measuring only indaziflam, in or on the commodity.

Commodity	Parts per million
Almond, hulls	0.15
Fruit, citrus, group 10–10	0.01
Fruit, pome, group 11–10	0.01
Fruit, stone, group 12	0.01
Grape	0.01
Nut, tree, group 14	0.01
Olive	0.01
Pistachio	0.01
Sugarcane, refined sugar [1]	0.01

[1] Tolerance without a corresponding U.S. registration.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0307; FRL–8864–1]

Mancozeb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mancozeb in or on almonds, cabbage, lettuce, peppers, and broccoli. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 6, 2011. Objections and requests for hearings must be received on or before June 6, 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–2005–0307. 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://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–2005–0307 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 6, 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–2005–0307, 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 November 30, 2005 (70 FR 71836) (FRL–7747–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 3E6536 for mandarin oranges/mandarins; PP 4F4324 for almond nuts and almond hulls; PP 4F4333 for broccoli, cabbage, lettuce, and peppers) by Dow AgroSceinces LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petitions requested that 40 CFR 180.176 be amended by establishing tolerances for residues of the fungicide mancozeb, zinc manganese ethylenebis dithiocarbamate, in or on mandarin

oranges/mandarins at 5.0 parts per million (ppm) (PP 3E6536), almond nuts at 0.1 ppm and almond hulls at 10.0 ppm (PP 4F4324); and broccoli at 13.0 ppm, cabbage at 10.0 ppm, lettuce at 10.0 ppm, and peppers at 7.0 ppm (PP 4F4333). That notice referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is setting the tolerances at levels different than originally requested in the petitions, with the exception of almond. The reason for these changes is explained in Unit IV.D. The request for mandarin oranges has been withdrawn.

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 mancozeb including exposure resulting from the tolerances established by this action.

Mancozeb is a member of the ethylene bisdithiocarbamate (EBDC) group of fungicides that also includes the related active ingredients maneb and metiram. 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 mancozeb 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 mancozeb on almond, cabbage, leaf lettuce, peppers, and broccoli, EPA completed two risk assessments in 2007:

- A mancozeb risk assessment which considered all existing and proposed uses for mancozeb, and
- An ETU risk assessment that considered exposure to ETU from all sources (mancozeb, metiram, and maneb) for all existing and proposed uses.

Although the 2007 mancozeb review showed risks that were acceptable, the 2007 ETU review demonstrated unacceptable cancer risks, therefore preventing the Agency from acting on the petitions for almond, cabbage, leaf lettuce, peppers, and broccoli. 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 almond, cabbage, leaf lettuce, peppers, and broccoli. 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 mancozeb for acute, short-term, intermediate-term, chronic, and cancer risk (refer to risk assessment in the Docket EPA–HQ–OPP–2005–0307 titled "Mancozeb: Human Health Risk Assessment to Support Proposed New Uses on Broccoli, Cabbage, Lettuce, Peppers and Almonds"),
- A 2007 risk assessment for ETU for acute, short-term, intermediate-term and chronic risk (refer to risk assessment in the Docket EPA–HQ–OPP–2005–0307 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 risk assessment in the Docket EPA–HQ–OPP–2005–0307 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** 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 mancozeb 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 mancozeb, EPA also evaluated the risks of ETU, a contaminant, metabolite and degradation product of mancozeb and the other EBDC group of fungicides, which includes the related active ingredients metiram and maneb.

1. *Mancozeb.* Mancozeb is not acutely toxic via the oral, dermal or inhalation routes of exposure. Further, mancozeb is not a skin irritant nor is it a skin sensitizer, although it does cause mild eye irritation. The findings in multiple studies demonstrate that the thyroid is a target organ for mancozeb. Thyroid toxicity was manifested as alternations in thyroid hormones, increased thyroid weight, and microscopic thyroid lesions (mainly thyroid follicular cell hyperplasia). These effects are due to the ETU metabolite. In a subchronic study in the rat, neuropathology was seen (injury to peripheral nerves) microscopically with associated clinical signs (abnormal gait and limited use of rear legs) and loss of muscle mass. An acute neurotoxicity study with mancozeb has been completed and reviewed since the 2007 risk assessment; neuropathology was not observed, and minimal effects upon motor activity were observed at high doses. The Agency conducted a preliminary dietary assessment using a point-of-departure from this study and found no risk concerns. Other toxicity included increases in bilateral retinopathy in the chronic rat study. Elevated cholesterol and a mild, regenerative, anemia occurred in subchronic and chronic dog studies.

