Commodity	Parts per million
Beet, sugar, molasses	1.5
Brassica, head and stem subgroup 5A	0.1
Brassica, leafy, subgroup 5B	2.0
Bushberry subgroup 13-07B	0.6
Caneberry subgroup 13-07A	0.6
Cattle, fat	0.01
Cattle, kidney	0.20
Cattle, liver	0.10
Cattle, meat	0.03
Corn, field, grain	0.07
Corn, pop, grain	0.07
Corn, sweet, kernel plus cob with husks removed	0.3
Citrus, dried pulp	0.1
Egg	0.05
Feed commodities not otherwise listed	10.0
Food commodities not otherwise listed	5.0
Fruit, citrus group 10	0.05
Fruit, pome, group 11	0.05
Fruit, stone, group 12	0.3
Goat, fat	0.005
Goat, kidney	0.15
Goat, liver	0.05
Goat, meat	0.015
Grain, aspirated fractions	35.0
Grain cereal, forage, fodder and straw, group 16	10.0
Grain, cereal, group 15, except corn	4.0
Grape	1.0
Grape, raisin	5.0
Grass, forage, fodder, and hay group 17, forage	3.5
Grass, forage, fodder, and hay group 17, hay	18.0
Herb and spice, group 19	5.0
Hog, fat	0.005
Hog, liver	0.05
Hog, kidney	0.10
Hog, meat	0.01
Milk	0.03
Nut, tree, group 14	0.05
Okra	0.05
Pea and bean, succulent shelled, subgroup 6B	2.0
Pea and bean, dried shelled, subgroup 6C	0.2
Peppermint, tops	5.0
Pistachio	0.05
Poultry, fat	0.015
Poultry, liver	0.05
Poultry, meat byproducts	0.20
Poultry, meat	0.015
Rice, hulls	8.0
Sheep, fat	0.005
Sheep, kidney	0.15
Sheep, liver	0.05
Sheep, meat	0.015
Soybean, hulls	0.5
Soybean, seed	0.2
Spearmint, tops	5.0
Tomato, paste	0.1
Tomato, puree	0.1
Vegetable, bulb, group 3-07	0.5
Vegetable, cucurbit, group 9	1.5
Vegetable, foliage of legume, group 7	4.0
Vegetable, fruiting, group 8	0.05
Vegetable, leafy, except brassica, group 4	2.0
Vegetable, leaves of root and tuber, group 2	3.0
Vegetable, legume, edible, podded, subgroup 6A	2.0
Vegetable, root and tuber, group 1	1.0
Wheat, milled byproducts	5.0

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0013; FRL–8803–1]

Dinotefuran; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of dinotefuran in or on *Brassica*, leafy greens, subgroup 5B and turnip, greens. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0013. 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: Sidney Jackson, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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?

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 cite at *http://www.gpoaccess.gov/ecfr*.

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–2009–0013 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 February 16, 2010.

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–2009–0013, 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 April 8, 2009 (74 FR 15971) (FRL–8407–4), 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 8E7433) by IR-4, IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.603 be amended by establishing tolerances for combined residues of the insecticide dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine and its major metabolites DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)-urea, expressed as dinotefuran in or on *Brassica*, leafy greens, subgroup 5B at 17 parts per million (ppm) and turnip, greens at 17.0 ppm. That notice referenced a summary of the petition prepared by Valent USA Corporation and Mitsui Chemical Inc., the registrants on behalf of IR-4, 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 revised the proposed tolerance of 17.0 ppm for both *Brassica*, leafy greens, subgroup 5B, and turnip, greens to 15.0 ppm. The reason for these changes are 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 tolerances for combined residues of dinotefuran in or on *Brassica*, leafy greens, subgroup 5B at 15.0 ppm and turnip, greens at 15.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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 tissues are the nervous system and the immune system, with effects seen in several species. Nervous system toxicity is manifested as clinical signs and decreased motor activity seen after acute dosing (in both rats and rabbits) and increased motor activity seen after repeated dosing; these findings are consistent with effects on the nicotinic cholinergic nervous system. Immune system toxicity is manifested as decreases in spleen and thymus weights, seen in multiple studies and species (including dogs, rats, and mice). There are also indications of endocrine-related toxicity, manifested in the reproductive toxicity study (in rats) as decreases in primordial follicles and altered cyclicity in females, and abnormal sperm parameters in males at the Limit Dose; changes in testes or ovary weight were also seen in several species (mouse, dog, and rat).

