Cosmetic Act (FFDCA) Considerations for *Bacillus thuringiensis* Cry1F Protein.'' This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES.**

B. Analytical Enforcement Methodology

EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation. An analytical method for enforcement purposes was, however, submitted by Dow AgroSciences LLC and determined by the Agency to be suitable for quantitative measurements of the Cry1F protein in soybean tissue. The Dow AgroSciences LLC Cry1F Enzyme-Linked Immunosorbent Assay (ELISA) method is fully discussed in the January 13, 2014 document entitled, ''Federal Food, Drug and Cosmetic Act (FFDCA) Considerations for *Bacillus thuringiensis* Cry1F Protein.''

IV. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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

V. Congressional Review Act

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

List of Subjects in 40 CFR Part 174

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

Dated: January 30, 2014.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

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

■ 2. Revise § 174.504 to read as follows:

§ 174.504 *Bacillus thuringiensis* Cry1F protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in the food and feed commodities of corn, field; corn, sweet; corn, pop; cotton; and soybean are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn, field; corn, sweet; corn, pop; cotton, and soybean.

§ 174.520 [Removed]

■ 3. Remove § 174.520.

[FR Doc. 2014–02932 Filed 2–11–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0925; FRL–9904–22]

Thiram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiram in or on strawberry. Taminco, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 12, 2014. Objections and requests for hearings must be received on or before April 14, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0925, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington,

DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0925 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 April 14, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0925, by one of the following methods:

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

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

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of January 16, 2013 (78, FR 3379) (FRL–9375–4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8106) by Taminco, Inc., 7540 Windsor Drive, Suite 411, Allentown, PA 18195. The petition requested that 40 CFR 180.132 be amended by increasing the level of the tolerance for residues of the fungicide thiram, in or on strawberry to 20 parts per million (ppm). This request was made to support a change in the preharvest interval (PHI) from 3 days to 1 day for strawberry on the label for Spotrete-F (EPA Reg. No. 45728–26). That document referenced a summary of the petition prepared by Taminco, Inc., the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

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

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

Thiram is a dimethyl dithiocarbamate fungicide. Thiram has been shown to cause neurotoxicity following acute and subchronic exposures. In the acute and subchronic neurotoxicity studies submitted, 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-guideline study published in the open literature, 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 DNT study. 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 pre- and post-natal exposures to rats for two generations. There is evidence of quantitative susceptibility in the developmental neurotoxicity (DNT) study. However, there is low concern for the increased susceptibility seen in the DNT study since the dose response is well defined with a clear NOAEL and this endpoint is used for assessing the acute dietary risk for the most sensitive population. Thiram is classified as ''not likely to be carcinogenic to humans'' based on lack of evidence for carcinogenicity in mice or rats. There are no mutagenic/genotoxic concerns with thiram. The available toxicological database for thiram suggests that this chemical has a low to moderate acute-toxicity profile.

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 document Thiram. Update to the Aggregate Risk Assessment to Support the Requested PHI Reduction and Increased Tolerance Request on Strawberry at page 9 in docket ID number EPA–HQ–OPP–2012–0925.

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*.

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

Exposure/Scenario	PoD	Uncertainty/FQPA SFs	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute Dietary (General Population).	$BMDL_{10}$ = 64.94 mg/kg.	UF_A = 10x ..... UF_H = 10x FQPA SF = 1x	Acute RfD = 0.6494 mg/kg/day. aPAD = 0.6494 mg/kg/day	Acute Neurotoxicity Study—Rat. MRID 42912401. LOAEL = 150 mg/kg/day based on FOB effects (lethargy, lower temperature, reduced startle response, no tail-pinch response), reduced motor activity, and reduced brain weights.
Acute Dietary (Females 13–49 years old).	NOAEL = 1.4 mg/kg	UF_A = 10x ..... UF_H = 10x FQPA SF = 1x	Acute RfD = 0.014 mg/kg/day. aPAD = 0.014 mg/kg/day	Dev. Neurotoxicity Study—Rat. MRID 46455201. LOAEL = 3.7 mg/kg/day based on increases in motor activity seen in female offspring on PND 17.
Chronic Dietary (All populations).	NOAEL = 1.5 mg/kg	UF_A = 10x ..... UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.015 mg/kg/day. cPAD = 0.015 mg/kg/day.	Co-critical: (1) Combined Chronic Toxicity/Carcinogenicity Study—Rat and (2) Chronic Oral Toxicity-Dog. LOAEL = 7.3 mg/kg/day based on changes in hematology, clinical chemistry, incidences of bile duct hyperplasia, and reduction in mean body-weight gain from the chronic toxicity/carcinogenicity rat study in conjunction with elevated cholesterol levels and increased liver weights reported in the Chronic Oral Toxicity Study in Dogs at a LOAEL = 7.23 mg/kg/day.
Short- and Intermediate-Term Incidental Oral.	No incidental oral residential exposure.			
Short-Term Dermal (1–30 days).	NOAEL = 1.4 mg/kg/day.	UF_A = 10x ..... UF_H = 10x FQPA SF = 1x (Dermal-absorption factor = 1%)	Residential LOC for MOE = 100. Occupational LOC for MOE = 100	Dev. Neurotoxicity Study—Rat MRID 46455201. LOAEL = 3.7 mg/kg/day based on increases in motor activity seen in female offspring on PND 17.
Intermediate-Term Dermal (1 to 6 months).	NOAEL = 1.4 mg/kg/day.	UF_A = 10x ..... UF_H = 10x FQPA SF = 1x (Dermal-absorption factor = 1%)	Residential LOC for MOE = 100. Occupational LOC for MOE = 100	Dev. Neurotoxicity Study—Rat MRID 46455201. LOAEL = 3.7 mg/kg/day based on increases in motor activity seen in female offspring on PND 17.