Mancozeb is rapidly absorbed and eliminated in the urine. In oral rat metabolism studies with radiolabelled

mancozeb 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 mancozeb does not bio-accumulate. Mancozeb has been tested in a series of *in vitro* and *in vivo* genotoxicity assays, which have shown that it exhibits weak genotoxic potential.

Thyroid follicular cell adenomas and carcinomas were increased in high-dose males and females in the combined rat toxicity/carcinogenicity study with mancozeb. Doses in a mouse study were too low to assess carcinogenicity, and there were no treatment-related changes in tumor rates. Historically, mancozeb's potential for carcinogenicity has been based on its metabolite ETU, which is classified as a probable human carcinogen. However, since ETU is known to be the chemical causing the thyroid tumors observed, the cancer assessment has been done only for ETU rather than the parent compound.

Developmental defects in the rat developmental toxicity study included hydrocephaly, skeletal system defects, and other gross defects which occurred at a dose causing maternal mortality and did not indicate increased susceptibility of offspring. Abortions occurred in the rabbit developmental toxicity study at the high dose which also caused maternal mortality, and there was no indication of enhanced susceptibility of offspring in the rabbit. There was no evidence of reproductive toxicity in the 2-generation reproduction study in rats.

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 mancozeb, 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 gain.

Specific information on the studies received and the nature of the adverse effects caused by mancozeb as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "Mancozeb: Human Health Risk Assessment to Support Proposed New Uses on Broccoli, Cabbage, Lettuce, Peppers and Almonds" on pages 13–15 in docket ID number EPA–HQ–OPP–2005–0307.

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 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–2005–0307.

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 mancozeb and ETU used for human risk assessment is discussed in Unit IV.B. of the final rule published in the **Federal Register** 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 mancozeb, EPA considered exposure under the petitioned-for tolerances as well as all existing mancozeb tolerances in 40 CFR 180.176. In evaluating dietary exposure to ETU, EPA considered exposure under the petitioned-for tolerances discussed in this document as well as all existing uses of the EBDC group of fungicides (maneb, metiram, mancozeb) including the uses for which there are maneb tolerances even though all maneb registrations have been canceled. EPA assessed dietary exposures from mancozeb 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 mancozeb and ETU. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII).

a. *Mancozeb.* The following assumptions were made for the acute exposure assessments: The Agency conducted a highly refined, probabilistic acute dietary assessment incorporating maximum percent crop treated information for new and existing uses, field trial or monitoring data, and processing and cooking factors.

b. *ETU.* The following assumptions were made for the acute exposure assessments: The Agency conducted a highly refined, probabilistic acute dietary assessment incorporating maximum percent crop treated 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 commodities would not be treated with more than one EBDC in a season, as there are label restrictions regarding treatment with multiple EBDCs. Percent crop treated was estimated by summing the percent crop treated 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. *Mancozeb.* The chronic dietary exposure and risk assessment for mancozeb (non-cancer and cancer) incorporated average values based either on field trial data or monitoring data and average percent crop treated data for new and existing uses, as well as processing and cooking factors.

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 non-linear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Mancozeb degrades and/or metabolizes to ETU which causes thyroid tumors; therefore, EPA has historically attributed mancozeb's 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 $(mg/kg/day)^{-1}$ for ETU (based on liver tumors in female mice) for risk assessment. Therefore, cancer risk from exposure to mancozeb has been calculated by estimating exposure to mancozeb-derived ETU and using Q_1^* for ETU. The same approach has been taken for the other EBDCs. EPA's estimated exposure to mancozeb-derived ETU and ETU from other EBDCs included ETU residues found in food as well as ETU formed by metabolic conversion on parent mancozeb 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 mancozeb, the Agency estimated the PCT for existing uses as follows:

Apple, 41%; asparagus, 34%; barley, 0.9%, beet, sugar, 2.9%; cantaloupe, 10%; carrot, 13%; casaba, 10%; corn, field, 1%; corn, sweet, 22%; cottonseed, oil, 0.8%; cucumber, 32%; grape, 14%; honeydew melon, 13%; oat, 1%; onion, dry bulb, 77%; peanut, 2.3%; pear, 51%; potato, 50%; pumpkin, 10%; rice, 1%; rye grain, 1%; squash, summer, 86%; squash, winter, 10%; tomato, 80%; watermelon, 30%; wheat, grain, 2.3%.

