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

This 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) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 17, 2013.

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. In § 180.651, in paragraph (a), add alphabetically the following commodities to the table to read as follows:

§ 180.651 Imazosulfuron; tolerances for residues.

(a) * * *

Commodity	Parts per million
Melon subgroup 9A	0.02
* * * * *	
Vegetable, tuberous and corm, subgroup 1C	0.02

* * * * *

[FR Doc. 2013–17823 Filed 7–23–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0628; FRL–9393–2]

Mancozeb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mancozeb in or on walnuts and tangerines. United Phosphorus requested the tolerance for walnuts and Dow AgroSciences requested the tolerance for tangerines under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 24, 2013. Objections and requests for hearings must be received on or before September 23, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0628, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's eCFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–

OPP–2012–0628 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 September 23, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0628, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 2, 2012 (77 FR 25954) (FRL–9346–1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7935) by United Phosphorus, Inc., 630 Freedom Business Center, King of Prussia, PA 19406. The petition requested that 40 CFR 180.176 be amended by establishing tolerances for residues of the fungicide mancozeb in or on walnuts at 0.75 parts per million (ppm). That document referenced a summary of the petition prepared by United Phosphorus, the registrant, which is available in the docket (EPA–HQ–OPP–2012–0044), *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

In the **Federal Register** of September 28, 2012 (77 FR 59578) (FRL–9364–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8062) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.176 be amended by establishing tolerances for residues of the fungicide mancozeb in or on tangerine at 10 ppm. The proposed tolerance supports imports of mandarins, tangerines, and clementines. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket (EPA–HQ–OPP–2012–0628) *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the level at which the tolerance is being established for walnut. The reason for this change is explained 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 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 ingredient metiram, the only other registered EBDC. A third EBDC, maneb, is no longer registered for use. Mancozeb and metiram are metabolized to ethylenethiourea (ETU) in the body and both 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. 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 ingredient metiram.

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 is 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 microscopically (injury to peripheral nerves) with associated clinical signs (abnormal gait and limited use of rear legs) and loss of muscle mass. Decreased motor activity occurred in the acute neurotoxicity study. In the developmental neurotoxicity study, there was no maternal toxicity and pup effects were limited to decreased body weight. 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 radiolabeled 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. There was evidence of sensitivity in the developmental neurotoxicity study with mancozeb with decreased pup body weight observed in the absence of maternal toxicity; the selected endpoints are protective for these pup effects.

An immunotoxicity study has been reviewed and mancozeb did not show any immunotoxicity potential.

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 thyroxine (T_4), increases or decreases in triiodothyronine (T_3), compensatory increases in levels of thyroid stimulating hormone (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.

An immunotoxicity study on ETU did not show any immunotoxicity potential.

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 Section 3 Uses on Walnuts and Tolerances for Imported Tangerines''* on pages 70–75 in docket ID number EPA–HQ–OPP–2012–0628.

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 *www.regulations.gov* in the document titled ''Ethylene Thiourea (ETU); Aggregate Human Health Risk Assessment of the Common Metabolite/Degradate Ethylene Thiourea (ETU) to Support Proposed New Section 3 Use on Walnuts and Tolerance for Imported Tangerines'' on pages 30–33 in docket ID number EPA–HQ–OPP–2012–0628.

