pomace, wet.

3. Revising the tolerance expression in § 180.217. The reasons for these changes are explained in Unit V.D.

EPA did not receive comments on the **Federal Register** notice of November 30, 2005, but comments were received on the **Federal Register** proposed rule of September 16, 2009. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *."

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

Metiram is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides that also includes the related active ingredients mancozeb and maneb. Mancozeb, maneb, and metiram are all metabolized to ethylenethiourea (ETU) in the body and all degrade to ETU in the environment. Therefore, EPA has considered the aggregate or combined risks from food, water, and non-occupational exposure resulting from metiram alone and ETU from all sources (*i.e.,* the other EBDC fungicides) for this action.

In response to the petitions submitted to establish tolerances for residues of metiram on bananas and grapes, EPA completed two risk assessments in 2007: A metiram risk assessment which considered all existing and proposed uses for metiram and an ETU risk assessment that considered exposure to ETU from all sources (mancozeb, maneb, and metiram) for all existing and proposed uses.

Although the 2007 metiram review showed risks that were acceptable, the 2007 ETU review demonstrated unacceptable cancer risks, therefore preventing the Agency from acting on the petition for bananas and grapes. The Agency worked to refine the cancer risk assessment for ETU. A refined cancer risk assessment for ETU from all sources has been completed and the Agency is now prepared to act on the proposed tolerances for bananas and wine grapes. Because the 2010 ETU review dealt strictly with refining the cancer risk, the Agency will be relying on three risk assessments to support this tolerance document. These assessments are as follows:

- A 2007 risk assessment for metiram for acute, chronic, and cancer risk (refer to the risk assessment in docket ID number EPA–HQ–OPP–2005–0308 titled "Metiram: Human Health Risk Assessment for PP#9E6006. Petition for the Establishment of Import Tolerances on Grapes and Bananas").
- A 2007 risk assessment for ETU for acute, short-term, intermediate-term, and chronic risk (refer to the risk assessment in docket ID number EPA–HQ–OPP–2005–0308 titled "Ethylenethiourea (ETU) from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU").
- A 2010 addendum to the 2007 ETU assessment for cancer risk (refer to the risk assessment in docket ID number EPA–HQ–OPP–2005–0308 titled "Addendum to the Aggregate Human Health Risk Assessment of the Common Metabolite/Degradate Ethylene Thiourea (ETU) to Support New Tolerances on Imported Grapes and Bananas for Metiram and for New Tolerances for Mancozeb on Almonds, Broccoli, Cabbage, Lettuce, and Peppers").

In the **Federal Register** issue of April 16, 2010 (75 FR 19967) (FRL–8822–2), the voluntary cancellation of the last product containing maneb registered for use in the United States was announced by the Agency. Therefore, it is important to note that since all products for maneb have been cancelled and there are limited existing stocks for maneb still in the channels of trade, the risk assessments for ETU likely overestimates the exposures to this common metabolite. EPA's assessment of exposures and risks associated with metiram and ETU 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. In addition to evaluating metiram, EPA also evaluated the risks of ETU, a contaminant, metabolite, and degradation product of metiram and the other EBDC group of fungicides, which includes the related active ingredients mancozeb and maneb.

1. *Metiram.* Metiram is not acutely toxic via the oral, dermal, or inhalation routes of exposure, nor is it a skin or eye irritant. It is, however, a strong-to-severe skin sensitizer. The thyroid is a target organ for metiram. Thyroid effects observed in subchronic studies in rats include increased thyroid weights, increased thyroid stimulating hormone (TSH), and decreased T_4 (serum thyroxin) values. Metiram degrades and/or is metabolized to ETU. In oral rat metabolism studies with radiolabelled metiram and other EBDCs, an average 7.5% *in vivo* metabolic conversion of EBDC to ETU occurred, on a weight-to-weight basis. Metabolism data indicate metiram does not bio-accumulate.

The nervous system is a target for metiram. Neurotoxic signs and neuropathology have been observed in subchronic studies in rats following oral dosing with metiram. Signs of neurotoxicity occurred after 2 weeks of dosing, including reduced forelimb grip strength, hind limb paralysis, muscle wasting, and ataxia. Neuropathology findings indicated decreased areas of myelinated axons in the sciatic, sural, and tibial nerves.

Metiram has been tested in a series of *in vitro* and *in vivo* genotoxicity assays. Metiram did not cause bacterial gene mutation, but there was evidence of mammalian gene mutation in two studies. The genotoxic effect was not considered to be related to the metabolism of metiram to ETU.