In the 2007 chronic risk assessment for mancozeb, the Agency estimated the PCT for existing uses as follows:

Apple, 26%; asparagus, 16%; barley, 0.2%, beet, sugar, 1.3%; carrot, 9%; casaba, 8%; corn, field, 1%; corn, sweet, 12%; cottonseed, oil, 0.2%; cucumber, 18%; grape, 9%; honeydew melon, 8%; oat, 1%; onion, dry bulb, 38%; peanut, 0.9%; pear, 32%; potato, 36%; pumpkin, 8%; rice, 1%; rye grain, 1%; squash, summer, 41%; squash, winter, 8%; tomato, 49%; watermelon, 28%; wheat, grain, 0.9%.

In the 2007 acute risk assessment for ETU the Agency estimated the PCT for existing uses as follows:

Apple, 65%; asparagus, 30%; barley, 2%; bean, 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%; grape, wine, 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%; wheat, grain, 3.5%.

In the 2007 chronic risk assessment for ETU the Agency estimated the PCT for existing uses as follows:

Apple, 42%; asparagus, 21%; barley, 2%; bean, 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%; grape, wine, 60%; guar, seed, 1%; honeydew melon, 6%; kale, 6%; 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%; wheat, grain, 2%.

For the 2010 ETU cancer risk assessment the Agency estimated the PCT for existing uses as follows:

Apple, 51%; asparagus, 15%; barley, 1%; bean, 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%; grape, wine, 26%; 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%; wheat, grain, 11%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most

recent 6 to 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 1. 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%.

In the 2007 acute risk assessment for mancozeb, the Agency estimated the PCT for new uses as follows:

Almond, 35%; broccoli, 9%; cabbage, 47%; cabbage, Chinese, 47%; head lettuce 66%; leaf lettuce 61%; pepper, bell, 48%; pepper, non-bell, 48%.

In the 2007 chronic risk assessment for mancozeb, the Agency estimated the PCT for new uses as follows:

Almond, 35%; broccoli, 7%; cabbage, 42%; cabbage, Chinese, 42%; head lettuce 58%; leaf lettuce 59%; pepper, bell, 43%; pepper, non-bell, 43%.

For the 2007 ETU acute assessment, the Agency estimated the PCT for new uses as follows:

Almond, 50%; broccoli, 22%; cabbage, 82%; cabbage, Chinese, 82%; pepper, bell, 88%; pepper, non-bell, 88%.

For the 2007 ETU chronic assessment, the Agency estimated the PCT for new uses as follows:

Almond, 45%; broccoli, 17%; cabbage, 57%; cabbage, Chinese, 57%; pepper, bell, 73%; pepper, non-bell, 73%.

For the 2010 ETU cancer assessment, the Agency estimated the PCT for new uses as follows:

Almond, 28%; broccoli, 15%; cabbage, 62%; cabbage, Chinese, 62%; pepper, bell, 74%; pepper, non-bell, 74%.

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 three 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 poses 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 mancozeb may be applied in a particular area.

2. *Dietary exposure from drinking water*—i. *Mancozeb.* The Agency has determined that mancozeb 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 ppb for ground water 0.21.

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. *Mancozeb.* Mancozeb is currently registered for use on the following residential sites: Home gardens, golf courses, and sod farms (potential exposure to mancozeb is from residues remaining on transplanted turf). The Agency has determined that it is appropriate to aggregate chronic exposure through food with short- and intermediate-term residential exposures to mancozeb. Since residues of mancozeb are not expected in drinking water, only mancozeb food residues are considered.