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

Exposure/ Scenario	PoD	Uncertainty/FQPA SFs	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Short- and Intermediate-Term Inhalation.	Current assessment does not warrant an inhalation assessment.			
Cancer (oral, dermal, inhalation).	''Not Likely to be Carcinogenic to Humans''.			

Point of Departure (PoD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). 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.

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.

A refined probabilistic acute dietary exposure assessment was performed using maximum percent crop treated *(PCT)* values, tolerance, the highest residue found during field-trials, distribution of field trial residues, Federal Drug Administration (FDA) monitoring data for apples, and empirical processing factors. Dietary risk estimates were determined considering exposures from food and drinking water using estimated drinking water concentrations (EDWCs) for surface water sources.

ii. *Chronic exposure.* A refined chronic dietary-exposure assessment was performed using tolerance level residues and average estimated PCT.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has classified thiram as ''Not Likely to be Carcinogenic to Humans,'' therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and 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.

The Agency estimated the PCT in the acute dietary risk assessment for existing uses as follows apples: 10%; peaches: 2.5%; and strawberry: 30%. The Agency estimated the PCT in the chronic dietary risk assessments for existing uses as follows apples: 5%; peaches: 1.0%; and strawberry: 20%.

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 chemical name may be applied in a particular area.

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/oppefed1/models/water/index.htm*.

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 0.0478 parts per billion (ppb) and 0.0025 ppb for chronic exposures (for non-cancer assessments) for surface water. Ground water sources were not included (for acute or chronic exposures), as the EDWCs for ground water are minimal in comparison to those for surface water. Surface water EDWCs were incorporated in DEEM–FCID into the food categories ''water, direct, all sources'' and ''water, indirect, all sources'' for the dietary assessments.

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; therefore, there are no residential handler exposure scenarios applicable to thiram. However, there is potential for residential post-application dermal exposure from treated golf course greens and tees. Residential exposures resulting from dermal contact with thiram-treated turf were assessed for children 6 to <11 years old, children 11 to <16 years old, and adults. When use is restricted to greens and tees, the duration of exposure is 1 hour to reflect the anticipated time a player would be spending in contact with those areas. Inhalation post-application exposures for golf courses were not assessed since inhalation exposures are thought to be negligible in outdoor post-application scenarios.

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 Web site 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 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.* There was no evidence of increased susceptibility following *in utero* exposure to rats or rabbits or following pre- and post natal exposures to rats. There is evidence of quantitative susceptibility in the DNT study. Offspring effects (increased locomotor activity in females on PND 17) occurred at a lower dose than maternal effects (increased number of rearing events and elevated incidences of hyperactivity in females at weeks 8 and 13). There is low concern for the enhanced susceptibility seen in the DNT study because: (1) Clear NOAELs/LOAELs were established for the offspring effects; (2) the dose-response is well defined; (3) the behavioral effect of concern were observed only in females on one evaluation time period; and (4) the dose/endpoint is used for acute dietary risk for the most sensitive population subgroup (females 13–49 years old). Consequently, there are no residual uncertainties for pre- and post-natal toxicity.

3. *Conclusion.* 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 with acceptable neurotoxicity, developmental, and reproductive toxicity studies.

ii. Thiram has been shown to cause neurotoxicity following acute and subchronic exposures only. There was no evidence of increased susceptibility following *in utero* exposure to rats or rabbits or following pre- and post-natal exposures to rats. Evidence of quantitative susceptibility was demonstrated in the DNT study; however, there is low concern for the susceptibility seen in the DNT study because clear NOAELs/LOAELs were established for the offspring effects, the dose-response is well defined, and the dose/endpoint is used for acute dietary risk for the most sensitive population (females 13–49 years old) and therefore is protective. Consequently, there are no residual uncertainties for pre- and post-natal toxicity.

iii. There is no other evidence that thiram results in increased susceptibility in *in utero,* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study, only in the DNT.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to thiram in drinking water. In addition, the acute dietary exposure analysis used FDA apple monitoring data and field trial data along with the maximum percent crop treated. The chronic dietary exposure analysis used tolerance level residues except for apple along with the average percent crop treated. In addition, washing studies were incorporated into the dietary analyses since thiram is not a systemic pesticide and will wash off during normal washing procedures. 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 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.* An acute aggregate risk assessment takes into account acute

exposure estimates from dietary consumption of food and drinking water. Using DEEM–FCID™, acute dietary exposure at the 99.9th exposure percentile is estimated at 0.020104 mg/kg bw/day for the general U.S. population (3.1% of the aPAD) and 0.010887 mg/kg bw/day (78% of the aPAD) for females 13–49 years old, the population subgroup with the highest estimated acute dietary exposure to thiram.

2. *Chronic risk.* The chronic aggregate risk assessment takes into account exposure estimates from dietary consumption of thiram (food and drinking water). Dietary risk estimates were determined considering exposures from food and drinking water using EDWCs for surface water sources. Using DEEM–FCID™, dietary exposure is estimated at 0.001384 mg/kg bw/day for the general U.S. population (9.2% of the cPAD) and 0.008369 mg/kg bw/day (56% of the cPAD) for children 1–2 years old, the population subgroup with the highest estimated chronic dietary exposure to thiram.

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

In aggregating short- and intermediate-term risk, the Agency routinely combines background chronic dietary exposure (food + water) with short/intermediate-term residential exposure (dermal only). The combined exposure may then be used to calculate an MOE for aggregate risk. Using the golfer scenario for adult males, adult females, and children >6 years old, combined with the applicable subpopulation with the greatest dietary exposure, the total short/intermediate-term food and residential aggregate MOEs are 600, 600, and 370, respectively. As these MOEs are greater than 100, the short- and intermediate-term aggregate risks do not exceed the Agency's LOC. For children <6 years old, there is no residential exposure, therefore, a short/intermediate term aggregate risk assessment is not required for this population.

4. *Aggregate cancer risk for U.S. population.* Thiram is classified as ''Not Likely to be Carcinogenic to Humans'' based on lack of evidence for carcinogenicity in mice or rats; therefore, thiram is not expected to pose a 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 (colorimetric analytical method) 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; email address: *residuemethods@epa.gov*.

B. International Residue Limits

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

The Codex has established MRLs for ''total dithiocarbamates, determined and expressed as mg carbon disulfide per kg'' in or on strawberry at 5 ppm. This MRL differs from the tolerance amendment for thiram on strawberry that was requested by the petitioner. As U.S. tolerances are currently established on the individual dithiocarbamates, compatibility is not possible with the proposed tolerances. EPA is considering modifying all tolerances for dithiocarbamates, including thiram, to express them in terms of carbon disulfide. At that time, the tolerance expression will be compatible with CODEX; however, the U.S. tolerance level for strawberry cannot be harmonized with the CODEX MRL level because of differences in agricultural practices between the U.S. and foreign countries where strawberries are grown. Actual residues seen in the U.S. field trials submitted to support the proposed strawberry tolerance amendment exceeded the CODEX MRL.

C. Revisions to Petitioned-for Tolerances

The Agency has revised the tolerance expression to clarify:

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

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, the tolerance for residues of thiram, in or on strawberry, is amended to increase the level of the tolerance to 20 ppm.

VI. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power

and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: January 27, 2014.

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, revise the introductory text of paragraph (a) and revise the entry for ''Strawberry'' in the table in paragraph (a) to read as follows:

§ 180.132 Thiram; tolerances for residues.

(a) *General.* Tolerances for residues of the fungicide thiram (tetramethyl thiuram disulfide), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified is to be determined by measuring only thiram.

Commodity	Parts per million	Expiration/ revocation date
* * * * *		
Strawberry	20	None.
* * * * *		

[FR Doc. 2014–03074 Filed 2–11–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0791; FRL–9905–22]

Linuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of linuron in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes a tolerance with regional registrations in or on parsley leaves, as it will be superseded by a tolerance without regional registrations. IR–4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 12, 2014. Objections and requests for hearings must be received on or before April 14, 2014, and must be filed in accordance with instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0791, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0791 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 April 14, 2014. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).