NEVADA—OZONE (8-HOUR STANDARD)

Designated area	Designation [a]		Category/classification	
	Date [1]	Type	Date [1]	Type
Las Vegas, NV:				
Clark County (part)	([2])	Nonattainment	([2])	Subpart 1.
That portion of Clark County that lies in hydrographic areas 164A, 164B, 165, 166, 167, 212, 213, 214, 216, 217, and 218 but excluding the Moapa River Indian Reservation and the Fort Mojave Indian Reservation.[b]				
Rest of State		Unclassifiable/Attainment.		
Carson City				
Churchill County				
Clark County				
(part) remainder				
Douglas County				
Elko County				
Esmeralda County				
Eureka County				
Humboldt County				
Lander County				
Lincoln County				
Lyon County				
Mineral County				
Nye County				
Pershing County				
Storey County				
Washoe County (Reno Area)				
White Pine County				

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[b] The use of reservation boundaries for this designation is for purposes of CAA planning only and is not intended to be a federal determination of the exact boundaries of the reservations. Nor does the specific listing of the Tribes in this table confer, deny or withdraw Federal recognition of any of the Tribes listed or not listed.
[1] This date is June 15, 2004, unless otherwise noted.
[2] The effective date is September 13, 2004.

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BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0155; FRL–7368–1]

Dinotefuran; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of dinotefuran *N*-methyl-*N*'-nitro-*N*'-[(tetrahydro-3-furanyl)methyl)]guanidine and its metabolites DN [1-methy-3-(tetrahydro-3-furylmethyl)]guanidine and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on vegetable, leafy, except Brassica, group 4. Mitsui Chemicals, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective September 17, 2004. Objections and requests for hearings must be received on or before November 16, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0155. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–8291; e-mail address: *kumar.rita@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers;

greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides 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 and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 2, 2003 (FR 39547) (FRL–7312–8), 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 2F6427) by Mitsui Chemicals, Inc., Chiyoda-ku, Tokyo, Japan. That notice included a summary of the petition prepared by Mitsui Chemicals, Inc., the registrant. One comment was received from a private citizen, in support of this notice.

The petition requested that 40 CFR 180.603 be amended by establishing a tolerance for combined residues of the insecticide dinotefuran, *N*-methyl-*N'*-nitro-*N'*-[(tetrahydro-3-furanyl)methyl)]guanidine and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)]guanidine and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran, in or on vegetable, leafy, except Brassica, group 4 at 5.0 parts per million (ppm).

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of dinotefuran, *N*-methyl-*N'*-nitro-*N'*-[(tetrahydro-3-furanyl)methyl)]guanidine and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)]guanidine and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea] expressed as dinotefuran on vegetable, leafy, except Brassica, group 4 at 5.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by dinotefuran are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity in rats	NOAEL: 38/384 male and female (M/F) milligrams/kilogram/day (mg/kg/day) LOAEL: 384 M mg/kg/day based on adrenal histopathology; 1,871 F mg/kg/day based on decreased body weight/body weight gain, changes in hematology/clinical chemistry, changes in organ weights, and adrenal histopathology
870.3100	90–Day oral toxicity in mice	NOAEL: 4,442/5,414 M/F mg/kg/day LOAEL: 10,635/11,560 M/F mg/kg/day, based on decreased body weight, body weight gain
870.3150	90–Day oral toxicity in dogs	NOAEL: 307/not determined M/F mg/kg/day LOAEL: 862 M mg/kg/day, based on body weight gain, hemorrhagic lymph nodes; <59 F, based on decreased body weight, body weight gain

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3200	28–Day dermal toxicity (rats)	*Systemic* NOAEL: 1,000 mg/kg/day LOAEL: not determined (no effects seen) *Dermal* NOAEL: 1,000 M, ≤**200** F mg/kg/day LOAEL: not determined/ ≤1,000 M/F mg/kg/day based on lack of effects in males, increase in acanthosis/ hyperkeratosis in high dose females (lower doses not evaluated histopathologically)
870.3465	28–Day inhalation toxicity (rat)	NOAEL: < 0.22 M mg/L, 0.22 F mg/ LOAEL: decreased body weight gain, food consumption M; increased clinical signs (protruding eyes) F
870.3700	Prenatal developmental toxicity study (rats)	*Maternal* NOAEL: 300 mg/kg/day LOAEL: 1,000 mg/kg/day based on body weight gain and food consumption *Developmental* NOAEL: 1,000 mg/kg/day LOAEL: not determined (no effects seen)
870.3700	Prenatal developmental toxicity study (rabbits)	*Maternal* NOAEL: 52 mg/kg/day LOAEL: 125 mg/kg/day based on body weight gains, food consumption, and necropsy findings *Developmental* NOAEL: 300 mg/kg/day LOAEL: > 300 mg/kg/day (no effects seen)
870.3800	Reproduction and fertility effects (rats)	*Parental/systemic* NOAEL: 241/268 M/F mg/kg/day LOAEL: 822/907 M/F mg/kg/day, based on decreased food consumption, weight gain in males, soft feces in females, and decreased spleen weights in both sexes *Reproductive (tentative)* NOAEL: 241/268 M/F mg/kg/day LOAEL: 822/907 M/F mg/kg/day, based on decreased uterine weights and microscopic alterations in the uterus and vagina of F_0 females, decreased numbers of primordial follicles in F_1 females, altered estrous cyclicity in F_0 and F_1 females, increase in abnormal sperm morphology in F_0 and F_1 males, decreased testicular sperm count in F_0 males, and decreased in sperm motility in F_1 males *Developmental* NOAEL: 241/268 M/F mg/kg/day LOAEL: 822–935/907–1,005 M/F mg/kg/day based on decreased body weights, body weight gains, and spleen weights in F and F_2 males and females, decreased thymus weights in F_2 males and females, and decreased forelimb grip strength (F_1 males) or hindlimb grip strength (F_1 females)
870.4100	Chronic toxicity (rats)	See 870.4300 Combined chronic toxicity/carcinogenicity (rats)
870.4100	Chronic toxicity (dogs)	NOAEL: <20/22 M/F mg/kg/day LOAEL: 20/108 M/F mg/kg/day based on decreased thymus weight, decreased food efficiency, body weight, and body weight gain in females, decreased thymus weight in males
870.4200	Carcinogenicity (rats)	See 870.4300 Combined chronic toxicity/carcinogenicity (rats)

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.4200	Carcinogenicity (mice)	NOAEL: <3 M, <4 F mg/kg/day LOAEL: 3/4 M/F mg/kg/day based on decreased spleen weights at week 79 terminal sacrifice in males and increased ovarian weights at week 53 in females
870.4300	Combined chronic toxicity/carcinogenicity (rats)	NOAEL: 99.7/127.3 M/F mg/kg/day LOAEL: 991/1,332 M/F mg/kg/day based on decreased body weight gain, food efficiency in females, increased incidences of kidney pelvic mineralization and ulceration in males
870.5100	Bacterial reverse mutation test	*Negative*, ± S9 up to 16,000 µg/plate
870.5100	Bacterial reverse mutation test	*Negative*, ± S9 up to limit dose of 5,000 µg/plate
870.5300	*In vitro* mammalian cell gene mutation test	*Negative*, ± S9 up to 2,002 µg/mL (Mouse lymphoma L5178Y cells)
870.5375	*In vitro* mammalian chromosome aberration test	*Negative* for clastogenic/aneugenic activity up to 2,000 µg/mL (CHL/IU cells)
870.5395	*In vivo* mammalian cytogenics-micronucleus assay	*Negative* at oral doses up to 1,080 mg/kg/day for 2 days
870.6200	Acute neurotoxicity screening battery	NOAEL: 750 M, 325 F mg/kg/day LOAEL: 1,500 M, 750 F mg/kg/day based on decreased motor activity on day 1
870.6200	Subchronic neurotoxicity screening battery	NOAEL: 33/40 M/F mg/kg/day LOAEL: 327/400 M/F mg/kg/day based on increased motor activity during week 2
870.7485	Metabolism and pharmacokinetics (rats)	Absorption was > 90% regardless of dose. The radiolabel was widely distributed through the body and was completely excreted within 168 hours of treatment. Urine was the primary elimination route, accounting for 88–99.8%. Excretion into the urine was rapid, being 84–99% complete within 24 hours of treatment. Absorption of the radioactivity was linear within the dose range of 50 and 1,000 mg/kg. Elimination of radioactivity was fast for all groups with a $T_{1/2}$ ranging from 3.64 to 15.2 hours for the low and high doses, respectively. Radioactivity was rapidly transferred from maternal blood to milk and widely distributed in the fetal tissues. The C_{max} for milk and fetal tissues was detected 0.5 hours after maternal treatment. The concentrations of radioactivity in fetal tissue and maternal milk declined quickly and were below detection limits 24 hours post-treatment. After IV or oral treatment, 75–93% of the administered radiolabeled test material, or nearly 93–97% of total urinary radiolabel, was excreted unchanged in the urine. The parent compound was also the primary component in the plasma, milk, bile, feces, and most tissues collected 4-8 hours after treatment and at both dose levels. Less than 10% of the parent compound was metabolized into numerous minor metabolites that were not well resolved by High Performance Liquid Chromotography (HPLC) or 2D-TLC. For all parameters measured in this study, no sex-related or dose-related differences or label position effects were found.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
Special study:	Neonatal rat metabolism study (12–day old rat pups)	After a single oral 50 mg/kg dose of G-^{14}C MTI-446 to 12–day old rats, absorption was high (absorption could not be adequately determined but may have approached 80%) and the radiolabel was widely distributed within the body. Approximately 32–36% of the administered dose was excreted within 4 hours of treatment. Urine was the primary elimination route as indirectly evidenced by finding high radioactive areas in the kidneys and bladder by whole body autoradiography. No areas of tissue sequestration were found and no gender-related differences were identified. The test material was essentially not metabolized, the parent compound accounting for >97% of the radiolabel in the excreta, plasma, kidneys, and stomach, and nearly 61–83% in intestines (and contents), and liver.

B. Toxicological Endpoints

The dose at which NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAELs of concern are identified is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

Three other types of safety or UFs may be used. ''Traditional UFs,'' the ''special FQPA safety factor,'' and the '' default FQPA safety factor.'' By the term ''traditional UF,'' EPA is referring to those additional UFs used prior to FQPA passage to account for data base deficiencies. These traditional UFs have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (aRfD or cRfD) where the RfD is equal to the NOAEL divided by an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of safety factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated.

A summary of the toxicological endpoints for dinotefuran used for human risk assessment is shown in following Table 2.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DINOTEFURAN FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including infants and children)	NOAEL = 125 mg/kg/day UF = 100 Acute RfD = 1.25 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 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, erythema) seen following a single dose.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DINOTEFURAN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Chronic dietary (All populations)	LOAEL= 20 mg/kg/day UF = 1,000 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.02 mg/kg/day	Chronic toxicity study in dogs LOAEL = 20 mg/kg/day based on decreased thymus weight in males
Short-term Incidental oral (1 to 30 days)	NOAEL= 33 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Subchronic neurotoxicity study in rats LOAEL = 327 mg/kg/day based on increased motor activity during week 2
Intermediate-term Incidental oral (1 to 6 months)	NOAEL= 22 mg/kg/day	Residential LOC for MOE =100 Occupational = NA	Chronic toxicity study in dogs LOAEL = 108 mg/kg/day based on decreased body weight and body weight gain in females
Short-term dermal (1 to 30 days)	No quantitation required	Residential LOC for MOE = NA Occupational LOC for MOE = NA	No quantitation required. No systemic toxicity was seen at the limit dose in a 28–day dermal toxicity study in which neurotoxicity was evaluated. No developmental toxicity concerns.
Intermediate-term dermal (1 to 6 months)	Oral study NOAEL = 22 mg/kg/day (dermal absorption rate = 30%)	Residential LOC for MOE =100 Occupational LOC for MOE =100	Chronic toxicity study in dogs LOAEL = 108 mg/kg/day based on decreased body weight and body weight gain in females
Long-term dermal (>6 months)	Oral study LOAEL= 20 mg/kg/day (dermal absorption rate = 30%)	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 1,000	Chronic toxicity study in dogs LOAEL = 20 mg/kg/day based on decreased thymus weight in males
Short-term inhalation (1 to 30 days)	Inhalation study LOAEL = 60 mg/kg/day	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 1,000	28–day inhalation toxicity study in rats LOAEL = 60 mg/kg/day based on decreased body weight gain in males
Intermediate-term inhalation (1 to 6 months)	Inhalation study LOAEL = 60 mg/kg/day	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 1,000	28–day Inhalation toxicity study in rats LOAEL = 60 mg/kg/day based on decreased body weight gain in males
Long-term inhalation (<6 months)	Oral study LOAEL= 20 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 1,000	Chronic toxicity study in dogs LOAEL = 20 mg/kg/day based on decreased thymus weight in males
Cancer (oral, dermal, inhalation)			Not required; no evidence of carcinogenicity

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Currently there are no tolerances established for dinotefuran on any commodity. Risk assessments were conducted by EPA to assess dietary exposures from dinotefuran in food as follows:

i. *Acute exposure*. Acute dietary 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 conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: The dietary risk analyses incorporated tolerance level residues and assumed 100% of the leafy vegetables had been treated with dinotefuran. The acute risk estimates are below the Agency's level of concern (<100% aPAD) for the general U.S. population and all population subgroups.