The two scenarios that were evaluated for mancozeb are the "short/intermediate-term home garden aggregate (adult)" which considers residential handler exposures (inhalation) to adult applicators combined with average food exposures and the "short/intermediate-term treated turf aggregate (toddler)" which considers residential incidental oral exposures to toddlers combined with average food exposures. The only postapplication scenario for adults in contact with treated turf (golf courses) is via the dermal route of exposure. Since no dermal endpoints were selected for mancozeb, a quantitative risk assessment for this scenario is not required.

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 mancozeb.

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 postapplication garden exposures (dermal) plus average daily food and drinking water exposure for adults and postapplication 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. And the last 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/body weight (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 mancozeb, and ETU derived from mancozeb and the other EBDC chemicals, which are all dithiocarbamates. For the purposes of this action, EPA has concluded that mancozeb 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). 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 can not be linked with carbon disulfide 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 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*—i. *Mancozeb.* In the rat developmental study, developmental effects were observed in the presence of severe maternal effects, including maternal mortality and clinical signs. In the rabbit developmental study, developmental effects (spontaneous abortions) were observed at the same dose (80 mg/kg/day) at which maternal effects included mortality and clinical signs. In the rat reproduction study, no effects were observed in offspring, while thyroid effects and body weight gain decrements occurred in adults.

ii. *ETU.* There was evidence of increased susceptibility of fetuses to ETU in the rat developmental studies because hydrocephaly occurred at doses below that causing maternal toxicity. Acceptable reproductive and rabbit developmental toxicity studies were 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. *Mancozeb.* In the 2007 assessment, EPA retained the presumptive 10X FQPA safety factor for the protection of children due to the absence of a required developmental neurotoxicity study. That study has recently been received. Neurotoxicity was not observed in the study, and the young animals did not show susceptibility, as compared to the adults, for the slight toxicity that was observed (reduced body weight gain). Additionally, since the completion of the 2007 assessment, EPA has imposed a new data requirement for immunotoxicity data and such data has

not been submitted for mancozeb. The absence of an immunotoxicity study does not raise significant uncertainty. In the absence of that study, the available toxicity data for mancozeb have been thoroughly examined for any information which suggests a potential for immunotoxicity. The analysis did not reveal such information and the Agency does not believe that conducting the immunotoxicity study will result in a point of departure (POD) less than the currently selected PODs for risk assessment.

Because EPA is relying on the 2007 assessment in evaluating acute and chronic risks, EPA is retaining the children's safety factor determination in that assessment (retain the additional 10X factor). EPA expects that once that determination is revisited, the children's safety factor will be lowered or removed entirely due to the submission of the DNT study and the fact that immunotoxicity is not a concern with mancozeb. These changed circumstances certainly do not support an additional safety factor higher than 10X. Further, as discussed below, EPA believes that the 2007 risk assessment does not underestimate exposure to mancozeb. Accordingly, EPA concludes that the 2007 determination on the children's safety factor protects the safety of infants and children.

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

No further safety factor to protect is needed for the following reasons. First, the Agency determined that the degree of concern for the susceptibility seen in ETU developmental studies was low. The reasons for this conclusion are:

- 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 mancozeb converts to ETU in mammalian systems, the extensive toxicity database with mancozeb on developmental effects provide extensive information about pre- and post-natal toxicity of ETU;
- There is a clear NOAEL for these effects and the dose-response relationship, although steep, is well characterized in the numerous developmental studies in rats.
- The developmental endpoint with the lowest NOAEL was selected for deriving the acute RfD.
- The target organ (thyroid) was selected for deriving the chronic RfD as well as endpoints for non-dietary exposures (incidental oral, dermal, and inhalation). Since the ETU doses selected for overall risk assessments will address the concern for developmental and thyroid toxicity, there are no residual uncertainties with regard to prenatal and/or postnatal toxicity.

Second, the information on ETU gleaned from the extensive mancozeb database on effects other than development effects also reduces, to a degree, the uncertainty arising from the significant datagaps for ETU.

Third, EPA has concluded that the exposure assessment, although refined, is unlikely to under-estimate 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 Notice:

- 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, and
- A 2010 addendum to the 2007 ETU assessment for cancer risk—and that the percent crop treated estimates differ slightly between reviews.

In comparing the percent crop treated 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 percent crop treated estimated. The percent crop treated 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 number EPA–HQ–OPP–2005–0307.

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 acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk (Mancozeb).* The mancozeb acute aggregate assessment considers acute exposure to mancozeb only and not ETU. Further, this assessment is based on residues of mancozeb in food only since residues of mancozeb are not expected in drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to mancozeb will occupy 6.9% of the aPAD for females 13–49 years of age, the only population group of concern.

2. *Acute risk (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.

3. *Chronic risk (Mancozeb).* There are no long-term residential exposure scenarios for mancozeb and there is not likely to be residues of mancozeb in drinking water. Therefore, the long-term or chronic (non-cancer) aggregate risk for mancozeb includes contribution from food alone. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to mancozeb from food will utilize 3.3% of the cPAD for children 1–2 years of age, the population group receiving the greatest exposure.

4. *Chronic Risk (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 58% of the cPAD for children (1 to 2 years old), the population group receiving the greatest exposure.

5. *Short-and intermediate-term risk (Mancozeb).* 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).

Mancozeb is currently registered for uses that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food with short- and intermediate-term residential exposures to mancozeb. The two scenarios that were evaluated for mancozeb are the following:

i. *Short/intermediate-term home garden aggregate (adult).* The aggregate short/intermediate-term home garden MOEs for adults are 110,000. Because for mancozeb EPA is concerned only with MOEs that are below 1,000, this MOE does not raise a risk concern.

ii. *Short-term treated turf aggregate (toddler).* The mancozeb short-term aggregate risk (MOE) for toddlers exposed to treated turf is 1,100. Because for mancozeb EPA is concerned only with MOEs that are below 1,000, this MOE does not raise a risk concern.

6. *Short- and intermediate-term risk (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).

Mancozeb is currently registered for uses that could result in short- and intermediate-term residential exposure to ETU. The 2007 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.

i. *ETU short/intermediate-term home garden aggregate.* The ETU short/intermediate-term home garden aggregate MOEs for adults is 13,000 and 17,000 for youth, respectively. Because for ETU EPA is concerned only with MOEs that are below 1,000, this MOE does not raise a risk concern.

ii. *ETU short-term treated turf aggregate (toddlers).* The ETU short-term treated turf aggregate MOE for toddlers is 1,100. Because for ETU EPA is concerned only with MOEs that are below 1,000, this MOE does not raise a risk concern.

iii. *ETU short/intermediate-term treated turf aggregate.* The ETU short-term treated turf aggregate MOE for golfers is 6,100. Because for ETU EPA is concerned only with MOEs that are below 1,000, this MOE does not raise a risk concern.

7. *Aggregate cancer risk for U.S. population (mancozeb and ETU).* As noted earlier in this document, mancozeb degrades and/or metabolizes to ETU which causes the same types of thyroid tumors as those seen when animals are dosed with mancozeb; therefore, EPA has historically attributed mancozeb's 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 doses for the general population and the food, water and recreational doses 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 above, 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 market basket 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 percent crop treated 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.

8. *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 mancozeb residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for the enforcement of tolerances for the plant commodities which are the subject of this request. The Pesticide Analytical Method (PAM) Vol. II lists Methods I, II, III, IV, and A for the determination of dithiocarbamate residues in/on plant commodities. The Keppel colorimetric method (Method III) is the preferred method for tolerance enforcement. The Keppel method determines EBDCs as a group by degradation to CS_2. The analytical methodology for ETU is based on the original method published by Olney and Yip (JAOAC 54:165–169).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; *telephone number:* (410) 305–2905; *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 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.

There are no established or proposed Codex MRLs for residues of mancozeb; however, Codex limits for mancozeb and similar fungicides are grouped under dithiocarbamates measured as carbon disulfide. There are Codex MRLs for almonds; almond hulls; cabbages, head; lettuce, head; cos lettuce; peppers, sweet. Tolerances for the EBDC pesticides are expressed in terms of carbon disulfide (CS_2), which is the same as the Codex tolerance expression. The level of 0.1 ppm for almonds is also the same as the Codex MRL for almonds. However, for the reasons indicated below, the tolerance levels being established for the other subject crops cannot be harmonized with the associated Codex MRLs.

- Based on the calculations in the Agency's tolerance spreadsheet, in accordance with the Agency's "Guidance for Setting Pesticide Tolerances Based on Field Trial Data," the appropriate tolerance level for cabbage is 9.0 ppm. The tolerance level cannot be harmonized with Codex; the highest residue level in the crop field trials (6.0 ppm in CS_2 equivalents) is greater than the Codex MRL for cabbage (5 ppm).

- The available data indicate that the appropriate tolerance level for head lettuce is 3.5 ppm. The tolerance level cannot be harmonized with Codex; the highest residue level in the crop field trials (2.2 ppm in CS_2 equivalents) is considerably less than the Codex MRL of 10 ppm for head lettuce.

- The available data indicate that the appropriate tolerance level for leaf lettuce is 18 ppm. The tolerance level cannot be harmonized with Codex; the highest residue level in the crop field trials (14 ppm in CS_2 equivalents) is greater than the Codex MRL for Cos lettuce (10 ppm).

- The appropriate tolerance level for pepper is 12 ppm. The tolerance level cannot be harmonized with Codex as the Codex MRL has been established for sweet pepper only.

- The appropriate tolerance level for almond hulls is 4 ppm. This value cannot be harmonized with Codex as it is significantly below the Codex MRL of 20 ppm.

C. Response to Comments

The company Cerexagri, Inc. submitted a comment on the initial notice of filing in 2006. Cerexagri proposed that EPA reject the petitions for reasons primarily dealing with information included in the risk assessment provided by Dow AgroSciences in the petitions. The Agency conducts its own risk assessments and does not rely on those provided by registrants. For example, Cerexagri did not agree with Dow AgroSciences proposal to assume that "mancozeb uses will simply replace a share of the existing maneb market". Nor did Cerexagri agree with Dow AgroSciences use of market basket data to extrapolate expected residues on the proposed commodities. The EPA did not base PCT estimates for new commodities based on the assumption that one EBDC will replace another but instead used its standard market leader approach to determine appropriate PCT numbers. Further, the EPA relied on the results of the crop field trial data to estimate exposure to the proposed commodities and many other crops. Results of the Market Basket Survey were only used for commodities/chemicals associated with the survey. Therefore, the objections voiced by Cerexagri are not relevant to the conclusions reached by the Agency regarding these petitions.

Finally, Cerexagri requested that the EPA first engage in a public process that would seek the participation of the grower community, research community and other interested parties before determining which new uses of EBDC fungicides should be approved because approval of the uses requested in this petition may preclude the approval of other uses. EPA, however, has followed all procedural requirements in the FFDCA section. Moreover, in the time since this petition was submitted, no further uses of EBDCs have been requested.

D. Revisions to Petitioned-For Tolerances

All of the tolerance levels being established in this document, with the exception of almond, are different than the levels requested in the original tolerance petitions. EPA revised the tolerance levels based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's "Guidance for Setting Pesticide Tolerances Based on Field Trial Data."

V. Conclusion

Therefore, tolerances are established for residues of mancozeb, zinc manganese ethylenebis dithiocarbamate in or on almond at 0.1 ppm; almond, hulls at 4 ppm; broccoli at 7 ppm; cabbage at 9 ppm; lettuce, head at 3.5 ppm; lettuce, leaf at 18 ppm; and pepper at 12 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 tolerances 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) (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: March 21, 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 180.176 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.176 Mancozeb; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond	0.1
Almond, hulls	4
* * * * *	
Broccoli	7
Cabbage	9
* * * * *	
Lettuce, head	3.5
Lettuce, leaf	18
* * * * *	
Pepper	12
* * * * *	

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[FR Doc. 2011–7461 Filed 4–5–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0493; FRL–8863–1]

Ethiprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances (without U.S. registrations) for residues of the insecticide ethiprole [5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(ethyl)-sulfinyl]-1*H*-pyrazole-3-carbonitrile], including its metabolites and degradate, in or on rice and tea. Bayer CropScience LP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 6, 2011. Objections and requests for hearings must be received on or before June 6, 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–2009–0493. 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: Carmen Rodia, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; e-mail address: *rodia.carmen@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 section 408(g) of FFDCA, 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