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

■ 2. Section 180.1285 is revised to read as follows:

§ 180.1285 Polyoxin D zinc salt; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of polyoxin D zinc salt in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

[FR Doc. 2012–22315 Filed 9–11–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0433; FRL–9359–6]

Dinotefuran; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dinotefuran in or on multiple commodities which are identified and discussed later in this document. Also, due to the tolerances established by this document, the Agency is removing the existing tolerances for grape and potato as unnecessary. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 12, 2012. Objections and requests for hearings must be received on or before November 13, 2012, 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–2011–0433, 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: Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9367; email 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. 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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0433 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 November 13, 2012. 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–2011–0433, 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 September 7, 2011 (76 FR 55329) (FRL–8886–7), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7863) by IR–4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.603 be amended by establishing tolerances for residues of the insecticide dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furyl)methyl)guanidine, including its metabolites and degradates, in or on berry, low growing, except strawberry, subgroup 13–07H at 0.2 parts per million (ppm); watercress at 5.0 ppm; onion, green, subgroup 3–07B at 6.0 ppm; onion, bulb, subgroup 3–07A at 0.07 ppm; peach at 0.9 ppm; vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.9 ppm; and tea, plucked leaves at 25.0 ppm. That notice referenced a summary of the petition prepared by Mitsui Chemicals Agro, 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.

Also, due to the tolerances established by this document, the following existing tolerances are being removed as unnecessary: Grape and potato.

Based upon review of the data supporting the petition, EPA has

modified the levels for which tolerances are being established for the bulb onion subgroup 3–07A, the green onion subgroup 3–07B, peach, tea, and watercress. 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 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 dinotefuran including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dinotefuran 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. Dinotefuran has low acute toxicity by oral, dermal, and inhalation exposure routes. It is not a dermal sensitizer, but causes a low level of skin irritation. The main target of toxicity is the nervous system but effects on the nervous system were only observed at high doses. Nervous system toxicity was manifested as clinical signs and decreased motor activity seen after acute dosing (in both rats and rabbits) and changes in motor activity which are consistent with effects on the nicotinic cholinergic nervous system seen after repeated dosing. Typically, low to moderate levels of neonicotinoids, such as dinotefuran, activate the nicotinic acetylcholine receptors causing stimulation of the peripheral nervous system (PNS). High levels of neonicotinoids can over stimulate the PNS, maintaining cation channels in the open state which blocks the action potential and leads to paralysis.

Dinotefuran was well tolerated at high doses following dietary administration for ninety days to mice, rats, and dogs. The most sensitive effects were decreases in body weight and/or body weight gain but even these effects occurred at or near the limit dose. Changes in spleen and thymus weights were seen in mice, rats and dogs following subchronic and chronic dietary exposures. However, these weight changes were not corroborated with alterations in hematology parameters, histopathological lesions in these organs, or toxicity to the hematopoietic system. Furthermore, the toxicology data base contains immunotoxicity studies in mice and rats and a developmental immunotoxicity study in rats. In the immunotoxicity studies there were no effect on T-cell dependent antibody response (TDAR) when tested up to the limit dose in male and female mice and in male and female rats. There were no changes in spleen and thymus weight and there were no histopathological lesions in these organs in those studies. In the developmental immunotoxicity study, there was no evidence of an effect on the functionality of the immune system in rats that were exposed to dinotefuran at the limit dose during the prenatal, postnatal, and post-weaning periods. Consequently, the thymus weight changes seen in dogs and the spleen weight changes seen in mice and rats were not considered to be toxicologically relevant.

No systemic or neurotoxicity was seen following repeated dermal applications at the limit dose to rats for 28 days. No systemic or portal of entry effects were seen following repeated inhalation exposure at the maximum obtainable concentrations to rats for 28 days.

In the pre-natal studies, no maternal or developmental toxicity was seen at the limit dose in rats. In rabbits, maternal toxicity manifested as clinical signs of neurotoxicity but no developmental toxicity was seen. In the reproduction study, parental, offspring, and reproductive toxicity was seen at the limit dose. Parental toxicity included decreased body weight gain, transient decrease in food consumption, and decreased thyroid weights. Offspring toxicity was characterized as decreased forelimb grip strength or hindlimb grip strength in the F1 pups. There was no adverse effect on reproductive performance at any dose. In the developmental neurotoxicity study, no maternal or offspring toxicity was seen at any dose including the limit dose.

There was no evidence of carcinogenicity in male and female mice and in male and female rats fed diets containing dinotefuran at the limit dose for 78 weeks to mice and 104 weeks to rats. Dinotefuran was non-mutagenic in both *in vivo* and *in vitro* assays.

Specific information on the studies received and the nature of the adverse effects caused by dinotefuran 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* on pages 39–44 of the document titled ''Revised: Dinotefuran: Human Health Risk Assessment for Proposed Section 3 Uses on Tuberous and Corm Vegetables Subgroup 1C, Onion Subgroup 3–07A, Onion Subgroup 3–07B, Small Fruit Subgroup 13–07F, Berry Subgroup 13–07H, Peach, and Watercress, And a Tolerance on Imported Tea'' in docket ID number EPA–HQ–OPP–2011–0433.

