a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 6, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In §180.920, in the table, add alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Diethylene Glycol (CAS No. 111–46–6)	Without limitation	Solvent, stabilizer and/or anti-freeze
* * *	* *	* *

[FR Doc. 2010–20318 Filed 8–17–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0541; FRL–8841–1]

Mancozeb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mancozeb in or on multiple commodities which are identified and discussed later in this document. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action establishes a time-limited tolerance for residues of mancozeb in or on walnuts in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of mancozeb on walnuts to control walnut blight. This regulation establishes a maximum permissible level of residues of mancozeb in walnuts. The time-limited tolerance on walnuts expires and is revoked on December 31, 2013. Also, this action revises the introductory text of paragraphs (a) and (b).

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0541. 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–2005–0541 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 October 18, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2005–0541, 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 March 15, 2006 (71 FR 13389) (FRL–7767–3), 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 3E4173, 5E4570, 9E5054, and 9E5061) by the Interregional Research Project Number 4 (IR-4), 681 US Highway No. 1 South, North Brunswick, NJ 08902–3390. 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 the following commodities: (PP 3E4173) cucurbit vegetable crop group 9 at 4.0 parts per million (ppm); (PP 5E4570) mango, star apple (caimito), canistel, mamey sapote, sapodilla, and white sapote at 15.0 ppm; (PP 9E5054) ginseng at 2.0 ppm; (PP 9E5061) sugar apple, cherimoya, atemoya, custard apple, and sweetsop at 3.0 ppm. The notice included a summary of the petitions prepared by Dow AgroSciences, the registrant. However, in the **Federal Register** of September 16, 2009, (74 FR 47504) (FRL–8431–4) in a document titled "Mancozeb, Maneb, Metiram, and Thiram; Proposed Tolerance Actions," EPA proposed establishing tolerances for ginseng at 1.2 ppm, removing the existing tolerances for cucumber, melon and summer squash and establish a tolerance for the vegetable, cucurbit group 9 at 2.0 ppm, and revising the tolerance expression in § 180.176. The reasons why EPA determined the tolerances for ginseng and cucurbit vegetable crop group 9 should be different from the original IR-4 petition as well as the rationale for changing the tolerance expression are explained in Unit V.D.

EPA did not receive comments on the notice of March 15, 2006 but comments were received on the proposed rule of September 16, 2009. EPA's response to these comments is discussed in Unit V.C.

EPA is not establishing a tolerance for sweetsop. The reason why is explained in Unit V.D.

Separate from the actions being taken in response to the IR-4 petitions, EPA is also establishing a time-limited tolerance for residues of mancozeb in or on walnuts at 0.015 ppm in connection with an emergency use of mancozeb approved under FIFRA. This tolerance expires and is revoked on December 31, 2013.

III. Emergency Exemption for Mancozeb on Walnuts and FFDCA Tolerances

Walnut blight is a bacterial disease caused by *Xanthomonas campestris pv.juglandis*. It can result in severe economic losses due to undeveloped walnuts or early walnut-drop when the pathogen is present with free moisture during flowering and early nut development. Historically, walnut blight was managed by the application of copper products. Copper-resistant pathogens were found in some orchards and walnut losses in these orchards increased. Maneb was found to effectively manage walnut blight, and thus reduce walnut losses, where copper-resistant populations occurred and EPA has allowed use of maneb on walnut under an emergency exemption on a longstanding basis in the State of California. However, registrants have requested all products containing the active ingredient maneb be cancelled. Additionally, the Agency has been notified by the EBDC Task Force that there are no existing stocks of products containing maneb available for use on walnuts during 2010. Therefore, for the 2009-2010 growing season, the State of California requested an emergency exemption for use of mancozeb. This is the first time that California has requested mancozeb for this use. It represents an equivalent agricultural tool since mancozeb and maneb are related compounds.