Metiram degrades and/or metabolizes to ETU which causes thyroid tumors; therefore, EPA has historically attributed metiram's potential for carcinogenicity to the formation of ETU, which is classified as a probable human carcinogen. The Agency has used the cancer potency factor (Q_1*) of 0.0601 (milligram/kilogram/day (mg/kg/day) ^{1}) for ETU (based on liver tumors in female mice) for risk assessment.

Developmental toxicity was observed for metiram in the rat (increased incidence of post-implantation loss, decreased litter size, and decreased litter weight) at a dose level where minimal maternal toxicity (decreased body-weight gains) was observed. However, there is low concern for the qualitative susceptibility observed in the rat study since the dose response was well characterized; there was a clear NOAEL (no observed adverse effect level)/LOAEL (lowest observed adverse effect level) for maternal and developmental toxicity; and the doses selected for risk assessment were based on neurotoxicity and address concerns for developmental toxicity and thyroid toxicity, which occurred at higher doses. Additionally, in a rabbit developmental study, in which the maternal animals were adequately assessed, maternal toxicity observed included abortions and decreased body-weight gains.

2. *ETU.* The thyroid is a target organ for ETU; thyroid toxicity in subchronic and chronic rat, mouse, and dog studies included decreased levels of T_4, increases or decreases in T_3, compensatory increases in levels of TSH, increased thyroid weight, and microscopic thyroid changes, chiefly hyperplasia. Overt liver toxicity was observed in one chronic dog study. ETU is classified as a probable human carcinogen based on liver tumors in female mice.

Developmental defects in the rat developmental study were similar to those seen with metiram, and included hydrocephaly and related lesions, skeletal system defects, and other gross defects. These defects showed increased susceptibility to fetuses because they occurred at a dose which only caused decreased maternal food consumption and body weight (BW) gain.

Specific information on the studies received and the nature of the adverse effects caused by metiram as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "Metiram: Human Health Risk Assessment for PP#9E6006. Petition for the Establishment of Import Tolerances on Grapes and Bananas" on pages 18–21 in docket ID number EPA–HQ–OPP–2005–0308.

Additionally, specific information on the studies received and the nature of the toxic effects caused by ETU as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "Ethylenethiourea (ETU) from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU" on pages 16–17 in docket ID number EPA–HQ–OPP–2005–0308.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for metiram used for human risk assessment is shown in Table 1 of this unit.

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

Exposure/scenario	POD and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	There was no appropriate endpoint attributable to a single dose in the available toxicity studies.		
Acute dietary (Females 13–50 years of age).	NOAEL = 10 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 10x UF_{DB}	Acute RfD = 0.01 mg/kg/day ..... aPAD = 0.01 mg/kg/day	Developmental Toxicity (Rabbit). LOAEL = 40 mg/kg/day, based on abortions.
Chronic dietary (All populations)	NOAEL = 0.4 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 10x UF_{DB}	Chronic RfD = 0.0004 mg/kg/day cPAD = 0.0004 mg/kg/day	Subchronic Oral Toxicity (Rat, bridging study). LOAEL = 6.7 mg/kg/day based on decreased forelimb grip strength.

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

Exposure/scenario	POD and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhalation) ..	Q_1* = 6.01x10 ^{2} (mg/kg/day) ^{1} Metiram is classified as Group B2 carcinogen (probable human carcinogen); use low-dose extrapolation for human risk assessment, based on ETU. Quantitative cancer risk assessments for metiram and other EBDCs are based on exposure to the ETU degradate.		

EBDC = ethylene bisdithiocarbamate. ETU = ethylenethiourea. FQPA SF = Food Quality Protection Act Safety Factor. LOC = level of concern. LOAEL = lowest observed adverse effect level. Mg/kg/day = milligram/kilogram/day. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). POD = point of departure. Q_1* = cancer potency factor. RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

A summary of the toxicological endpoints for ETU used for human risk assessment is discussed in Unit IV.B. of the final rule published in the **Federal Register** issue of August 18, 2010 (75 FR 50902) (FRL–8841–1).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metiram, EPA considered exposure under the petitioned-for tolerances as well as all existing metiram tolerances in 40 CFR 180.217. In evaluating dietary exposure to ETU, EPA considered exposure under the petitioned-for tolerances discussed in this document as well as all existing and proposed uses of the EBDC group of fungicides (mancozeb, maneb, and metiram,) including the uses for which there are maneb tolerances even though all maneb registrations have been cancelled. EPA assessed dietary exposures from metiram and ETU 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 metiram and ETU. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and the 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII).

a. *Metiram.* The following assumptions were made for the acute exposure assessments: The Agency conducted a refined probabilistic assessment using a distribution of either field trial or monitoring data for commodities considered to be either non-blended or partially blended. Average field trial or monitoring residues were used for blended commodities. Maximum percent crop treated (PCT) and relevant processing factors were also included in the assessment. The PCT information is not available for the proposed import tolerances; however, percent imported factors were incorporated for wine grapes. It was assumed 100% of imported wine grapes would contain residues of metiram. EPA assumed 100% of bananas are imported and would contain residues of metiram.

b. *ETU.* The following assumptions were made for the acute exposure assessments: The Agency conducted a highly refined, probabilistic acute dietary assessment incorporating maximum PCT information for new and existing EBDC uses, field trial, or monitoring data for existing EBDC uses, and processing and cooking factors. It was assumed that PCT of total EBDCs could not exceed 100%; and if commodities were treated with more than one EBDC in a season, the combination of EBDC applications leading to the highest total exposure potential was assumed to occur.

The PCT was estimated by summing the PCT for the individual EBDCs. For residue values, EPA used either market basket survey data or field trial data. For a few commodities mancozeb-derived ETU from mancozeb field trial data were used for both mancozeb and maneb because maneb field trial data were not available and application rates were sufficiently similar to estimate maneb-derived ETU values.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII.

a. *Metiram.* To estimate chronic dietary exposure and risk to metiram per se, a refined assessment was conducted using average field trial or average monitoring residues. In addition, average PCT and relevant processing factors were included. The PCT information is not available for the proposed import tolerances; however, percent imported factors were incorporated for bananas and wine grapes. It was assumed 100% of imported wine grapes would contain residues of metiram. EPA assumed 100% of bananas are imported and would contain residues of metiram.

b. *ETU.* Chronic anticipated residues were calculated from field trial data on EBDCs or monitoring data for ETU. Averages of the field trial and market basket survey residues were used. EPA also used PCT data.

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

Metiram degrades and/or metabolizes to ETU which causes thyroid tumors; therefore, EPA has historically attributed metiram's potential for carcinogenicity to the formation of ETU, which is classified as a probable human carcinogen. The Agency has used the Q_1* of 0.0601 (mg/kg/day) ^{1} for ETU (based on liver tumors in female mice) for risk assessment. Therefore, cancer risk from exposure to metiram has been calculated by estimating exposure to metiram-derived ETU and using the Q_1* for ETU. The same approach has been taken for the other EBDCs. EPA's estimated exposure to metiram-derived ETU and ETU from other EBDCs included ETU residues found in food as well as ETU formed by metabolic conversion on parent metiram in the body (conversion rate of 0.075).

EPA relied on the same estimates used for the chronic exposure assessment in assessing cancer risk.

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 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.

In the 2007 acute risk assessment for metiram, the Agency estimated the PCT for existing uses as follows: Apple, 25% and potatoes, 10%.

In the 2007 chronic risk assessment for metiram the Agency estimated the PCT for existing uses as follows: Apple, 15% and potatoes, 10%.

In the 2007 acute risk assessment for ETU the Agency estimated the PCT for existing uses as follows: Apple, 65%; asparagus, 30%; barley, 2%; beans, dried, 2.5%; beets, sugar, 15%; Brussels sprouts, 32%; cantaloupe, 12.5%; carrot, 2.5%; casaba, 12.5%; cauliflower, 15%; celery, 12%; chickpea, 2.5%; Chinese waxgourd, 15%; chive, 20%; collards, 10%; corn, field, 2.5%; corn, sweet, 17.5%; cottonseed, oil, 3.5%; cranberry, 31%; cucumber, 40%; eggplant, 65%; fennel, Florence, 12%; fig, 1%; garlic, 25%; grape, 81.5%; guar, seed, 1%; honeydew melon, 12.5%; kale, 5%; leek, 25%; mustard greens, 5%; oat, 2%; onion, dry bulb, 85%; peanut, 3.5%; pear, 55%; potato, 85%; pumpkin, 15%; rice, 2.5%; rye grain, 2%; squash, summer, 35%; squash, winter, 0%; tomato, fresh, 80%; tomato, processed, 25%; turnip tops, 86%; walnut, 37.5%; watermelon, 55%; and wheat, grain, 3.5%.