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 dinotefuran used for human risk assessment is shown in the Table of this unit. EPA notes that in the last final rule for dinotefuran, published in the **Federal Register** of December 18, 2009 (74 FR 67098) (FRL–8803–1), the points of departure for many exposure scenarios differ than what is reported in this document. Since the last risk assessment, the Agency has re-evaluated the dinotefuran toxicological database and updated the hazard characterization and dose response assessment. This toxicology database reevaluation has resulted in changes to the toxicity endpoints, points of departure, and safety factors for several routes of exposure from those presented in previous EPA risk assessments for dinotefuran. For a more detailed discussion of the endpoint selection and reasons for the changes, refer to Appendix A.3 on pages 44–47 in the document titled ''Dinotefuran: Human Health Risk Assessment for Proposed Section 3 Uses on Tuberous and Corm Vegetables Subgroup 1C, Onion Subgroup 3–07A, Onion Subgroup 3–07B, Small Fruit Subgroup 13–07F, Berry Subgroup 13–07H, Peach, and Watercress, And a Tolerance on Imported Tea'' in docket ID number EPA–HQ–OPP–2011–0433.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 125 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 1.25 mg/kg/day. aPAD = 1.25 mg/kg/day	Developmental Toxicity Study in Rabbits LOAEL = 300 mg/kg/day based on clinical signs in does (prone position, panting, tremor and erythema) seen following the first dose on Gestation Day 6.
Chronic dietary (All populations)	NOAEL= 99.7 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 1.0 mg/kg/day. cPAD = 1.0 mg/kg/day	Chronic Toxicity/Carcinogenicity Study in Rats LOAEL = 991 mg/kg/day based on decreased body weight gain and nephrotoxicity.
Incidental Oral Short-Term (1–30 days).	NOAEL= 99.7 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	LOC for MOE = 100	Chronic Toxicity/Carcinogenicity Study in Rats LOAEL = 991 mg/kg/day based on decreased body weight gain and nephrotoxicity.

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dinotefuran, EPA considered exposure under the petitioned-for tolerances as well as all existing dinotefuran tolerances in 40 CFR 180.603. EPA assessed dietary exposures from dinotefuran in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for dinotefuran. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues for all current and proposed crops.

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 assumed 100 PCT and tolerance-level residues for all current and proposed crops.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that dinotefuran does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for dinotefuran. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dinotefuran in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dinotefuran. 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 First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of dinotefuran for acute exposures are estimated to be 91.31 parts per billion (ppb) for surface water and 3.5 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 25.16 ppb for surface water and 3.5 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 91.31 ppb was used to assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 25.16 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).

Dinotefuran is currently registered for the following uses that could result in residential exposures: Turf, ornamentals, vegetable gardens, pets, indoor aerosol sprays, and crack and crevice sprays. EPA assessed residential exposure using the following assumptions: Residential handler exposures were not assessed because no dermal or inhalation hazards were identified. For this same reason, post-application residential dermal and inhalation exposure scenarios were not assessed. The Agency only considered post-application scenarios in which incidental oral exposures to children are expected. The oral exposures assessed included incidental oral exposures from turf, ant bait, ready to use garden trigger sprayers, dog and cat spot on treatment, indoor broadcast, and indoor crack and crevice uses. Of all these scenarios, treated turf was determined to result in the highest levels of exposure.

In assessing risks from residential exposures, EPA combines different residential sources of exposure that could reasonably be expected to occur on the same day. While it is possible for children to be exposed to indoor broadcast sprays on hard surfaces/carpets and to spot-on treatment to cats or dogs on the same day, these exposures have not been combined in this assessment because incidental oral hand-to-mouth exposure from treated turf is higher and still results in an MOE that does not exceed the Agency's LOC.

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.''

EPA has not found dinotefuran to share a common mechanism of toxicity with any other substances, and dinotefuran does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dinotefuran 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.* In the pre-natal studies, no maternal or developmental toxicity was seen at the limit dose in rats. In rabbits, maternal toxicity manifested as clinical signs of neurotoxicity but no developmental toxicity was seen. In the reproduction study, parental, offspring, and reproductive toxicity was seen at the limit dose. Parental toxicity included decreased body weight gain, transient decrease in food consumption, and decreased thyroid weights. Offspring toxicity was characterized as decreased forelimb grip strength or hindlimb grip strength in the F1 pups. There was no adverse effect on reproductive performance at any dose. In the developmental neurotoxicity study, no maternal or offspring toxicity was seen at any dose including the limit dose.