No adverse effects in fetuses were seen in the developmental toxicity studies in rats or rabbits, at maternally toxic doses, and offspring effects in the reproduction study occurred at the same doses causing parental effects. Acceptable oncogenicity and mutagenicity studies provide no indication that dinotefuran is carcinogenic or mutagenic.

Review of available studies including developmental toxicity studies in rats and rabbits, a reproductive toxicity study in rats, and acute and subchronic neurotoxicity studies in rats led to the conclusions that there is low concern for prenatal and/or postnatal toxicity resulting from exposure to dinotefuran. However, there is a concern for neurotoxicity and developmental neurotoxicity resulting from exposure to dinotefuran. Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for dinotefuran, the degree of concern for the effects observed in the rat reproduction study is characterized as low, noting these effects occurred in the presence of parental toxicity and only at the highest dose tested. For all toxicity endpoints established for dinotefuran, a NOAEL lower than this offspring NOAEL is used. No residual uncertainties were identified.

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* in the document ''Dinotefuran: Human Health Risk

Assessment for Proposed Uses on *Brassica* Leafy Vegetables Subgroup 5B and Turnip Greens,'' dated August 6, 2009, page 11 in docket ID number EPA–HQ–OPP–2009–0013–0004.

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-, intermediate-, 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*.

A summary of the toxicological endpoints for dinotefuran used for human risk assessment can be found at *http://www.regulations.gov* in document ''Dinotefuran: Human Health Risk Assessment for Proposed Uses on *Brassica* Leafy Vegetables Subgroup 5B and Turnip Greens,'' dated August 6, 2009, page 14 in docket ID number EPA–HQ–OPP–2009–0013–0004.

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.

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 assumed 100 percent crop treated (PCT) and tolerance level residues of dinotefuran.

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 of dinotefuran in all registered raw agricultural commodity uses.

iii. *Cancer*. Dinotefuran is classified as ''not likely to be a carcinogen'' based on the absence of significant tumor increases in two acceptable rodent carcinogenicity studies. Therefore, no exposure assessment for quantifying cancer risk was performed.

iv. *Anticipated residue and PCT information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for dinotefuran. Tolerance level residues and/or 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*.

The Agency has determined that it is appropriate to estimate for parent dinotefuran and its metabolites/degradates MNG, DN, UF, and DN-2-OH + DN-3-OH in drinking water.

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 dinotefuran and its metabolites for acute exposures are estimated to be 75.78 parts per billion (ppb) for surface water and 2.75 ppb for ground water.

For chronic exposures, non-cancer assessments are estimated to be 20.97 ppb for surface water and 2.75 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 75.78 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration value of 20.97 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: Professional turf management, professional ornamental production, and residential lawns. The risk assessment was conducted using the following residential exposure assumptions: Outdoor uses for turf farms, golf courses, residential lawns, and ornamentals.

There is a potential for short-term and intermediate-term exposures to homeowners in residential settings during the application of pesticide products containing dinotefuran. There is also a potential for exposure from entering areas previously treated with dinotefuran such as lawns where children might play, or golf courses and home gardens that could lead to exposures for adults (gardens) or adults and youth (golf).

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 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 FQPA 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*. Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility (qualitative or quantitative) following *in utero* exposure to dinotefuran. In the 2–generation reproduction study in the rat there was evidence of increased qualitative susceptibility in the offspring. However, the level of concern for the observed susceptibility (decreased body weight, decreased thymus weight, and decreased grip strength) is low because:

i. Clear NOAELs and LOAELS are established for the endpoints of concern for parental and offspring toxicity.

ii. The effects in the offspring were seen in the presence of parental toxicity.

iii. The effects were seen only at the highest dose tested (Limit Dose of 1,000 milligrams/kilograms/day (mg/kg/day).

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF was reduced to 1X for acute exposure, however, a safety factor of 10X has been retained for assessing chronic dietary and short- and intermediate-term inhalation exposure due to a lack of a NOAEL in the chronic dietary (dog) and 28–day inhalation toxicity studies. That decision is based on the following findings:

i. The toxicity database for dinotefuran is complete except for developmental neurotoxicity testing. The Agency has available a newly submitted dose-range finding developmental neurotoxicity and immunotoxicity study on dinotefuran in rats. Under the conditions of the study, dinotefuran did not affect the distribution of splenocyte subpopulations (total B cell, total T cells, helper/DTH T cells, cytotoxic T cells, and natural killer cells) in the weanlings of F_1 generation. It did not affect the anti-SRBC antibody forming cell response (humoral immunity) and NK cell activity (innate immunity). Therefore, it was concluded that dinotefuran showed no evidence of an effect on the functionality of the immune system in rats that were exposed to dinotefuran during the prenatal, postnatal, and post-weaning periods. Although, this study was a dose-range-finding study for a developmental immunotoxicity study, it examined all the parameters which would have been required in a regular developmental immunotoxicity study and the highest tested dose (1,035 mg/kg) was slightly greater than the limit dose (1,000 mg/kg). Considering the results and conduct of the study, EPA believes that this range-finding study provides sufficient data for understanding the immunotoxic potential of dinotefuran in young animals and satisfies the data requirement for a developmental immunotoxicity study. With respect to the requirement for an adult immunotoxicity study, the Agency has analyzed the entire data base of dinotefuran and that of a structurally related chemical, clothianidin. Clothianidin was found to produce similar effects on the thymus and spleen as dinotefuran in the repeated dosing studies, and an immunotoxicity study was conducted in both adult and the offspring animals. No immunotoxicity was found in either the adults or the offspring treated with clothianidin. Based on the available information, EPA believes that conducting an immunotoxicity study in adult rats would probably not provide additional information on the immunotoxicity of dinotefuran and certainly would not impact the risk assessment of this pesticide.

ii. There is concern for developmental neurotoxicity following exposure to dinotefuran, and a developmental neurotoxicity (DNT) study in rats is required. Evidence of neurotoxicity in the dinotefuran data base includes changes in motor activity observed in acute and subchronic neurotoxicity studies, decreased grip strength in adult offspring in the 2–generation rat study and maternal clinical signs (prone position and tremor) in the rabbit developmental study. These effects occurred at doses ranging from approximately 300 to 1,500 mg/kg/day. Because of a concern for these neurotoxic effects, EPA required a DNT study to determine possible effects on the nervous system in the developing young. However, the Agency determined that a database uncertainty factor (UF_{DB}) is not needed to account for the lack of the DNT study based on the following:

- The developmental neurotoxicity data for other neonicotinoid compounds (thiacloprid, imidacloprid and clothainadin) where neurotoxicity (in the presence of decreased pup body weight) was seen in only one compound (imidacloprid). Based on these data EPA concluded that the results of the required dinotefuran DNT study would not likely impact the regulatory doses selected for dinotefuran.
- No concerns for developmental neurotoxicity were seen in the range-finding DNT study for dinotefuran where the offspring LOAEL was the Limit Dose (1,035 mg/kg/day) based on decreased body weight and the offspring NOAEL was 317 mg/kg/day. Establishment of such a high LOAEL in the range-finding study clearly indicates that in order to elicit toxicity, dose selection for the definitive DNT study will likely result in a point of departure much higher than those currently used for overall risk assessment (range from 2.0 to 125 mg/kg/day).

In the current risk assessment, a point of departure for neurotoxicity was used in two risk assessment scenarios: (1) A NOAEL of 125 mg/kg/day was used for general population acute dietary risk based on transient clinical signs (prone position, tremor, erythema) seen at 300 mg/kg/day (LOAEL) following a single dose and no longer apparent after 24 hours; (2) a NOAEL of 33 mg/kg/day was used for short-term incidential oral risk based on increased motor activity seen at 327 mg/kg/day following multiple doses. Similar or lower points of departure for other systemic toxicities were used for the other risk assessment scenarios: The NOAEL of 33 mg/kg/day, which was used for assessment of short-term incidental oral risk, the chronic RfD is based on an extrapolated NOAEL of 2.0 mg/kg/day based on decreased thymus weight, the intermediate term incidental oral exposure is based on a NOAEL of 22 mg/kg/day based on changes in body weight/body weight gain, and the short and the intermediate inhalation exposure endpoints are based on an extrapolated NOAEL of 6.0 mg/

kg/day based on decreased body weight and food consumption.

Therefore, the Agency believes there are reliable toxicity data showing that the points of departures used for the overall risk assessment of dinotefuran are protective of infants and children.

iii. There is no evidence that dinotefuran results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. Although there is evidence of increased qualitative susceptibility in the two generation reproduction study in the rat, the degree of concern is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of dinotefuran.

iv. A safety factor of 10X has been retained for chronic dietary and short- and intermediate-term inhalation exposure due to a lack of a NOAEL in the chronic dietary (dog) and 28–day inhalation toxicity studies. For the chronic Reference Dose (RfD) the default 10X UF was deemed to be adequate based on the magnitude and the nature of response at the LOAEL in the study: (1) At the LOAEL, the decreased thymus weight was limited to one sex (males) with no corroborative histopathological lesions in the thymus glands; (2) this appears to be a species specific effect since no treatment-related effects on the thymus (weight or histopathology) was seen following chronic exposures to mice or rats; and (3) there is high confidence that the extrapolated NOAEL of 2.0 mg/kg/day (LOAEL = 20 ÷ 10; UF = 2.0) will be protective of the systemic toxicity seen at higher doses in mice (LOAEL = 34 mg/kg/day) and rats (LOAEL = 991 mg/kg/day) following chronic exposures.

For the short- and intermediate-term inhalation exposures, the default 10X UF is deemed to be adequate since following exposures for 28–days, no toxicity to the target organ (respiratory system) was seen at any concentration; and the endpoint of concern was generalized systemic toxicity characterized by decreased body weight gain and food consumption in one sex (males).

v. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessment utilized proposed and registered tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assessments, acute and chronic exposure/risks will not be underestimated. Furthermore, 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 as well as incidental oral exposure of toddlers. 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 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-, intermediate-, 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 dinotefuran will occupy 3.5% of the aPAD for children 1 to 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 68% of the cPAD for children 1 to 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. Because there are existing residential uses of dinotefuran, short- and intermediate-term aggregate risk assessments based on exposure from oral, inhalation, and dermal routes were considered. However, the toxicological effects for oral and inhalation routes of exposure are different (i.e., neurotoxicity for oral and decrease in body weight for inhalation); and therefore, these exposure scenarios have not been combined. Also, because no systemic toxicity was seen at the limit dose in a 28–day dermal toxicity study, no quantification of short-term dermal risk is required. Therefore, only short-term oral residential hand-to-mouth exposures for toddlers need to be aggregated with chronic food and drinking water exposures. However, these exposures were not aggregated, and instead as a worst-case estimate of risk, intermediate-term dermal and oral residential hand-to-mouth exposures for toddlers were aggregated with chronic food and drinking water exposures. The point of departure for intermediate-term dermal and oral exposures is a NOAEL of 22 mg/kg/day versus the point of departure for short-term oral exposures which is 33 mg/kg/day.

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). An intermediate-term aggregate risk assessment was performed as a screening level assessment. Intermediate-term aggregate risk assessments were performed for adults and children. For children, the subgroup with the highest estimated chronic dietary exposure (children 1 to 2 years old) was aggregated with residential exposures to children playing on treated lawns (dermal and oral hand-to-mouth exposures) in order to calculate the worst case intermediate-term aggregate risk to children. Intermediate term is a worst case because the short- and intermediate-term incidental oral exposures are the same and the POD for intermediate-term risk is lower than the POD for short term risk. Further, intermediate dermal plus incidental oral exposures are combined (same toxic effect), thus the total intermediate-term exposure is higher than short term exposure.The reciprocal MOE method was used to conduct the intermediate-term aggregate risk assessment for children, since the levels of concern are identical for all MOEs in the calculation. For adults, the aggregate risk index (ARI) method was used, since levels of concern are not identical for all types of exposure in the calculation. For children, the aggregate MOE is 430. Because the level of concern is for