For the 2007 chronic risk assessment for ETU the Agency estimated the PCT for existing uses as follows: Apple, 42%; asparagus, 21%; barley, 2%; beans, dried, 1%; beets, sugar, 6%; Brussels sprouts, 21%; cantaloupe, 6%; carrot, 8%; casaba, 6%; cauliflower, 5%; celery, 12%; chickpea, 1%; Chinese waxgourd, 5%; chive, 10%; collards, 10%; corn, field, 1%; corn, sweet, 11%; cottonseed, oil, 2%; cranberry, 31%; cucumber, 20%; eggplant, 45%; fennel, Florence, 12%; fig, 1%; garlic, 25%; grape, 60%; guar, seed, 1%; honeydew melon, 6%; kale, 5%; kohlrabi, 1%; leek, 10%; mustard greens, 5%; oat, 2%; onion, dry bulb, 60%; peanut, 2%; pear, 40%; potato, 63%; pumpkin, 6%; rice, 1%; rye grain, 2%; squash, summer, 25%; squash, winter, 25%; tomato, fresh, 54%; tomato, processed, 54%; walnut, 31%; watermelon, 10%; and wheat, grain, 31%.

For the 2010 ETU cancer risk assessment the Agency estimated the PCT for existing uses as follows: Apple, 51%; asparagus, 15%; barley, 1%; beans, dried, 1%; beets, sugar, 3.5%; Brussels sprouts, 15%; cantaloupe, 7.5%, carrot, 5%; cauliflower, 10%; chickpea, 1%; collards, 31%; corn, field, 1%; corn, sweet, 6%; cottonseed, oil, 11%; cranberry, 45%; cucumber, 30%; eggplant, 30%; fig, 5%; flaxseed, 11%; garlic, 25%; grape, 6%; guar, seed, 1%; kale, 73%; leek, 15%; mustard greens, 22%; oat, 11%; onion, dry bulb, 75%; peanut, 2%; pear, 35%; potato, 67.5%; pumpkin, 20.5%; rice, 1%; rye grain, 11%; safflower, oil, 11%; squash, summer, 57%; squash, winter, 26%; tomato, fresh, 30%; tomato, processed, 30%; turnip tops, 36%; walnut, 36%; watermelon, 45%; and wheat, grain, 11%.

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%.

Percent crop treated information is not available for the proposed import tolerances; however, percent imported factors were incorporated for wine grapes.

In the 2007 acute risk assessment for metiram, the Agency estimated the percent imported factors for new uses as follows: Wine grape, 20%.

In the 2007 chronic risk assessment for metiram, the Agency estimated the percent imported factors for new uses as follows: Wine grape, 20%.

In the 2007 acute risk assessment for ETU the Agency estimated the percent imported for existing uses as follows: Wine grape, 81.5%.

For the 2007 chronic risk assessment for ETU the Agency estimated the percent imported for existing uses as follows: Wine grape, 60%.

For the 2010 ETU cancer risk assessment the Agency estimated the percent imported for existing uses as follows: Wine grape, 26%.

EPA estimates the percent crop treated for new uses (PCTn) of a pesticide represent the upper bound of use expected during the pesticide's initial 5 years of registration. The PCTn recommended for use in the chronic dietary assessment is calculated as the average PCT of the pesticide or pesticides that are the market leader or leaders, (*i.e.,* the pesticides with the greatest PCT) on that site over the 3 most recent years of available survey data. The PCTn recommended for use in the acute dietary assessment is the maximum observed PCT over the same period. Comparisons are only made among pesticides of the same pesticide types (e.g., the market leader for fungicides on the use site is selected for comparison with a new fungicide). The market leader included in the estimation may not be the same for each year since different pesticides may dominate at different times.

Typically, EPA uses USDA/NASS as the source data because it is publicly available and directly reports values for PCT. When a specific use site is not reported by USDA/NASS, EPA uses proprietary data and calculates the PCT given reported data on acres treated and

acres grown. If no data are available, EPA may extrapolate PCTn from other crops, if the production area and pest spectrum are substantially similar.

EPA refines PCTn estimates based on approaches other than the market leader approach if the previous PCTn estimates based on the market leader indicate that the chemical exposure potentially pose a risk of concern. EPA considers the pest or pest spectrum targeted by the chemical for the new uses and identifies other pesticides already registered on that crop that target the same pest or pest spectrum. The PCTn is calculated based on the data from the three most recently available pesticide usage surveys. If multiple chemicals are identified that target the same pest spectrum, then the one with the highest PCT is selected from each year/crop combination. Consideration is also given to the potential for the development of resistance for each chemical using data available from the Resistance Action Committees.

EPA has considered all available relevant information and concludes that it is unlikely that the PCTn values will be exceeded during the next 5 years.

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 metiram may be applied in a particular area.