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 dinotefuran is complete.

ii. The neurotoxic potential of dinotefuran has been adequately considered. Dinotefuran is a neonicotinoid and has a neurotoxic mode of pesticidal action. Consistent with the mode of action, changes in motor activity were seen in repeat-dose studies, including the subchronic neurotoxicity study. Additionally, decreased grip strength and brain weight was observed in the offspring of a multi-generation reproduction study albeit at doses close to the limit dose. For these reasons, a developmental neurotoxicity study was required. Upon review of the developmental neurotoxicity study, it was concluded that there is no evidence of a unique sensitivity to the developing nervous system since no effects on neurobehavioral parameters were seen in the offspring at doses that approached or exceeded the limit dose.

iii. There is no evidence that dinotefuran 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.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dinotefuran in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children for incidental oral exposures. These assessments will not underestimate the exposure and risks posed by dinotefuran.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dinotefuran will occupy 5.8% of the aPAD for children 1–2 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 dinotefuran from food and water will utilize 2.6% 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 dinotefuran is not expected.

3. *Short-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).

Dinotefuran is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to dinotefuran.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 3,000 for children 1–2 years old from hand to mouth exposure from treated turf, the scenario with the highest exposure. Because EPA's level of concern for dinotefuran is a MOE of 100 or below, this MOE is not of concern.

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

Intermediate-term exposure is not expected for the adult residential exposure pathway. Therefore, the intermediate-term aggregate risk would be equivalent to the chronic dietary exposure estimate. For children, intermediate-term incidental oral exposures could potentially occur from indoor uses. However, while it is possible for children to be exposed for longer durations, the magnitude of residues is expected to be lower due to dissipation or other activities. Since incidental oral short- and intermediate-term toxicity endpoints and points of departure are the same, the short-term aggregate risk estimate, which includes the highest residential exposure estimate (from turf), is protective of any intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dinotefuran is not expected to pose a cancer risk to humans.

6. *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 dinotefuran residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a high performance liquid chromatography/tandem mass spectrometry (HPLC/MS/MS) method for the determination of residues of dinotefuran, and the metabolites DN, and UF; an HPLC/ultraviolet (UV) detection method for the determination of residues of dinotefuran; and HPLC/MS and HPLC/MS/MS methods for the determination of DN and UF) 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 not established a MRL for dinotefuran for any of the commodities in this Notice.

C. Revisions to Petitioned-For Tolerances

Use of the Organization of Economic and Cooperation and Development tolerance calculation procedures indicates that the tolerances for residues in/on the onion subgroup 3–07A, onion subgroup 3–07B, peach, tea, and watercress should be established at 0.15 ppm, 5.0 ppm, 1.0 ppm, 50 ppm, and 8.0 ppm, respectively, instead of those values proposed.

V. Conclusion

Therefore, tolerances are established for residues of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furyl)methyl)guanidine, including its metabolites and degradates, in or on berry, low growing, except strawberry, subgroup 13–07H at 0.2 ppm; watercress at 8.0 ppm; onion, green, subgroup 3–07B at 5.0 ppm; onion, bulb, subgroup 3–07A at 0.15 ppm; peach at 1.0 ppm; vegetable, tuberous and corm, subgroup 1C at 0.05 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.9 ppm; and tea, dried at 50 ppm.

Also, the following existing tolerances are removed as unnecessary: Grape and potato. These commodities are covered by the new crop group tolerances for fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F, and vegetable, tuberous and corm, subgroup 1C.

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: August 28, 2012.

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 § 180.603 is amended by removing the entries for ''Grape'' and ''Potato'' and alphabetically adding the following entries and a footnote to the table in paragraph (a)(1) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Berry, low growing, except strawberry, subgroup 13–07H	0.2
* * *	*
* * *	*
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.9
* * *	*
* * *	*
Onion, bulb, subgroup 3–07A	0.15
Onion, green, subgroup 3–07B	5.0
Peach	1.0
* * *	*
* * *	*
Tea, dried[1]	50
* * *	*
* * *	*
Vegetable, tuberous and corm, subgroup 1C	0.05
Watercress	8.0

[1] There are no U.S. registrations for tea.

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[FR Doc. 2012–22205 Filed 9–11–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2012–0007; NIOSH–257]

42 CFR Part 88

RIN 0920–AA49

World Trade Center Health Program; Addition of Certain Types of Cancer to the List of WTC-Related Health Conditions

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Final rule.

SUMMARY: Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 amended the Public Health Service Act (PHS Act) to establish the World Trade Center (WTC) Health Program. The WTC Health Program, which is administered by the Director of the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), provides medical monitoring and treatment to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania, and to eligible survivors of the New York City attacks. In accordance with WTC Health Program regulations, which establish procedures for adding a new condition to the list of covered health conditions, this final rule adds to the List of WTC-Related Health Conditions the types of cancer proposed for inclusion by the notice of proposed rulemaking.

DATES: This final rule is effective October 12, 2012.

FOR FURTHER INFORMATION CONTACT: Frank J. Hearl, PE, Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Patriots Plaza, Suite 9200, 395 E St. SW., Washington, DC 20201. Telephone: (202) 245–0625 (this is not a toll-free number). Email: *WTCpublicinput@cdc.gov.*

SUPPLEMENTARY INFORMATION: This notice of final rulemaking is organized as follows: