

PART 52—[AMENDED]

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

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

Subpart B—Alabama

■ 2. In § 52.50(c) the table is amended by revising the entry for “Section 335–3–17.01” to read as follows:

§ 52.50 Identification of plan.

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(c) * * *

EPA-APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter 335–3–17 Conformity of Federal Actions to State Implementation Plans				
Section 335–3–17.01	Transportation Conformity	04/03/07	09/23/09 [Insert citation of publication].	
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0020; FRL–8431–9]

Thiram; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of thiram, (tetramethyl thiuram disulfide) in or on banana, import. Taminco Incorporated requested a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 2009, 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–2007–0020. 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: Bryant Crowe, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–0025; e-mail address: crowe.bryant@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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those 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–2007–0020 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before November 23, 2009.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0020, 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. Petition for Tolerance

In the **Federal Register** of June 27, 2007 (72 FR 35237) (FRL-8133-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP) 6E7144 by Taminco, Inc. (inadvertently listed as Tamico, Inc. in the notice of filing), 1950 Lake Park Drive, Smyrna, GA 30080. The petition requested that 40 CFR 180.132 be amended by establishing an import tolerance for residues of the fungicide thiram, (tetramethyl thiuram disulfide), in or on banana, whole at 0.5 parts per million (ppm); and banana, pulp at 0.3 ppm. The notice referenced a summary of the petition prepared by Taminco, Inc., the registrant, which is available to the public in the docket, <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 determined an increase in the tolerance for banana, whole at 0.80 ppm, formerly proposed at 0.5 ppm; and the removal of banana, pulp, formerly proposed at 0.3 ppm. The Agency has also identified the correct commodity expression for banana, whole as banana. The reason for these changes 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 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 the petitioned-for tolerance for residues of thiram in or on banana at 0.80 ppm. EPA's assessment of exposures and risks associated with establishing this tolerance follows.

A. Toxicological Profile

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

The available toxicological database for thiram suggests that this chemical has a low to moderate acute-toxicity profile. Thiram has been shown to cause neurotoxicity following acute and subchronic exposures. In the acute and subchronic neurotoxicity studies submitted to the Agency, neurotoxicity is characterized as lethargy, reduced and/or tail pinch response, changes in the functional-observation battery (FOB) parameters, increased hyperactivity, changes in motor activity, and increased occurrences of rearing events. No treatment-related changes were observed in brain weights or in the

histopathology of the nervous system. In a non-OPPTS Harmonized Test Guidelines study published in the open literature (which means no more than literature that is considered a non-compensable reference/citation which offers scientific data intended for the support of the registrant's action), chronic feeding of thiram to rats caused neurotoxicity, with onset of ataxia in some animals 5–19 months after beginning of treatment. However, no evidence of neurotoxicity was seen following chronic exposures in mice or rats in guideline studies submitted to the Agency. In addition, no adverse effects on the developing fetal nervous system were seen in a developmental neurotoxicity study (DNT). The chronic toxicity profile for thiram indicates that the liver, blood, and urinary system are the target organs for this chemical in mice, rats, and dogs. There is no evidence for increased susceptibility following *in utero* exposures to rats or rabbits and following prenatal and postnatal exposures to rats for two generations. There is low concern for the increased susceptibility seen in the developmental toxicity study since the dose response is well defined and this endpoint is used for assessing the acute dietary risk for the most sensitive population. Thiram is classified as "not likely to be a human carcinogen" based on lack of evidence for carcinogenicity in mice or rats. There are no mutagenic/genotoxic concerns with thiram.

Specific information on the studies received and the nature of the adverse effects caused by thiram 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 *Thiram in/on Imported Bananas. Revised Human-Health Risk Assessment*, pages 39–42 in docket ID number EPA-HQ-OPP-2007-0020.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction

with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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>; <http://www.epa.gov/oppfead1/trac/science>; and <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>.

A summary of the toxicological endpoints for thiram used for human risk assessment can be found at <http://www.regulations.gov> in the document *Thiram in/on Imported Bananas. Revised Human-Health Risk Assessment*, pages 27–28 in docket ID number EPA–HQ–OPP–2007–0020.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiram, EPA considered exposure under the petitioned-for tolerances as well as all existing thiram tolerances in 40 CFR 180.132. EPA assessed dietary exposures from thiram 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.