After having reviewed the submission, EPA determined that an emergency condition exists for California, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for the use of mancozeb on walnuts for control of walnut blight in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of mancozeb in or on walnuts. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires on December 31, 2013, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on walnuts after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether mancozeb meets FIFRA's registration requirements for use on walnuts or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of mancozeb by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than California to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for mancozeb, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. 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.

EPA completed the Reregistration Eligibility Decision (RED) for mancozeb in September, 2005 (*http://www.epa.gov/oppsrrd1/REDs/mancozeb_red.pdf*). The Agency determined that most uses for the active ingredient mancozeb were eligible for reregistration provided that the risk mitigation measures identified in the RED were adopted and labels were amended to reflect these measures. Certain uses (foliar use on cotton, use on pineapple seed pieces, use on residential lawns/turf, use on athletic fields/turf, and use on pachysandra) were not eligible for reregistration and have since been voluntarily canceled by mancozeb registrants and deleted from all mancozeb labels.

In assessing mancozeb risk for the RED, EPA included the uses associated with the petitions submitted by IR-4 to establish tolerances for residues of mancozeb on cucurbit vegetable crop group 9 (PP 3E4173), mango, star apple, canistel, mamey sapote, sapodilla, white sapote (PP 5E4570), ginseng (PP 9E5054), sugar apple, cherimoya, atemoya, custard apple, and sweetsop (PP 9E5061). Additionally, EPA considered exposure to residues of mancozeb on walnut in connection with a pending petition (PP 5F4582) submitted by the registrant. No action was taken on these petitions until the mitigation measures outlined in the RED were implemented and existing stocks for the cancelled uses moved through the channels of trade. The registrant later withdrew the petition request to establish tolerances for mancozeb on walnuts.

While these mitigation measures were being implemented several things changed regarding the mancozeb/ETU risk profile. First, EPA determined that it was appropriate to retain the 10X FQPA Safety Factor for acute dietary risk due to lack of the developmental neurotoxicity study. Second, the registrant submitted additional petitions in 2004 that were not considered in the RED to establish tolerances for residues of mancozeb in or on almond (PP 4F4324), cabbage, leaf lettuce, peppers and broccoli (PP 4F4333). Therefore, based on these changes, EPA conducted an additional risk assessment in 2007 for mancozeb which assessed all uses (refer to risk assessment in the Docket EPA–HQ–OPP–2005–0541 titled "Mancozeb: Human Health Risk Assessment to Support Proposed New Uses on Broccoli, Cabbage, Lettuce, Peppers and Almonds").

To date, EPA is still working to refine the risk assessment for ETU which incorporates the pending new uses for mancozeb that were submitted to EPA in 2004 (almond, cabbage, leaf lettuce, peppers and broccoli). In the meantime, EPA is moving forward to establish a time-limited tolerance on walnut to support the emergency exemption as well as establish permanent tolerances for cucurbit vegetable group 9, mango, star apple, canistel, mamey sapote, sapodilla, white sapote, ginseng, sugar apple, cherimoya, atemoya, and custard apple. EPA is relying on an assessment conducted for mancozeb in 2007 (refer to risk assessment in the Docket EPA–HQ–OPP–2005–0541 titled "Mancozeb: Human Health Risk Assessment to Support Proposed New Uses on Broccoli, Cabbage, Lettuce, Peppers and Almonds"), an assessment for ETU from 2007 (for short- and intermediate-term aggregate exposures; refer to risk assessment in the Docket EPA–HQ–OPP–2005–0541 titled "Ethylenethiourea (ETU) from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU"), and the assessment completed in the RED for exposures to ETU since that is still valid and accounts for exposure to all of the commodities discussed in this rule (refer to risk assessment in the Docket EPA–HQ–OPP–2005–0176 titled "ETU from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degradate ETU to Support Reregistration"). Since the 2007 ETU assessment includes the use on almond, cabbage, leaf lettuce, peppers and broccoli, uses for which tolerances do not exist and are not being established at this time, the estimates for short- and intermediate-term aggregate risk for ETU are likely overestimates.