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 shown in Tables 1 and 2 of this unit.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Adult Males, Females > 49, and Children ≥ 6 years).	NOAEL = 500 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 5 mg/kg/day aPAD = 5 mg/kg/day	Acute neurotoxicity study in the rat. LOAEL 1,000 mg/kg/day based on decreased motor activity.
Acute dietary (Children < 6 years).	NOAEL = 500 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF UF_{DB} = 10x	Acute RfD = 5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute neurotoxicity study in the rat. LOAEL 1,000 mg/kg/day based on decreased motor activity.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (Females 13–49 years).	NOAEL = 1.28 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF UF_{DB} = 10x	Acute RfD = 1.3 mg/kg/day aPAD = 0.13 mg/kg/day	Developmental toxicity study in the rat. LOAEL = 512 mg/kg/day based on hydrocephaly and other malformations.
Chronic dietary (Adult Males, Females > 49, and Children ≥ 6 years).	NOAEL = 4.83 mg/kg/day. UF_A = 3x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.16 mg/kg/day cPAD = 0.16 mg/kg/day	Toxicity/Carcinogenicity in the rat. LOAEL = 30.9 mg/kg/day based on thyroid toxicity.
Chronic dietary (Females 13–49 years and Children < 6 years).	NOAEL = 4.83 mg/kg/day. UF_A = 3x UF_H = 10x FQPA SF UF_{DB} = 10x	Chronic RfD = 0.16 mg/kg/day cPAD = 0.016 mg/kg/day	Toxicity/Carcinogenicity in the rat. LOAEL = 30.9 mg/kg/day based on thyroid toxicity.
Inhalation all durations (Adult Males, Females > 49 years, and Children ≥ 6 years).	Inhalation study NOAEL = 0.079 mg/L (21 mg/kg/day). UF_A = 3x UF_H = 10x FQPA SF = 1x	LOC for MOE = 30	Subchronic Inhalation in the rat. LOAEL = 0.326 mg/L based on thyroid toxicity.
Inhalation all durations (Females 13–49 years and Children < 6 years).	Inhalation study NOAEL= 0.079 mg/L (21 mg/kg/day). UF_A = 3x UF_H = 10x FQPA SF UF_{DB} = 10x	LOC for MOE = 300	Subchronic Inhalation in the rat. LOAEL = 0.326 mg/L based on thyroid toxicity.
Cancer (Oral, dermal, inhalation).	Mancozeb's potential for carcinogenicity is due to the formation of the metabolite, ETU, which is classified as a probable human carcinogen. Mancozeb's cancer risk is calculated by estimating exposure to mancozeb-derived ETU and using the ETU cancer potency factor (Q_1^*) of 6.01×10^{-2} $(mg/kg/day)^{-1}$ to quantitate risk.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligrams/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. 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).

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETU FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	A study with acute toxicity applicable to the general population was not identified.		
Acute Dietary (Females 13–49 years).	NOAEL = 5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF UF_{DB} = 10x	Acute RfD = 0.05 mg/kg/day. aPAD = 0.005 mg/kg/day	Developmental Rat Toxicity. LOAEL = 10 mg/kg/day, based on hydrocephaly and other malformations.

TABLE 2—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETU FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (Adult Males, Females > 49, and Children ≥ 6 years).	NOAEL = 0.18 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0018 mg/kg/day. cPAD = 0.0018 mg/kg/day	Dog Chronic Oral Toxicity. LOAEL = 1.99 mg/kg/day based on thyroid toxicity.
Chronic dietary (Females 13–49 years and Children < 6 years).	NOAEL = 0.18 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF UF_{DB} = 10x	Chronic RfD = 0.0018 mg/kg/day. cPAD = 0.00018 mg/kg/day	Dog Chronic Oral Toxicity. LOAEL = 1.99 mg/kg/day based on thyroid toxicity.
Dermal short and intermediate-term (Children < 6 years old).	Oral study ..... NOAEL = 7 mg/kg/day (dermal absorption rate = 26%) UF_A = 10x UF_H = 10x FQPA SF = 10x	LOC for MOE = 1,000.	4-Week Range-Finding Dog Study. LOAEL = 34 mg/kg/day based on thyroid toxicity.
Dermal short and intermediate-term (Adult Males, Females. > 49 years, Children ≥ 6 years).	Oral study ..... NOAEL = 7 mg/kg/day (dermal absorption rate = 26%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	4-Week Range-Finding Dog Study. LOAEL = 34 mg/kg/day based on thyroid toxicity.
Dermal short- and intermediate-term (Females 13–49 years old).	Oral study ..... NOAEL = 5 mg/kg/day (dermal absorption rate = 26%) UF_A = 10x UF_H = 10x FQPA SF = 10x	LOC for MOE = 1,000.	Developmental Rat Toxicity. LOAEL = 10 mg/kg/day, based on hydrocephaly and other malformations.
Inhalation short- and intermediate-Term (Children < 6 years of age).	Oral study ..... NOAEL = 7 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF UF_{DB} = 10x	LOC for MOE = 1,000.	4-Week Range-Finding Dog Study. LOAEL = 34 mg/kg/day based thyroid toxicity.
Inhalation short- and intermediate-term (adult males, females > 49 years, children ≥ 6 years).	Oral study ..... NOAEL= 7 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	4-Week Range-Finding Dog Study. LOAEL = 34 mg/kg/day based thyroid toxicity.
Inhalation short- and intermediate-term (Females 13–49 years old).	Oral study ..... NOAEL = 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 10x	LOC for MOE = 1,000.	Developmental Rat Toxicity. LOAEL = 10 mg/kg/day, based on hydrocephaly and other malformations.
Cancer (Oral, dermal, inhalation).	ETU is classified as a probable human carcinogen. ETU's cancer potency factor (Q_1^*) is 6.01×10^{-2} $(mg/kg/day)^{-1}$.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligrams/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. 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).

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

(mancozeb and metiram). 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 for both mancozeb and ETU, EPA used food consumption information from the 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

a. *Mancozeb.* The Agency conducted a highly refined, probabilistic acute dietary assessment incorporating field trial or monitoring data from the EBDC/ETU Market Basket Survey, percent crop treated (PCT) information, and processing study results to assess the established uses of mancozeb. The monitoring data were used for several commodities (corn, cucumber, onion, pumpkin, potato, squash, starfruit, tomato, meat, and milk). For evaluation of the proposed new uses and tolerances, field trial data, processing factors, PCT data based on section 18 usage for walnuts, and percent imported commodity in domestic consumption data on tangerines for mancozeb were used to refine residue estimates. The entire distributions of residue data from field trials or monitoring data were used to generate residue distribution files (RDFs) for commodities that are considered to be not blended or partially blended. For commodities considered to be blended, the average residues incorporating the likely maximum estimated PCT was used as a point estimate.

b. *ETU.* The Agency conducted a highly refined, probabilistic acute dietary assessment incorporating field trial or monitoring data from the EBDC/ETU Market Basket Survey, PCT information, and processing study results to assess exposures to ETU from the established uses of mancozeb and metiram. The monitoring data were used for several commodities (corn, cucumber, onion, pumpkin, potato, squash, starfruit, tomato, meat, and milk). For evaluation of the proposed new uses and tolerances, field trial data, processing factors, PCT data based on section 18 usage for walnuts, and percent imported commodity in domestic consumption data on tangerines for mancozeb were used to refine residue estimates. The entire distributions of residue data from field trials or monitoring data were used to generate residue distribution files (RDFs) for commodities that are considered to be not blended or partially blended. For commodities considered to be blended, the average residues incorporating the likely maximum estimated PCT was used as a point estimate.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment for both mancozeb and ETU, EPA used food consumption information from the 2003–2008 food consumption data from the USDA NHANES/WWEIA.

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 PCT data for new and existing uses, as well as processing and cooking factors. Averages of the field trials were used for the walnuts and tangerines, while field trial and market basket survey data were used for established uses.

b. *ETU.* Chronic anticipated residues were calculated using average values based either on field trial data or monitoring data and average PCT data or average projected PCT as well as processing and cooking factors. Averages of the field trials were used for the walnuts and tangerines, while field trial and market basket survey data were used for established uses.

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 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.

The cancer risks were aggregated using the food and drinking water doses for the general population and the food, water and recreational doses for home gardeners (considered protective of other residential scenarios). 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.

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 the Q_1^* for ETU. The same approach has been taken for the other EBDCs. EPA's estimated exposure to mancozeb-derived ETU 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).

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.

For mancozeb and ETU derived from mancozeb, the following maximum PCT

estimates were used in the acute dietary risk assessment for the following crops: Apples: 45%; asparagus: 30%; barley: 2.5%; cantaloupes: 15%; carrots: 2.5%; celery: 2.5%; corn: 2.5%; cranberries: 20%; cucumbers: 50%; grapes: 20%; oats: 1%; onions: 70%; peanuts: 2.5%; pears: 50%; potatoes: 65%; pumpkins: 15%; rice: 2.5%; spinach: 2.5%; squash: 30%; sugar beets: 2.5%; sweet corn: 15%; tomatoes: 50%; watermelons: 50%; and wheat: 2.5%. A percent import value of 99% was used for banana.

For mancozeb and ETU derived from mancozeb, the following average PCT estimates were used in the chronic and cancer dietary risk assessments for the following crops: Apples: 40%; asparagus: 15%; barley: 1%; cantaloupes: 5%; carrots: 1%; celery: 1%; cherries: 1%; corn: 1%; cranberries: 20%; cucumbers: 25%; grapes: 10%; oats: 1%; onions: 60%; peanuts: 2.5%; pears: 40%; potatoes: 55%; pumpkins: 10%; rice: 1%; spinach: 1%; squash: 20%; sugar beets: 1%; sweet corn: 5%; tomatoes: 25%; watermelons: 40%; and wheat: 1%. A percent import value of 99% was used for banana.