2. *Dietary exposure from drinking water*—i. *Metiram.* The Agency has determined that metiram is very short-lived in soil and water, and would not reach water used for human consumption whether from surface water or ground water.

ii. *ETU.* ETU is highly water soluble, and may reach both surface and ground water under some conditions. The ETU surface water Estimated Drinking Water Concentrations (EDWCs) were generated using a combined monitoring/modeling approach. Results of a surface water monitoring study conducted by the ETU Task Force were used to refine the outputs of the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM–EXAMS) models; the site/scenario modeled was application of an EBDC fungicide on peppers in Florida, and was chosen to produce the highest EDWC acute values. The ground water EDWC was detected in a Florida community water system intake in a targeted ground water monitoring study conducted by the EBDC Task Force from 1999 to 2003. Both these surface and ground water values represent upper-bound conservative estimates of the total ETU residual concentrations that might be found in surface water and ground water due to the use of the EBDC fungicides.

Based on the PRZM/EXAMS and monitoring studies, the EDWCs of ETU acute and chronic exposures are estimated to be 25.2 parts per billion (ppb), and 0.1 ppb, respectively, for surface water. The EDWC for chronic exposure is estimated to be 0.21 ppb for ground water.

Estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 25.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment of ETU, the water concentration of value 0.21 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment of ETU, the water concentration of value 0.21 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).

i. *Metiram.* Metiram is not registered for any specific use patterns that would result in residential exposure.

ii. *ETU.* ETU non-dietary exposure is expected as a result of the registered uses of mancozeb and the other EBDCs on home gardens, golf courses, and sod farms. For ETU, aggregate exposure sources include food, drinking water, home gardening activities, and golfing. The Agency has determined that it is appropriate to aggregate chronic exposure through food with short- and intermediate-term residential exposures to ETU.

The three scenarios that were evaluated for ETU are as follows: The first is the Short/Intermediate-Term Home Garden Aggregate, which combines handler exposures (inhalation and dermal) and post application garden exposures (dermal) plus average daily food and drinking water exposure for adults and post application garden exposures (dermal) plus average daily food and drinking water exposure for youth. The second is the Short-Term Treated Turf Aggregate (Toddlers), which combines treated turf post application exposures (incidental oral and dermal) plus average daily food and drinking water exposure for toddlers. The third is the Short/Intermediate-Term Treated Turf Aggregate, which considers short-term residential exposures (dermal) plus average daily food and drinking water exposure for adults such as golfing on treated turf. This assessment is protective of adult and youth golfers. Although exposure to children golfing could be almost twice that of the adult golfer because of increased surface area (SA)/BW ratios, younger golfers are not expected to use the golf course for the same length of time as adolescents and adults. The shorter duration on the golf course for younger golfers offsets the higher SA/BW; therefore, risks from short-term post-application exposures to young golfers are likely to be similar to risks for adult golfers.

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."

As previously mentioned, the risk estimates summarized in this document are those that result only from the use of metiram, and ETU derived from metiram and the other EBDC chemicals, which are all dithiocarbamates. For the purposes of this action, EPA has concluded that metiram does not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external peer review of the

data on a potential common mechanism of toxicity.

EPA concluded that the available evidence does not support grouping the dithiocarbamates based on a common toxic effect (neuropathology) occurring by a common mechanism of toxicity (related to metabolism to carbon disulfide (CS_2)). After a thorough internal and external peer review of the existing data bearing on a common mechanism of toxicity, EPA concluded that the available evidence shows that neuropathology cannot be linked with CS_2 formation. For more information, please see the December 19, 2001 memo, "The Determination of Whether Dithiocarbamate Pesticides Share a Common Mechanism of Toxicity" on the Internet at *http://www.epa.gov/oppsrrd1/cumulative/dithiocarb.pdf.*

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*—i. *Metiram.* Developmental toxicity was observed in the rat (increased incidence of post-implantation loss, decreased litter size, and decreased litter weight) at a dose level where minimal maternal toxicity (decreased BW gains) was observed. However, there is low concern for the qualitative susceptibility observed in the rat study since the dose response was well characterized; there was a clear NOAEL/LOAEL for maternal and developmental toxicity; and the doses selected for risk assessment were based on neurotoxicity and address concerns for developmental toxicity and thyroid toxicity, which occurred at higher doses. In a rabbit developmental study, in which the maternal animals were adequately assessed, maternal toxicity observed included abortions and decreased BW gains. No qualitative or quantitative sensitivity was identified in the young in this study for the developmental effects assessed. Although many developmental effects were assessed, a new study was required because the study did not assess soft tissue and internal structures of the head. In a recently submitted developmental rabbit study with ETU, developmental effects in the brain were not observed at dose levels below those currently used for quantifying metiram risks, reducing concerns for these effects (see further description of study in this unit).