exposures with a MOE of less than 100, this MOE does not raise a safety concern. For adults, the total aggregate ARI is 5.9. Because the level of concern using the ARI approach is with an ARI of less than 1, the total aggregate ARI for dinotefuran does not raise a safety concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenic effects in two acceptable carcinogenicity studies, dinotefuran was classified as ''not likely to be carcinogenic to humans'' and 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

Three methods for plants have been available for enforcement of tolerances: A high performnce liquid chromatography mass spectrometry (HPLC/MS/MS) method for the determination of residues of dinotefuran, DN, and UF; a HPLC/UV method for the determination of dinotefuran; and a HPLC/MS and HPLC/MS/MS method for the determination of DN and UF. An additional LC/MS/MS method was developed by Wildlife International, Ltd. (Project No. 236C–113), entitled ''Laboratory Validation of Method(s) for the Analysis of MTI-446 and its metabolites DN and UF in Multiple Crop Substrates,'' to quantitate residues in mustard greens. The method was validated using untreated mustard greens fortified separately with dinotefuran, DN and UF at 0.01 for each analyte. Adequate recovery data were provided. Based on the method validation data and concurrent recovery data, the submitted LC/MS/MS method for leafy *Brassica* greens is adequate for enforcement and data collection purposes.

Adequate enforcement methodologies as described above are available to enforce the tolerance expression. The methods 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 Codex, Canadian, or Mexican maximum residue limits for residues of dinotefuran in or on plant commodities.

C. Revisions to Petitioned-For Tolerances

EPA has revised the tolerance levels for residues of dinotefuran from the, proposed 17 ppm for both *Brassica*, leafy greens, subgroup 5B and turnip greens to 15 ppm each based on analysis of field trial data and the North American Free Trade Agreement (NAFTA) MRL Spreadsheet.

Additionally, EPA has revised the tolerance expression to clarify, (1) that, as provided in section 408(a)(3) of FFDCA, the tolerance covers metabolites and degradates of dinotefuran not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. These changes were made to both the tolerance expressions for plant commodities and animal commodities. They result in no substantive change to the meaning of the tolerance but clarify the existing language.

V. Conclusion

Therefore, tolerances are established for residues of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the commodities listed below in § 180.603. Compliance with the tolerance levels specified is to be determined by measuring only the sum of dinotefuran and its metabolites DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on *Brassica*, leafy greens, subgroup 5B at 15.0 ppm and turnip, greens at 15.0 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) (Pub. L. 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: December 10, 2009.

G. Jeffrey Herndon,

Acting 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 revising the introductory text in paragraphs (a)(1) and (2); and alphabetically adding ''*Brassica*, leafy greens subgroup 5B'' and ''Turnip, greens'' to the table in paragraph (a)(1) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of dinotefuran and its metabolites DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on the commodities listed in the table below:

Commodity	Parts per million
* * *	* *
Brassica, leafy greens, subgroup 5B	15.0
* * *	* *
Turnip, greens	15.0
* * *	* *

(2) Tolerances are established for residues of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine in or on the commodities listed in the table below:

* * * * *

[FR Doc. E9–30131 Filed 12–17–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0773; FRL–8801–8]

Prometryn; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of prometryn in or on celeriac, roots; celeriac, tops; cilantro, leaves; coriander, dried leaves; leaf petioles subgroup 4B; okra; parsley, leaves; parsley, dried leaves; and increases the tolerance level for carrot, root. Additionally, the tolerance for celery is removed since it is included in the leafy petioles subgroup 4B and the regional tolerance for parsley leaves is removed since it is superseded by the tolerance established in this action. Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 18, 2009. Objections and requests for hearings must be received on or before February 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0773. 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: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305-6463; e-mail address: *madden.barbara@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 test guidelines referenced in this document electronically, please go to http://