In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA performed

a refined probabilistic acute dietary-exposure assessment using percent crop treated (PCT), distributions of field-trial residue values, and empirical processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA performed a conservative chronic dietary-exposure assessment performed using 100 PCT, average field-trial residues, and empirical processing factors.

iii. *Cancer.* Thiram is considered as “Not Likely to be Carcinogenic to Humans” based on the results (no increase in tumor incidence) in the rat chronic toxicity/carcinogenicity study, and the mouse carcinogenicity study. Thus, an exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCFA 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 FFDCFA 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 FFDCFA section 408(b)(2)(E) and authorized under FFDCFA 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 FFDCFA 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 FFDCFA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

+Caneberries <2.5%; Cherries <2.5%; Cotton <2.5%; Peaches < 2.5%; Prunes <2.5%; Soybeans <2.5%; Pears 5%; Apples 7%; and Strawberries 55%

+ = Crops not known to be listed on active end-use products registrations when BEAD SLUA report was run (data years 2001 to 2007).

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 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%.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for thiram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppfead1/models/water/index.htm>.

Because monitoring data are unavailable, estimates of thiram concentrations were made with only mathematical models. The modeling was based on turf application (the highest application rate) for this assessment.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of thiram for acute exposures are estimated to be 47.8 parts per billion (ppb) for surface water and 0.84 ppb for ground water. For chronic, exposures for non-cancer assessments are estimated to be 2.5 ppb for surface water and 0.84 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 0.0478 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.0025 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).

Thiram is not available for sale or use by homeowner applicators. However, there is potential residential exposure to thiram from treated golf courses and tees. All thiram turf uses that would conceivably lead to children's exposure on treated turf have been cancelled by the registrant. Therefore, EPA assessed residential exposure and risk only for the following scenario: Post-application (dermal contact) with thiram treated turf assessed during short-term and intermediate-term exposure.

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."

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

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines

based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No quantitative or qualitative sensitivity was seen in a rat developmental toxicity study, three rabbit developmental toxicity study, and two 2-generation reproduction studies in the rat. Quantitative sensitivity was seen in the DNT in rats. In the DNT study, the maternal NOAEL (3.7 milligrams/kilogram/day (mg/kg/day)) is based on decreased body weight, body weight gain, and food consumption, clinical signs of toxicity, and FOB, while the developmental NOAEL (1.4 mg/kg/day) is based on increased locomotor activity seen in postnatal day (PND) 17 females. These data indicate that PND 17 females experienced an adverse effect at a dose level that failed to elicit a response in adult animals. Quantitative susceptibility was also reported in an unacceptable/OPPTS Harmonized Test Guideline prenatal developmental toxicity study in rats. However, this finding was determined to be unreliable due to numerous technical deficiencies in the conduct of the study and because the results of that study were not replicated in a guideline study that was conducted in accordance with the Agency's Good Laboratory Practice (GLP) regulations. There is low concern for the enhanced susceptibility seen in the DNT study since clear NOAELs/LOAELs have been identified for the effects of concern, and the dose-response relationships for the effects of concern are well-characterized.

3. *Conclusion.* The existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under FQPA. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for thiram is complete, except for the requirements for an immunotoxicity study and cholinesterase activity assessment screening assay. EPA began requiring neurotoxicity testing and functional immunotoxicity testing of all food and non-food use pesticides on December 26, 2007. Acceptable acute, subchronic and developmental neurotoxicity

studies are available for thiram. However, since this requirement went into effect well after the tolerance petition was submitted, immunotoxicity studies are not yet available for thiram. In the absence of specific immunotoxicity studies, EPA evaluated the available thiram toxicity data to determine whether an additional database uncertainty factor (UF) is needed to account for potential immunotoxicity and determined that an additional UF is not required to account for potential immunotoxicity. No evidence of immunotoxicity was found in the thiram database. Due to the lack of evidence of immunotoxicity for thiram, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL that are lower than the current regulatory endpoints and an additional factor for database uncertainties (UFDB) is not needed to account for potential immunotoxicity. Thiram is a dithiocarbamate pesticide. Unlike organophosphates and *N*-methyl carbamates pesticides, dithiocarbamates generally have little or no cholinesterase inhibiting properties and there is no evidence of cholinesterase inhibition in the thiram database. However, subchronic exposure to another dithiocarbamate has been reported to elicit cholinesterase inhibition. Given that this is an isolated finding reported in one study for only one other chemical in the class, the Agency has required the cholinesterase assay for thiram as confirmatory data out of an abundance of caution. EPA believes that the current regulatory endpoints are protective for all potential adverse health effects that this compound may elicit, and no additional factor is needed to account for the lack of the cholinesterase assay.

ii. There is low concern for the enhanced susceptibility seen in the DNT study since clear NOAELs/LOAELs have been identified for the effects of concern, and the dose-response relationships for the effects of concern are well-characterized. No increased sensitivity was seen in the other acceptable guideline studies which examined prenatal and postnatal exposure.

iii. An acceptable/guideline DNT study has been submitted and reviewed by the Agency. The study results have been incorporated into the risk assessment and are the basis for the point of departure for the acute females 13+ dietary assessment and all short-term and intermediate-term (incidental oral, dermal, inhalation, and aggregate) assessments.

iv. There are no residual uncertainties in the hazard or exposure database. The dietary food for the acute exposure

assessment was performed based on the estimated maximum of PCT. The refinements are based on reliable data and will not underestimate the exposure and risk. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to thiram in drinking water. EPA used similarly conservative assumptions in the residential exposure assessment. These assessments will not underestimate the exposure and risks posed by thiram.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to thiram will occupy 96% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to thiram from food and water will utilize 57% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of thiram is not expected.

3. *Short-term and Intermediate-term risks.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered a background exposure level). Thiram is currently registered for use(s) (i.e., golf courses) that could result in short-term and intermediate-term residential exposures and the Agency has determined that it is appropriate to

aggregate chronic exposure to thiram through food and water with short-term and intermediate-term exposures for thiram.

Using the golfer scenario exposure assumption described in this unit for short-term and intermediate-term exposures, EPA has concluded that the total short-term and intermediate-term food, water, and residential exposures results in an aggregate MOE of 580. These MOEs are greater than 100, and therefore does not exceed the Agency's LOC.

4. *Aggregate cancer risk for U.S. population.* The Agency has classified thiram as “Not Likely to be Carcinogenic to Humans,” based on the results (no increase in tumor incidence) in the rat chronic toxicity/carcinogenicity study, and the mouse carcinogenicity study. Based on these data, EPA concludes that thiram poses no greater than a negligible cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC), Method A7193) is available to enforce the tolerance expression. 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

There are currently no established Canadian or Mexican maximum residue limits (MRLs) for thiram. The Codex Alimentarius has established MRLs, for “total dithiocarbamates, determined and expressed as mg carbon disulfide per kg” in banana of 2 mg/kg. As U.S. tolerances are established on the individual dithiocarbamates, compatibility is not possible with the proposed tolerance.

C. Revisions to Petitioned-For Tolerances

EPA determined the tolerance for banana, to be established at 0.80 ppm based on the rounding procedure outlined in the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard of Operating Procedures (SOP)*. Also rather than

setting tolerances on “banana, whole” and “banana, pulp” as requested by the petitioner, EPA has set a tolerance on “banana” which is the standardized term EPA uses for tolerances on bananas as per Table 1 of OPPTS Harmonized Test Guideline 860.1000.

V. Conclusion

Therefore, tolerances are established for residues of thiram, tetramethylthiuram disulfide, in or on banana at 0.80 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the

various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: September 8, 2009.

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 § 180.132 paragraph (a) is revised to read as follows:

§ 180.132 Thiram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide thiram (tetramethyl thiuram disulfide) in or on raw agricultural commodities as follows:

Commodity	Parts per million	Expiration/revocation date
Apple	7.0	None
Banana ¹	0.80	3/31/14
Peach	7.0	None
Strawberry	7.0	None

¹ No U.S. registrations as of September 23, 2009.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0854; FRL-8429-7]

Meptyldinocap; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes import tolerances for combined residues of meptyldinocap, 2-(1-methylheptyl)-4,6-dinitrophenyl (2E)-2-butenate and 2,4-DNOP, 2,4-dinitro-6-(1-methylheptyl)phenol expressed as meptyldinocap in or on grape. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 23, 2009. Objections and requests for hearings must be received on or before November 23, 2009, 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-2008-0854. 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: Mary L. Waller, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460-0001; telephone number: (703) 308-9354; e-mail address: waller.mary@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