It is also important to note that since most products for maneb have been cancelled or will be shortly and there are limited existing stocks for maneb still in the channels of trade, the risk assessments for ETU likely overestimate the exposures to this common metabolite. Additionally, the risk estimates for mancozeb include uses for which tolerances do not exist and are not being established at this time, and therefore, the numbers reported are an over estimate of the potential risks.

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 last 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 T4, increases or decreases in T3, 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 toxic 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 www.regulations.gov in the document titled "Mancozeb: Human Health Risk Assessment to Support Proposed New Uses on Broccoli, Cabbage, Lettuce, Peppers and Almonds," pp. 13-15 in docket ID number EPA–HQ–OPP–2005–0541.

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 document titled "ETU from EBDCs: Health Effects Division (HED) Human Health Risk Assessment of the Common Metabolite/Degraduate ETU to Support Reregistration. Chemical ID No. 600016. DP Barcode No. D305129," pp. 9-11 in docket ID number EPA–HQ–OPP–2004–0078.

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 (Females 13–50 years of age)	NOAEL = 128 milligrams/kilograms/day (mg/kg/day) UF_A =10x UF_H = 10x UF_{DB}=10x	Acute RfD = 0.13 mg/kg/day Acute PAD = 0.13 mg/kg/day	Developmental Toxicity in the rat LOAEL = 512 mg/kg/day based on hydrocephaly and other malformations
Acute dietary (General population including infants and children)	No appropriate endpoint was identified from oral toxicity studies.		

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
Chronic dietary (All populations)	NOAEL= 4.83 mg/kg/day UF_A = 10x UF_H = 10x UF_{DB}=10x	Chronic RfD = 0.005 mg/ kg/day Chronic PAD = 0.005 mg/ kg/day	Toxicity/Carcinogenicity in the rat LOAEL = 30.9 mg/kg/day based thyroid toxicity (changes in thyroid hormone levels, microscopic thyroid changes and changes in thyroid weights)
Incidental oral short- or intermediate term (1 to 30 days)	NOAEL= 9.24 mg/kg/day UF_A = 10x UF_H = 10x UF_{DB}=10x	LOC for MOE = 1,000	Subchronic Toxicity Study in the rat LOAEL = 17.82 mg/kg/day based on decreased T4
Dermal short- and intermediate term (1 to 30 days)	Mancozeb has low dermal absorption. No systemic toxicity observed via the dermal route at 1,000 mg/ kg/day. Developmental effects were noted at doses much higher than those where systemic toxicity was observed in the maternal animals (in oral studies) indicating that developmental effects will not occur below 1,000 mg/kg/day the limit dose, from dermal exposure.		
Dermal long-term	Dermal (or oral) study NOAEL= 4.83 mg/kg/day (dermal absorption rate = 1% UF_A = 10x UF_H = 10x UF_{DB}=10	LOC for MOE = 1,000	Toxicity/Carcinogenicity in the rat LOAEL = 30.9 mg/kg/day based on thyroid toxicity (changes in thyroid hormone levels, microscopic thyroid changes and changes in thyroid weights)
Inhalation short-, intermediate-, or long-term	NOAEL = 0.079 mg/L [equivalent to 21 mg/kg/day] UF_A = 10x UF_H = 10x UF_{DB}=10x	LOC for MOE = 1,000	Subchronic Inhalation in the rat LOAEL = 0.326 mg/L based on thyroid hyperplasia and decreased T4 (females)
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 x 10^{-2} $(mg/kg/day)^{-1}$ to provide a quantitative estimate of risk.		

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

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 (Females 13–50 years of age)	NOAEL = 5 milligrams/kilograms/day (mg/kg/day) UF_A = 10x UF_H = 10x UF_{DB}=10x	Acute RfD = 0.005 mg/kg/day Acute PAD = 0.005 mg/kg/day	Developmental Toxicity in the rat (Khera Study, MRID No. 45937601) LOAEL = 10 mg/kg/day based on developmental defects of the brain
Acute dietary (General population including infants and children)	No appropriate endpoint attributable to a single exposure (dose) was identified.		
Chronic dietary (All populations)	NOAEL= 0.18 mg/kg/day UF_A = 10x UF_H = 10x UF_{DB}= 10x	Chronic RfD = 0.0002 mg/kg/ day Chronic PAD = 0.0002 mg/kg/ day	Chronic Oral Toxicity in the dog. LOAEL = 1.99 mg/kg/day based on thyroid toxicity (increased thyroid weight and macroscopic changes in the thyroid – hypertrophy, follicular dilation)
Incidental Oral (Short- and Intermediate-Term)	NOAEL= 7 mg/kg/day UF_A = 10x UF_H = 10x UF_{DB}=10x	Residential LOC = 1,000	4 week range-finding dog study LOAEL = 34 mg/kg/day based on thyroid toxicity (decreased levels of thyroid hormones, gross thyroid lesions)

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
Dermal (Short- and Intermediate-Term)	NOAEL = 5 mg/kg/day DA = 26% UF_A = 10x UF_H = 10x UF_{DB}= 10x	LOC for MOE = 1,000	Developmental Toxicity in the rat (Khera Study, MRID No. 45937601) LOAEL = 10 mg/kg/day based on developmental defects of the brain
Dermal (Long-Term)	NOAEL = 0.18 mg/kg/day DA = 26% UF_A = 10x UF_H = 10x UF_{DB}= 10x	LOC for MOE = 1,000	Chronic Oral Toxicity in the dog LOAEL = 1.99 mg/kg/day based on thyroid toxicity (increased thyroid weight and macroscopic changes in the thyroid – hypertrophy, follicular dilation)
Inhalation (Short- and Intermediate-Term)	Inhalation (or oral) study NOAEL= 5 mg/kg/day UF_A = 10x UF_H = 10x UF_{DB}= 10x Inhalation toxicity is assumed to be equivalent to oral toxicity.	LOC for MOE = 1,000	Developmental Toxicity in the rat (Khera Study, MRID No. 45937601) LOAEL = 10 mg/kg/day based on developmental defects of the brain
Inhalation (Long-Term)	NOAEL = 0.18 mg/kg/day UF_A = 10x UF_H = 10x UF_{DB}= 10x Inhalation toxicity is assumed to be equivalent to oral toxicity.	LOC for MOE = 1,000	Chronic Oral Toxicity in the dog LOAEL = 1.99 mg/kg/day based on thyroid toxicity (increased thyroid weight and macroscopic changes in the thyroid – hypertrophy, follicular dilation)
Cancer (Oral, dermal, inhalation)	$Q1^* = 6.01 \times 10^{-2}$ $(mg/kg/day)^{-1}$ ETU is classified as a probable human carcinogen. Cancer risk is quantitified with a linear low-dose extrapolation approach based on liver tumors in female mice.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. DA = Dermal Absorption.

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 discussed in this document including additional proposed uses that the Agency is not establishing tolerances for at this point (almonds, cabbage, lettuce, broccoli, and pepper) 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). 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.

The Dietary Exposure Evaluation Model (DEEM(TM)) analysis evaluated the individual food consumption as reported by respondents in the 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 proposed uses that the Agency is not establishing tolerances at this time (almonds, cabbage, lettuce, broccoli, and pepper) 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 uses, field trial or monitoring data, 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 Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (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 proposed uses that the Agency is not

establishing tolerances at this time (almonds, cabbage, lettuce, broccoli, and pepper) and existing uses, as well as processing and cooking factors.

b. *ETU*. Chronic anticipated residues were calculated from field trial 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. Cancer risk is quantified using a linear or non-linear 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 non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized.

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 (Q1*) 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 Q1* 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).

EPA relied on 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.

For mancozeb the Agency estimated the PCT for existing uses as follows:

Cantaloupes 5%; pumpkins 5%; sugar beets 5%; tobacco 5%; cucumber 10%; garlic 10%; sweet corn 10%; grapes 15%; squash 15%; asparagus 20%; eggplant 20%; tomatoes 25%; apples 30%; cranberries 30%; watermelons 35%; pears 40%; onions 50%; and potatoes 54%. Beans, green; carrots; cherries; corn (field); cotton; oranges; peaches; peanuts; pecans; prunes, plums; strawberries; walnuts; and wheat all average less than 1%.

For ETU the Agency estimated the PCT for existing uses of mancozeb, maneb and metiram.

a. *Mancozeb*. For mancozeb, the PCT was identical to that listed in this unit.

b. *Maneb*. For maneb, the Agency estimated the PCT for existing uses as follows:

Almonds 10%; apples 1%; dry beans 1%; green beans 5%; broccoli 5%; Brussels sprouts 21%; cabbage 15%; carrots 1%; cauliflower 5%; celery 5%; collards 10%; field corn 1%; eggplant 55%; garlic 25%; grapes 1%; mustard greens 5%; kale 5%; lettuce 65%; onions; 10%; pears 1%; peppers 30%; potatoes 5%; pumpkins 5%; spinach 15%; squash 5%; sugar beets 1%; sweet corn 1%; tomatoes 5%; walnuts 30%; watermelons 5%; wheat 5%.

c. *Metiram*. For metiram, the Agency estimated the PCT for existing uses as follows:

Apples 15%; asparagus 1%; peaches 1%; potatoes 10%; squash 1%.

The PCT estimates for mancozeb and maneb on walnuts reflect usage of maneb on walnuts under an emergency exemption prior to the cancellation of maneb products and establishment of the emergency exemption use on walnuts for mancozeb. Going forward, EPA expects mancozeb use on walnuts to replace maneb. However, for this present action, EPA concludes it is reasonable to use the risk assessment that relied upon the PCT estimates in this unit for walnuts because: EPA does not expect mancozeb use on walnuts to be higher than the prior maneb use; mancozeb residues on walnuts and the consumption level of walnuts are insignificant compared to residue and consumption levels of other mancozeb-treated commodities (e.g., melons and apples); and ETU residues from maneb and macozeb are equivalent.

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

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to

residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which 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. The values are listed in Table 3 of this unit.

TABLE 3.— SURFACE AND GROUND WATER VALUES.

	Acute	Chronic	Cancer
Surface Water EDWC	0.1 to 25.2 ppb	0.10 ppb	0.10 ppb
Ground Water EDWC	0.21 ppb	0.21 ppb	0.21 ppb

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

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

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

i. *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.

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 dietary 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 the Short/Intermediate-Term Home Garden Aggregate which combines handler exposures (inhalation and dermal) and post application garden exposures (dermal) plus average daily food and drinking water exposure for adults and post application garden exposures (dermal) plus average daily food and drinking water exposure for youth, the 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 Short/Intermediate-Term Treated Turf Aggregate (Adults "Golfers") which considers short-term residential exposures (dermal) plus average daily food and drinking water exposure for adults such as golfing on treated turf.

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 in Unit IV., 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.* The toxicity database for mancozeb is not complete. The new requirement for an immunotoxicity study has not been met. 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. A developmental neurotoxicity (DNT) study has been submitted, and EPA has recently completed a review of this study. 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). Since the review of the DNT was completed after the most recent risk assessment was finished, EPA has not had the opportunity to re-evaluate the need for an FQPA factor. For this assessment, EPA has retained the presumptive 10X FQPA safety factor for the protection of children, but will re-visit the need for the safety factor for the next tolerance action.

No additional FQPA Safety Factor is needed beyond the 10X database uncertainty factor applied to account for the data gap for a developmental neurotoxicity study with mancozeb. The reasons for this conclusion are:

a. There is a lack of evidence of pre- and/or postnatal susceptibility resulting from exposure to mancozeb

b. There are no residual uncertainties concerning toxicity, and

c. The exposure assessment, although refined, is unlikely to under-estimate potential exposures.

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-generaltion reproduction study; and a comparative thyroide study in adults and offspring. Given these multiple datagaps 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:

a. The teratogenic effects of ETU have been well-characterized in numerous studies in the published literature, as well as in a guideline study submitted by the registrant. In addition, since metabolism studies have shown that approximately 7.5% of mancozeb converts to ETU in mammalian systems, the extensive toxicity database with mancozeb provide extensive information about toxicity of ETU;

b. 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.

c. The developmental endpoint with the lowest NOAEL was selected for deriving the acute RfD.

d. The target organ toxicity (thyroid toxicity) 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 pre- and/or post-natal toxicity.

Second, the information on ETU gleaned from the extensive mancozeb database 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.

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 per se from food only since residues of mancozeb per se 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 dietary (food only) exposure 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).* Since there are no dermal endpoints selected for mancozeb, the home garden aggregate risk assessment does not include dermal exposure. Further, since residues of mancozeb are not expected in drinking water, only mancozeb food residues are considered. This assessment combines residential handler exposures (inhalation) to adult applicators plus average food exposures. The exposure value used for food represents the highest exposure found from all adult populations in the mancozeb chronic dietary exposure assessment.

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).* Since there are no dermal endpoints selected for mancozeb and no likelihood of residues in drinking water, the mancozeb short-term treated turf aggregate risk assessment for toddlers combines residential incidental oral exposures with average food residues. The exposure value used for food represents the highest exposure found from all child populations in the mancozeb chronic dietary exposure assessment.

With a 5–day interval between application and transplant for the sod farm use, which is now on the registered label, 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 and maneb are currently registered for uses that could result in short- and intermediate-term residential exposure to ETU and the Agency has determined that it is appropriate to aggregate chronic exposure through food with short- and intermediate-term residential exposures to ETU. The three scenarios that were evaluated for ETU are the following:

i. *ETU Short/Intermediate-Term Home Garden Aggregate*. The ETU short/intermediate-term home garden aggregate combines handler inhalation and dermal exposures and post application garden dermal exposures plus average daily food and drinking water for adults exposed to ETU. For youth exposed to ETU, the assessment combines post application garden dermal exposures with average food and drinking water. Only mancozeb is registered for use in home garden settings. Average food and drinking water exposure values reflect the most highly exposed adult or youth subpopulation from the average daily dietary assessment, and consider ETU derived from mancozeb, metiram, and maneb applications. The existing and proposed food uses were included in the food and drinking water exposure estimates.

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 short-term treated turf aggregate risk assessment combines treated turf post application incidental oral and dermal exposures with average daily food and drinking water exposure for toddlers. Maneb and mancozeb are both registered for applications to sod farms. Average food and drinking water exposure values, including all sources of ETU, reflect the most highly exposed children's subpopulation from the chronic dietary assessment.

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 (Adults "Golfers").* The short/intermediate-term treated turf aggregate risk assessment combines dermal exposures for adults golfing on treated turf exposed to ETU with average daily food and drinking water exposures. Only mancozeb uses are relevant for this scenario.

The ETU short-term treated turf aggregate MOE for adults ("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 Unit IV.C.iii., 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 2.3×10^{-6}.

EPA generally considers cancer risks in the range of 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 log 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, 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. 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.

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 and/or ETU residues.

V. 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 carbon disulfied (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 maximum residue limits for residues of mancozeb per se; however, Codex limits for dimethyldithiocarbamates fungicides are grouped under dithiocarbamates. There are Codex MRLs for cucumber (2 ppm), melons (0.5 ppm), pumpkins (0.2 ppm), and summer squash (1 ppm).

C. Response to Comments

As discussed in Unit II. of this document, in the **Federal Register** of September 16, 2009, EPA proposed tolerance actions for mancozeb. EPA did receive comments on the proposed rule; however, many of those comments are not related to the uses proposed in this action. Therefore, EPA is only responding to the comment received that directly addresses issues that pertain to this action. EPA will respond to the additional comments in a future rule.

Comment. The Natural Resources Defense Council (NRDC) commented about the FQPA Safety Factor and the risks to infants of low iodide women. NRDC is concerned about the effects of the EBDC fungicides on women of child-bearing age. All of the EBDC fungicides have shown effects on the thyroid. They have noted that a decrease in thyroxine in pregnant and lactating women, such as has been observed in laboratory animals exposed to the EBDC fungicides, can result in neuro-developmental problems in their children. NRDC has specifically inquired whether the Agency considered the risks to the infants of low-iodide women, and has recommended that the Agency retain the FQPA factor of at least 10X, and possibly more.

Agency Response. EPA agrees with NRDC that protection from adverse effects in the thyroid in women of child-bearing age is important to protect the developing fetus from adverse outcomes. An adverse effect, even in the case of women with iodine deficiency, is not expected for the following reasons.

The mode of action for thyroid toxicity from the EBDCs is understood. ETU, which is the common metabolite of the EBDCs, acts by inhibiting thyroid peroxidase, an enzyme used in the synthesis of thyroid hormone. This enzyme inhibition ceases when exposure to ETU is removed and there is no subsequent change in enzyme function The other thyroid effects (organ weight and microscopic changes), are secondary to this enzyme inhibition as the body attempts to increase production of thyroid hormone by stimulating the thyroid in compensation.

People are protected from the enzyme inhibition because the EBDCs are regulated from the NOAEL for thyroid effects, which is below the dose at which there are thyroid effects in animals. Further, the EBDCs were tested in rats, which are much more sensitive to thyroid perturbations than are humans. Rats are more sensitive than humans because the serum half-life of the thyroid hormone, thyroxine, is much shorter in rats (less than 1 day) than in humans (5-9 days). The 10X interspecies uncertainty factor applied to the EBDCs to account for the possibility that humans are more sensitive than the test animals is therefore more than adequate to protect humans. The 10X intraspecies factor accounts for variability in sensitivity among species and gives protection for women with iodine deficiency. The combination of these factors is therefore expected to be protective for the fetus and pregnant women with regard to possible iodine deficiencies. The Agency has requested a comparative thyroid assay for ETU which will provide additional information on the potential susceptibility of developing organisms, including the developing fetus, to thyroid perturbation, and has retained an FQPA safety factor of 10X to account for the uncertainties associated with these missing data.

D. Revisions to Petitioned-For Tolerances

EPA is not establishing a tolerance for sweetsop because it is the same commodity as sugar apple. The Agency is establishing the tolerance on sugar apple because it is the preferred term for this commodity.

The ginseng tolerance is a reduction from the proposed 2.0 ppm to 1.2 ppm based on conclusions reached in the RED. The 2.0 tolerance recommendation is on a mancozeb per se basis; however EPA is now recommending for a tolerance on a carbon disulfide equivalents basis thus resulting in a tolerance recommendation of 1.2 ppm.

In regards to the cucurbit tolerance, based on available field trial data that showed mancozeb residues as high as 2.1 ppm on cucumber, 2.7 ppm on melons, and 1.75 ppm on summer squash, the Agency determined that individual tolerances should be set at 3.0 ppm, 3.0 ppm, and 2 ppm, respectively, which when converted to carbon disulfide equivalents using a rounded conversion factor of 0.6X is calculated as 1.8 ppm, 1.8 ppm, and 1.2 ppm, respectively. Because the representatives for crop group 9 include cucumber, muskmelon, and summer squash, EPA believes that these tolerances should be combined into a single crop group tolerance and decreased from their current individual

tolerance levels of 4 ppm to 2 ppm. EPA proposed these changes in the **Federal Register** of September 16, 2009, in a document proposing multiple changes to the mancozeb tolerances.

E. Revisions to Tolerance Expression

EPA is also in this action changing the mancozeb tolerance expression as proposed in the **Federal Register** of September 16, 2009. Currently, tolerances for mancozeb are established in 40 CFR 180.176(a) for residues of the fungicide mancozeb, a coordination product of zinc ion and maneb (manganese ethylenebisdithiocarbamate) and calculated as zinc ethylenebisdithiocarbamate (zineb). Mancozeb is a member of the class of dithiocarbamates, whose decomposition releases CS_2. In order to allow harmonization of U.S. tolerances with Codex Maximum Residue Limits (MRLs), the Agency determined that for the purpose of tolerance enforcement, residues of mancozeb should be calculated as carbon disulfide. Therefore, EPA is revising the introductory text containing the tolerance expression in 40 CFR 180.176(a) and (b).

VI. Conclusion

Therefore, tolerances are established for residues of mancozeb, zinc manganese ethylenebis dithiocarbamate in or on cucurbit vegetable crop group 9 at 2.0 ppm; mango, star apple, canistel, mamey sapote, sapodilla, and white sapote at 15.0 ppm; ginseng at 1.2 ppm; sugar apple, cherimoya, atemoya and custard apple at 3.0 ppm; and a time-limited tolerance in or on walnut at 0.015 ppm.

VII. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 10, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.176 is amended as follows.

i. In paragraph (a), revise the introductory text;

ii. In paragraph (a), in the table, remove the commodities Cucumber, Melon, and Summer squash and alphabetically add the following commodities;

iii. In paragraph (b), revise the introductory text;

iv. In paragraph (b), in the table, alphabetically add Walnut.

The amendments read as follows:

§ 180.176 Mancozeb; tolerances for residues.

(a) *General.* Tolerances are established for residues of mancozeb (a coordination product of zinc ion and maneb (manganese ethylenebisdithiocarbamate)), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those mancozeb residues convertible to and expressed in terms of the degradate carbon disulfide.

Commodity	Parts per million
* * * * *	
Atemoya	3.0
* * * * *	
Canistel	15.0
* * * * *	
Cherimoya	3.0
* * * * *	
Custard apple	3.0

Commodity	Parts per million
* * * * *	
Ginseng	1.2
* * * * *	
Mango	15.0
* * * * *	
Sapodilla	15.0
Sapote, mamey	15.0
Sapote, white	15.0
* * * * *	
Star apple	15.0
Sugar apple	3.0
* * * * *	
Vegetable, cucurbit, group 9	2.0

* * * * *

(b) *Section 18 emergency exemptions.* Time limited tolerances are established in connection with use of the pesticide under a section 18 emergency exemption granted by EPA for residues of mancozeb (a coordination product of zinc ion and maneb (manganese ethylenebisdithiocarbamate)), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only those mancozeb residues convertible to and expressed in terms of the degradate carbon disulfide. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
* * * * *	*	*
Walnut	0.015	12/31/13

* * * * *

[FR Doc. 2010–20453 Filed 8–17–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0099; FRL–8836–2]

Flubendiamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes, reassesses, modifies and revokes tolerances for residues of flubendiamide, N^2-[1,1-dimethyl-2-(methylsulfonyl)ethyl-3-iodo-N^1-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in/on multiple food and livestock commodities which are identified, and will be discussed in detail later in this document. Bayer CropScience, LP in c/o Nichino America, Inc. (U.S. subsidiary of Nihon Nohyaku Co., Ltd.) requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0099. 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 (7504P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax number: (703) 308–0029; 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 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–2007–0099 in the subject line on the first page of your submission. All objections and requests for a hearing