As a further refinement, the commodity having the highest PCT results with livestock feed uses had these values applied to meat and milk (potato; 65% CT maximum for acute and 55% CT average for chronic).

For ETU derived from metiram, the following maximum PCT estimates were used in the acute dietary risk assessment: apples: 15%; potatoes: 10%. A 31% imported commodity in domestic consumption was used for wine grapes.

For ETU derived from metiram, the following average PCT estimates were used in the chronic and cancer dietary risk assessment: Apples: 10%; potatoes: 5%. A 31% imported commodity in domestic consumption was used for wine grapes.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

Also, for the acute risk assessment for mancozeb and ETU derived from mancozeb, the Agency estimated PCT for the following uses for mancozeb, which were recently approved in 2011: Almond, 25%; broccoli, 6%; cabbage, 47%; cabbage, Chinese, 47%; head lettuce 75%; leaf lettuce 66%; pepper, bell, 48%; pepper, non-bell, 48%. For the chronic risk assessment for mancozeb and ETU derived from mancozeb, the Agency estimated PCT as follows: Almond, 18%; broccoli, 5%; cabbage, 42%; cabbage, Chinese, 42%; head lettuce 67%; leaf lettuce 62%; pepper, bell, 44%; pepper, non-bell, 44%. Since metiram is not registered for use on these crops, all potential ETU exposure on these crops will result from use of mancozeb.

EPA developed these refined PCT values based on a detailed chemical-specific analysis. EPA has considered all available relevant information and concludes that it is unlikely that the PCT values for these uses will be exceeded during the next 5 years. Further discussion of how these PCT values were derived can be found at *www.regulations.gov* in the document titled ''Percent Crop Treated for new Uses (PCTn) of Mancozeb on Almonds, Broccoli, Cabbage, Pepper, Pumpkin, and Winder Squash, PC Code: 014504; DP Barcode: 360397; Lettuce, both head and Other; PC Code: 014504; DP Barcode: 364745, NON PRIA, Parent DP: 635267; and Percent Crop Treated with Maneb for Collards, Mustard Greens, Turnip Greens, and Kale'' in docket ID number EPA–HQ–OPP–2012–0628.

For mancozeb and ETU derived from mancozeb, a maximum PCT projected estimate of 50% for walnuts and a maximum percent import consumption value of 35% for tangerines were used in the acute dietary risk assessment. An average PCT estimate of 40% for walnuts as well as an average percent imported commodity in domestic consumption value of 29% for tangerines were used in the chronic and cancer dietary risk assessments.

The walnut information is an amalgamation of the USDA/NASS and private pesticide market research data. The PCT values for walnuts are derived from survey data reported in 2006, 2010, and 2011. Only the state of California is represented in the survey data as 99% of the walnuts grown in the United States are grown in that state. The percent of imported fresh mandarin oranges in domestic consumption was calculated with data for the reporting period of 2008–2013 obtained from the Foreign Agricultural Service (FAS) USDA/Office of Global Analysis (FAS, 2013).

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 water 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 water 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 acute and 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).

1. *Mancozeb.* Mancozeb is currently registered for use on the following residential sites: Home gardens, golf courses, and sod farms (where treated sod could be transplanted to a residential setting). The Agency has determined that it is appropriate to aggregate chronic exposure through food with short-term residential exposures to mancozeb.

The exposure scenario that was evaluated for mancozeb was the residential handler home garden use which considers residential handler exposures (inhalation) to adult applicators combined with average food exposures. Dermal exposure was not evaluated because no effects were observed in a mancozeb 28-day dermal toxicity study.

For post-application, dermal exposure to home gardeners (adults and youth) harvesting vegetables from treated gardens and golfers (adults and youth) contacting mancozeb-treated turf after application is possible. However, as no dermal hazard was identified for mancozeb, a quantitative dermal post-application assessment (non-cancer/short-term and cancer) for the dermal exposure to home gardeners and golfers (adults and youth) was only performed for its metabolite, ETU.

The previous mancozeb risk assessment had evaluated the short/intermediate-term exposure of toddlers to treated turf from the sod farm use. In the most recent risk assessment, the Agency considered post-application exposure resulting from this scenario to be negligible for the following reasons: (1) Mancozeb has a post-harvest interval (PHI) of 5 days for sod; (2) it is unlikely that sod treated with mancozeb would be installed more than once per year; (3) transplanted sod requires constant and significant watering which will result in decreased mancozeb residues on the transplanted sod; and (4) it is unlikely that adults or children will spend any significant amount of time on recently transplanted sod until it is rooted which typically occurs around 2 weeks after transplanting. Therefore, dermal and incidental oral post-application scenarios were not quantitatively assessed for the sod farm use of mancozeb. There are no post-application exposure risks of concern anticipated from the use of mancozeb on sod farms.

ii. *ETU.* ETU non-dietary exposure is expected as a result of the registered uses of mancozeb, which is currently registered for use on the following residential sites: home gardens, golf courses, and sod farms (where treated sod could be transplanted to a residential setting). There are no uses of metiram that will result in exposure in residential settings. The Agency has determined that it is appropriate to aggregate chronic exposure through food with short-term residential exposures to ETU.

The scenario that was evaluated for ETU was the residential home garden use, which considered handler garden exposures (inhalation and 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 females 13–49 years old and youths.

The previous risk assessment also considered treated turf (sod farm) post-application exposures to toddlers (incidental oral and dermal). This more recent risk assessment did not evaluate the sod farm use for the reasons outlined above in the mancozeb non-dietary exposure section.

The previous risk assessment also calculated risks for adult and youth golfers from golfing on treated turf. The more recent assessment concluded that for residential post-application, the gardening scenarios represent the most conservative exposure estimates and are used in the aggregate assessment. The gardening scenarios result in higher estimated exposure than the golfing scenarios and are therefore protective of any golfer risk.

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 metiram, the other registered EBDC chemical, both of which are 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 cannot 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. There was evidence of sensitivity in the developmental neurotoxicity study with mancozeb with decreased pup body weight occurring in the absence of maternal toxicity; risk assessment endpoints are protective for these pup effects.

ii. *ETU.* There is evidence of increased susceptibility of fetuses to ETU. Fetal malformations occurred mainly in rats, although hydrocephaly and domed head were observed in a rabbit developmental study with ETU. The malformations in rats occurred throughout the body. Hydrocephaly occurred in the absence of maternal toxicity after treatment with a single dose of ETU. There was a steep dose-response for the malformations in rats. An acceptable reproductive toxicity 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 for mancozeb.* EPA is retaining the 10X FQPA safety factor for women of childbearing age and for children less than 6 years old but has determined that reliable data show the safety of children greater than 6 years of age would be adequately protected if the FQPA safety factor were reduced to 1X. That decision is based on the following findings:

i. The toxicology database for mancozeb is complete, except that it lacks adequate data on the developing thyroid. Brain development is very sensitive to perturbations in thyroid hormones and it is possible that the developmental thyroid study (being conducted with ETU) could result in lower NOAELs for women of childbearing age (i.e., fetuses) and for children less than 6 years old. Results from the developmental thyroid study will not affect endpoints for children over 6 years of age (for whom the thyroid system is more developed) or adults as thyroid data for those populations are already available. Therefore, the FQPA safety factor is reduced to 1X for these populations.

ii. There was some evidence of neurotoxicity for mancozeb as seen in the acute and subchronic neurotoxicity studies; however, no neurotoxicity occurred in the DNT. Additionally, there are clear NOAELs identified for the effects observed in the toxicity studies. The doses and endpoints selected for risk assessment are protective of all neurotoxicological effects observed in the database.

iii. As noted above in Unit III.D.2., there was some evidence of increased susceptibility of rat pups to mancozeb exposure. Aside from the uncertainty resulting from the lack of adequate thyroid data (for which EPA is retaining the 10X FQPA safety factor), there are clear NOAELs for the offspring effects, and regulatory doses were selected to be protective of these effects.

iv. There are no residual uncertainties identified in the exposure databases. The acute, chronic, and cancer dietary exposure assessments were refined and used PCT estimates and monitoring residue values for several commodities, including some major contributors to the dietary risk such as milk and corn commodities. Monitoring or modeling data were used to derive estimated drinking water concentrations. The drinking water concentrations that were derived from monitoring data reflect the highest value found in a community well monitoring program. The drinking water concentrations from modeling used conservative, health-protective, high-end estimates and are unlikely to be exceeded. The residential exposure assessment used residential SOPs, which are based on conservative high-end assumptions such as maximum application rates and day 0 exposures. Given the overall conservative nature of the exposure assumptions, the aggregate (food, water, and residential) exposure and risk estimates presented in this assessment are not expected to underestimate actual exposure and risk expected based on the current and proposed use patterns.

4. *Conclusion for ETU.* EPA is retaining the 10X FQPA safety factor for women of childbearing age and for children less than 6 years old but has determined that reliable data show the safety of children 6 years of age or older would be adequately protected if the FQPA safety factor were reduced to 1X. That decision is based on the following findings:

i. The toxicology database for ETU is missing a developmental thyroid study, a reproduction study, and a developmental neurotoxicity (DNT) study. These data gaps are being addressed by an ongoing extended one-generation reproductive toxicity study. Because the developing brain is very sensitive to perturbations in thyroid hormones, it is possible that these studies could result in lower NOAELs for women of childbearing age (i.e., fetuses) and for children less than 6 years old; however, results from the developmental thyroid study will not affect points of departure for children greater than 6 years of age, who have a thyroid system similar to adults, adult females greater than 49 years of age (assumed to be beyond typical child-bearing age), or adult males since thyroid data for those populations are already available. Additionally, endpoints from the other segments of the extended one-generation study will not affect these latter populations, and the FQPA safety factor is being reduced to 1X for these populations.

ii. Although the ETU studies were inadequate in evaluating signs of neurotoxicity, there was no evidence of neurotoxicity seen in any study in the database. In any event, the Agency has determined that the selected endpoints would be protective of potential neurotoxicity. The basis for this is that the principal toxic effects occur in the thyroid; thyroid effects provide the most sensitive endpoint, which the Agency is regulating on. Although the extended 1-gen study being performed on ETU is evaluating the potential for effects on the developing brain, the Agency does not believe that a 10X FQPA safety factor is necessary to protect children 6 years old or older because: (1) The weight-of-evidence of the available data indicates that thyroid effects are the most sensitive effect of this chemical; (2) the Agency is regulating on the more sensitive thyroid effect; and (3) the Agency is retaining a 10X FQPA safety factor for the population most likely affected by the thyroid effects.

iii. As noted in Unit III.D.2., there is evidence of increased quantitative and qualitative susceptibility following increased *in utero* exposure to ETU. The developmental study with the lowest NOAEL was selected for the acute endpoint for women of childbearing age and is therefore protective of the developmental malformations. The only remaining developmental uncertainties are related to effects on the developing fetus caused by perturbations in the

still-not-completely-developed thyroid in children younger than 6 years old. Brain development being very sensitive to perturbations in thyroid hormones, it is possible that the extended 1-generation reproductive toxicity test, in which developmental thyroid effects will be evaluated, will result in lower NOAELs for these populations than are presently being used to assess risk; therefore, the Agency is retaining the 10X FQPA safety factor for females 13–49 years of age and for children less than 6 years of age.

iv. There are no residual uncertainties identified in the EBDC's (mancozeb or metiram) exposure databases for ETU assessment. The acute, chronic, and cancer dietary exposure assessments were refined and used PCT estimates and monitoring residue values for several commodities including some major contributors to the dietary risk such as milk and corn commodities. Monitoring or modeling data were used to derive estimated drinking water concentrations. The drinking water concentrations that were derived from monitoring data reflect the highest value found in a community well monitoring program. The drinking water concentrations from modeling used conservative, health-protective, high-end estimates and are unlikely to be exceeded. The residential exposure assessment used residential SOPs, which are based on conservative high-end assumptions such as maximum application rates and day 0 exposures. Given the overall conservative nature of the exposure assumptions, the aggregate (food, water, and residential) exposure and risk estimates presented in this assessment are not expected to underestimate actual exposure and risk expected based on the current and proposed use patterns.

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 to mancozeb will occupy 9.9% of the aPAD for children 1–2 years old, the population subgroup receiving the greatest exposure.

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 (from mancozeb and metiram) will occupy 60% 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 2.3% of the cPAD for children 1–2 years of age, the population group receiving the greatest exposure.