ii. *ETU.* There was evidence of increased susceptibility of fetuses to ETU in the rat developmental studies because hydrocephaly occurred at doses below those causing maternal toxicity. Recently the Agency reviewed a new developmental study in rabbits. Effects seen in the pups (decreased BW, domed heads, and hydrocephaly) were observed in the presence of maternal toxicity. The incidence of domed heads and hydrocephaly is within the range of historical controls. In addition, these effects are observed at levels higher than the effects observed in the rat study. An acceptable reproductive study was not available for ETU. As a result, the Agency evaluated the level of concern for the effects observed when considered in the context of all available toxicity data. In addition, the Agency evaluated the database to determine if there were residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the ETU risk assessment.

3. *Conclusion*—i. *Metiram.* Although there are no residual uncertainties for pre- and/or postnatal toxicity, the FQPA SF of 10X was retained due to database uncertainties for metiram. There are data gaps for a developmental neurotoxicity study (DNT), a developmental toxicity study in the rabbit and a 2-generation reproduction study in the rat. EPA determined that the FQPA SF must be retained to account for the lack of these studies, since the available data do not provide a basis to support reduction or removal of the factor.

No additional FQPA SF is needed beyond the 10X database uncertainty factor that was applied to account for the data gaps for a developmental neurotoxicity study, a developmental toxicity study in the rabbit, and a 2-generation reproduction study in the rat with metiram. The reasons for this conclusion are:

a. There are data gaps for studies that are critical for assessing effects on infants and children, but the Agency does have developmental toxicity (rat and rabbit) and reproduction data on metiram that provides some characterization of developmental and reproductive hazard. Although there was incomplete assessment of the fetal rabbit and there was incomplete measurement of some reproductive parameters in the reproduction study, the submitted studies provide a partial assessment of the effects of concern and sufficient information on pertinent toxic effects for EPA to conclude that a 10x database uncertainty factor is adequately protective.

b. Pre- and/or postnatal susceptibility has been adequately characterized in one species (rat).

c. The exposure assessment, although refined, is unlikely to underestimate potential exposures.

d. Although there is a data gap for a developmental neurotoxicity study, since the available metiram database includes NOAELs for neurotoxicity and neuropathology (decreased grip strength at lower doses, demyelination at high doses) in adult animals upon which risk assessments are based, this information helps to characterize the dose range at which effects can be expected in the developmental neurotoxicity study and thus informs dose selection for that study. Selected doses would be in the range of the dose levels from the prior studies at the NOAEL and LOAEL levels (0.4 and 6.7 mg/kg/day, respectively). Significant toxic effects occurring at doses more than 10-fold below these levels are unlikely.

ii. *ETU.* The toxicity database for ETU is not complete. EPA lacks the following studies: A DNT study, a 2-generation reproduction study, and a comparative thyroid study in adults and offspring. The Agency has recently received and evaluated a developmental toxicity study in rabbits. Given the remaining data gaps are for studies that directly assess the risk to the young, EPA does not have reliable data to remove or modify the presumptive 10X FQPA SF.

No additional safety factor beyond 10X is needed to account for the missing toxicity data for ETU for the following reasons:

a. The teratogenic effects of ETU have been well characterized in numerous studies in the published literature, as well as in a guideline study submitted by the registrant. In addition, since metabolism studies have shown that approximately 7.5% of the EBDCs (mancozeb, maneb, and metiram,) convert to ETU in mammalian systems, the extensive toxicity database on the EBDCs on developmental effects provide information about the pre- and postnatal toxicity of ETU as well as the parent compound;

b. There are clear NOAELs for developmental effects seen in the ETU developmental studies, and the dose-

response relationships, although steep, are well characterized.

c. The developmental endpoint with the lowest NOAEL was selected for deriving the acute PAD (aPAD).

d. Thyroid toxicity was selected for deriving the chronic PAD (cPAD) as well as endpoints for non-dietary exposures (incidental oral, dermal, and inhalation). Since the available ETU database includes NOAELs for thyroid toxicity in adult animals upon which risk assessments are based, this information helps to characterize the dose range at which effects can be expected in the developmental neurotoxicity study and thus would inform dose selection for the comparative thyroid study; selected doses would be in the range of these dose levels (NOAEL of 0.2 mg/kg/day and LOAEL of 2 mg/kg/day). Significant toxic effects occurring at doses more than 10-fold below these levels are unlikely.

e. Information on ETU gleaned from the extensive EBDC database on effects other than development effects also reduces, to a degree, the uncertainty arising from the significant data gaps for ETU.

f. EPA has concluded that the exposure assessment, although refined, is unlikely to underestimate potential exposures especially considering exposure to maneb was included even though all maneb products have been canceled. In making this judgment, EPA has taken into account that it is relying on three separate reviews in this document:

- A 2007 risk assessment for mancozeb for acute, short-term, intermediate-term, chronic, and cancer risk.
- A 2007 risk assessment for ETU for acute, short-term, intermediate-term, and chronic risk.
- A 2010 addendum to the 2007 ETU assessment for cancer risk—and that the PCT estimates differ slightly between reviews.

In comparing the PCT information from 2007 and 2010, there are some increases in usage for some crops, and there are decreases in usage for other crops. These differences appear to largely offset each other. Further, most of the increases are attributable to estimated increases in maneb usage but, as noted, maneb was canceled in 2010 and it is unlikely that existing stocks are sufficient to sustain prior usage levels much less any increased usage. An EPA sensitivity analysis of the main contributors to ETU exposure showed no significant increase in exposure from the changed PCT estimated. The PCT values used in these risk assessments are detailed in the memo titled "Mancozeb. Discussion on Percent Crop Treated Values Used in Aggregate and Chronic Assessments" in docket ID number EPA–HQ–OPP–2005–0308.

In any event, there are two other aspects of the exposure assessment that are likely to significantly overstate exposure to mancozeb and ETU. First, exposure estimates for some crops, including bananas, a high-consumption food, include the assumption that everything consumed in the United States has been treated. Second, the residue data used in the assessment for the proposed commodities and many other crops are based on crop field trials. Monitoring studies conducted for several crops have shown that residues on foods close to the point of consumption are much lower than the residues found in crop field trials.

For all of these reasons, EPA concludes that it has not underestimated exposure to mancozeb and ETU.

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 aPAD and 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*—i. *Metiram.* The metiram acute aggregate assessment considers acute exposure to metiram only and not ETU. Further, this assessment is based on residues of metiram in food only since residues of metiram are not expected in drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to metiram will occupy 22% of the aPAD for females 13–49 years of age, the only population group of concern.

ii. *ETU.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to ETU will occupy 87% of the aPAD for females 13–49 years of age, the only population group of concern.

2. *Chronic risk*—i. *Metiram.* There are no long-term residential exposure scenarios for metiram and there is not likely to be residues of metiram in drinking water. Therefore, the long-term or chronic (non-cancer) aggregate risk for metiram includes contribution from food alone. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to metiram from food will utilize 70% of the cPAD for children 1–2 years of age, the population group receiving the greatest exposure.

ii. *ETU.* The aggregate chronic risks were calculated using food and water exposure only because golfing and toddler transplanted turf exposure scenarios were considered to occur only on a short term basis. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ETU from food and water will utilize 50% of the cPAD for children (1 to 2 years old), the population group receiving the greatest exposure.

3. *Short- and Intermediate-term risk*—i. *Metiram.* 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).

A short- and/or intermediate-term adverse effect was identified; however, metiram is not registered for any use patterns that would result in short- and/or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and/or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- and/or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for metiram.

ii. *ETU.* Short- 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).

Although there are no residential uses for metiram, the previous ETU aggregate assessment included residential exposures to other EBDCs. Mancozeb is currently registered for uses that could result in short- and intermediate-term residential exposure to ETU. The 2007 ETU assessment also included products containing maneb which were expected to result in short- and intermediate-term exposure. As previously discussed, these products have since been cancelled. The Agency determined that

it was appropriate to aggregate chronic exposure through food with short- and intermediate-term residential exposures to ETU. The three scenarios that were evaluated for ETU are the following:

a. *ETU Short/Intermediate-Term Home Garden Aggregate.* The ETU short/intermediate-term home garden aggregate MOEs are 13,000 and 17,000 for adults and youth, respectively. For ETU EPA is concerned only with MOEs that are below 1,000, these MOEs do not raise a risk concern.

b. *ETU Short-Term Treated Turf Aggregate (Toddlers).* The ETU short-term treated turf aggregate MOE for toddlers is 1,100. For ETU EPA is concerned only with MOEs that are below 1,000; therefore, this MOE does not raise a risk concern.

c. ETU Short/Intermediate-Term Treated Turf Aggregate. The ETU short-term treated turf aggregate MOE for golfers is 6,100. For ETU EPA is concerned only with MOEs that are below 1,000; therefore, this MOE does not raise a risk concern.

4. *Aggregate cancer risk for U.S. population—Metiram and ETU.* As noted earlier in this document, EPA has historically attributed metiram's potential for carcinogenicity to the formation of ETU, which is classified as a probable human carcinogen (B2).

The cancer risks were aggregated using the food and drinking water exposures for the general population and the food, water and recreational exposures for golfers, home gardeners and athletes. The average daily dose was used for food and water exposures and the lifetime average daily dose was used for the recreational exposures. The aggregate doses were multiplied times the potency factor for ETU, 0.0601 $(mg/kg/day)^{-1}$ to determine the cancer risks. The risk is estimated to be 3×10^{-6}.

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the logarithmic scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described in this unit, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. This is particularly the case where some conservatism is maintained in the exposure assessment. Although the ETU exposure risk assessment is refined, it retains significant conservatism in that, for leafy greens, field trial data and not monitoring data on similar crops is used in estimating exposure. The leafy greens have tended to be among the top contributors to the aggregate risk (along with water and leaf lettuce). For other commodities, market basket data has shown reductions in residues one to two orders of magnitude lower than field trial data. Moreover, the only remaining EBDC registration for leafy greens (maneb) was canceled in 2010 but the exposure assessment does not take this into account. Additional conservatism is included in the exposure assessment by the assumption of 100 PCT for many commodities. Accordingly, EPA has concluded the aggregate cancer risk for all existing mancozeb and other EBDC uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

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 metiram and/or ETU residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The available analytical methodology is considered adequate for tolerance enforcement. The Pesticide Analytical Manual (PAM) Vol. II lists Methods I, II, III, IV, and A for the determination of dithiocarbamate residues in or on plant commodities. The Keppel Colorimetric Method (PAM Method III) is the preferred method for tolerance enforcement. The Keppel Colorimetric Method determines EBDCs as a group by degradation to CS_2. For determination of ETU residues, the Agency recommends the gas chromatography (GC) Method of Onley (Association of Analytical Communities (AOAC) 14th Edition 29.119:554).

The 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; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

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

There are no established or proposed CODEX MRLs for residues of metiram per se; however, CODEX limits for dimethyldithiocarbamates fungicides are grouped under dithiocarbamates. There are CODEX MRLs for banana and grapes.

Tolerances for the EBDC pesticides are expressed in terms of CS_2, which is the same as the CODEX tolerance expression. The level of 5 ppm for wine grapes is the same as the CODEX MRL, although the CODEX MRL is for simply "grapes." The recommended tolerance for banana (3 ppm) cannot be harmonized with CODEX because residues in field trials exceeded the CODEX MRL of 2 ppm.

C. Response to Comments

As discussed in Unit II., EPA proposed tolerance actions for metiram in the **Federal Register** issue of September 16, 2009. EPA did receive comments on the proposed rule; however, none of these comments are related to the uses in this action.

D. Revisions to Petitioned-For Tolerances

EPA has revised the tolerance expression to clarify that:

1. As provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of metiram not specifically mentioned.

2. Compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. The change in the tolerance expression has resulted in the existing tolerances for apple and potato needing to be modified. These tolerances are being modified by this document. In addition, as a follow-up to recommendations made in the Metiram RED document, a tolerance is being added for apple, pomace, wet at 2 ppm. All of these revisions were proposed in the **Federal Register** issue of September 16, 2009.

V. Conclusion

Therefore, tolerances are established for residues of metiram (a mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides), including its metabolites and degradates, in or on banana at 3 ppm and grape, wine at 5 ppm.

VI. Statutory and Executive Order Reviews

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

Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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: April 20, 2011.

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 180.217 is amended by revising the section heading and paragraph (a) to read as follows:

§ 180.217 Metiram; tolerances for residues.

(a) *General.* Tolerances are established for residues of a metiram (a mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those metiram residues convertible to and expressed in terms of the degradate carbon disulfide.

Commodity	Parts per million
Apple	0.5
Apple, pomace, wet	2
Banana [1]	3
Grape, wine [1]	5
Potato	0.2

[1] There are no U.S. registrations on bananas and grape, wine as of April 29, 2011.

* * * * *

[FR Doc. 2011–10333 Filed 4–28–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0266; FRL–8869–5]

Pyrasulfotole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes or revises tolerances for residues of pyrasulfotole in or on grain sorghum, grass, and livestock commodities. Bayer CropScience LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 29, 2011. Objections and requests for hearings must be received on or before June 28, 2011, 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–2010–0266. 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,