4. *Chronic risk (ETU).* There are no long-term residential exposure scenarios for ETU; the aggregate chronic risks were calculated using food and water exposure only. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ETU (from mancozeb and metiram) 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-term risk (mancozeb).* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Mancozeb is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food with short-term residential exposures to mancozeb. The scenario that was evaluated for mancozeb was the residential handler home garden use. The aggregate short-term home garden MOEs for adult males and females greater than 49 years old is 99,000 and the MOE for adult females 13–49 years old is 94,000. Because for mancozeb EPA is concerned only with MOEs that are below 30 (adult males and females greater than 49 years old) and 300 (adult females 13–49 years old), these MOEs do not raise a risk concern.

6. *Short-term risk (ETU).* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Mancozeb is currently registered for uses that could result in short-term residential exposure to ETU. There are no residential uses for metiram. The Agency determined that it was appropriate to aggregate chronic exposure through food with short-term residential exposures to ETU. The ETU short-term handler home garden aggregate MOE for adult females 13–49 years old is 27,000 and for adult males (and females older than 49 years old) is 42,000. The ETU short-term post-application home garden aggregate MOE for adult females 13–49 years old is 2,600 and for youths 11–16 years old is 3,100. Because for ETU EPA is concerned only with MOEs that are below 1,000 (adult females 13–49 years old) and 100 (adult males, females >49 years old and youth 11–16 years old), these MOEs do not raise a risk concern.

7. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

8. *Aggregate cancer risk for U.S. population.* 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.

The cancer aggregate risk estimates (home garden handler and post-application scenarios) for the U.S.

population are 2×10^{-6} and 3×10^{-6}, respectively.

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 mancozeb risk assessment is highly refined, the Agency believes there is some conservatism for the following reasons: (1) The linear low-dose extrapolation approach is conservative because it does not take into account certain human biological processes such as reversibility and repair; (2) the residential SOPs are based on conservative high-end assumptions such as maximum application rates and day 0 exposures; and (3) some food exposures are estimated based on tolerance-level residues. Accordingly, EPA has concluded the cancer risk for all existing mancozeb uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

9. *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 and/or ETU 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; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

There is no Codex MRL established for mancozeb on walnuts.

There is a MRL of 10 ppm established by Codex for the use of EBDC compounds on mandarins which is consistent with the 10 ppm tolerance on tangerine being established by this document.

C. Revisions to Petitioned-For Tolerances

Based on the evaluation of the residue data, the Agency is modified the tolerance for walnuts from the proposed level of 0.75 ppm to 0.70 ppm. EPA revised the tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of mancozeb, in or on walnut at 0.70 ppm and tangerine at 10 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).

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

This 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) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology

Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 16, 2013.

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. In § 180.176, add alphabetically the following commodities and the footnote to the table in paragraph (a) to read as follows:

§ 180.176 Mancozeb; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Tangerine[1]	10
* * * * *	
Walnut	0.70
* * * * *	

[1] There are no U.S. registrations for use of mancozeb on tangerine.

* * * * *

[FR Doc. 2013–17869 Filed 7–23–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1990–0010; FRL 9836–9]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Sola Optical U.S.A., Inc. Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region 9 is publishing a direct final Notice of Deletion of the Sola Optical U.S.A., Inc. Superfund Site (Site), located in Petaluma, California, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of California, through the California Regional Water Quality Control Board—San Francisco Bay Region, because EPA has determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: This direct final deletion is effective September 23, 2013, unless EPA receives adverse comments by August 23, 2013. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–HQ–SFUND–1990–0010, by one of the following methods:

- *http://www.regulations.gov*. Follow on-line instructions for submitting comments.
- *Email: rodriguez.dante@epa.gov*.
- *Fax:* (415)947–3528.
- *Mail:* Dante Rodriguez, U.S. EPA Region 9, mail code SFD–8–2, 75 Hawthorne Street, San Francisco, CA 94105.
- *Hand delivery:* U.S. EPA Region 9, 75 Hawthorne Street, mail code SFD–8–2, San Francisco, CA 94105.

Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID no. EPA–HQ–SFUND–1900–0010. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket

All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statue. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at:

Superfund Records Center, 95 Hawthorne St., Room 403, Mail Stop SFD–7C, San Francisco, CA 94105, (415) 536–2000, Mon–Fri: 8:00 a.m. to 5:00 p.m.;

or the Site Repository at

Petaluma Public Library, 100 Fairgrounds Drive, Petaluma, CA 94952, (707) 763–9801, Mon, Thurs, Fri, Sat: 10:00 a.m. to 6:00 p.m., Tues, Wed: 10:00 a.m. to 9:00 p.m.