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment EPA used the DEEM software with the FCID, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The dietary risk analyses incorporated tolerance level residues and assumed 100% of the leafy vegetables had been treated with

dinotefuran. The chronic risk estimates are below the Agency's level of concern (<100% cPAD) for the general U.S. population and all population subgroups.

iii. *Cancer*. Dinotefuran is classified as ''not likely to be a carcinogen,'' therefore, an exposure assessment for quantifying cancer risk was not conducted.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for dinotefuran in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of dinotefuran.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Groundwater (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. Both FIRST and PRZM/EXAMS incorporate an index reservoir environment, and both models include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to dinotefuran they are further discussed in the aggregate risk sections below.

Based on the Index Reservoir Screening Tool (FIRST) and SCI-GROW models, the EECs of dinotefuran for acute exposures are estimated to be 75.78 parts per billion (ppb) for surface water and 5.06 ppb for ground water. The EECs for chronic exposures are estimated to be 20.97 ppb for surface water and 5.06 ppb for ground 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 proposed to be registered for use on the following residential non-dietary sites: Professional turf management, professional ornamental production, residential indoor, lawn and garden. The risk assessment was conducted using the following residential exposure assumptions: Outdoor uses for turf farms, golf courses and residential lawns, ornamentals and vegetable gardens.

There is a potential for exposure to homeowners in residential settings during the application of 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, home gardens that could lead to exposures for adults. As a result, risk assessments have been completed for both residential handler and post-application scenarios.

Residential handlers may be exposed dermally and by inhalation during mixing, loading and application of dinotefuran for short-term durations. However, a short-term dermal endpoint was not identified. For this reason, and because the short-term and intermediate-term inhalation endpoints are the same, intermediate-term risks are assessed for residential handlers as a screen for their potential short-term exposures. Because common toxicity endpoints were identified for both dermal and inhalation routes, a combined risk from both routes of exposure is assessed. Combined risk was estimated by calculating an aggregate risk index (ARI). All residential handler estimated exposures meet or exceed the Agency's target ARI of 1, and are therefore, not of concern.

Residential post-application exposures are assumed to be mostly of short-term duration (1 to 30 days); although intermediate-term (1 to 6 months) exposures are possible. Because there are numerous dinotefuran use products and scenarios, those scenarios assessed were chosen to cover the major residential use sites (i.e. turf, home garden etc.) and highest use rates and exposures. The margins of exposure (MOEs) for post-application exposure to dinotefuran are above the target MOE of 100, and therefore, do not exceed Agency's level of concern for the following scenarios: (1) Exposure to adults and children from turf products; and (2) exposure to adults in vegetable gardens.

The Agency combines risks resulting from exposures to individual chemicals when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. For this assessment, the Agency has added together risk values for adults applying dinotefuran to residential lawns and then being exposed to the treated lawn. For children, dermal and incidental oral exposures from activities on treated lawn were combined. These are considered to represent worst case scenarios for co-occurring residential exposures.

The risks from the combined exposures of adults applying dinotefuran to residential lawns and then being dermally exposed from post-application activities on the treated lawn do not exceed the Agency's level of concern. Children's combined risks from activities on treated lawns do not exceed the Agency's level of concern.

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 other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to dinotefuran and 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

not assumed that dinotefuran has 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 the policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using UF (safety) in calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility (qualitative or quantitative) of rat or rabbit fetuses to *in utero* exposure to dinotefuran. There was no indication of increased (quantitative) susceptibility in the fetuses as compared to parental animals in the two generation reproduction study. Qualitative susceptibility was observed in the reproduction study; however, the degree of concern is low because the observed effects are well characterized (decreased body weight, decreased thymus weight, and decreased grip strength) and there are clear NOAELs/LOAELs.

3. *Conclusion*. Although there is generally low concern and no residual uncertainties for pre- and/or postnatal toxicity resulting from exposure to dinotefuran, some uncertainty is raised by a deficiency in the data (lack of a NOAEL in the chronic dog study) and the need for a developmental immunotoxicity study (DIT).

The absence of a NOAEL for the chronic dog study and the need for a DIT study generate some uncertainty regarding the protectiveness of chronic regulatory endpoint and long-term level of concern. Accordingly, EPA does not have reliable data supporting adoption of a safety factor other than the default additional 10X factor as specified in FFDCA section 408(b)(2)(C). The chronic endpoint and long-term level of concern have therefore been generated using a overall safety/uncertainty factor of 1,000 (representing 100X for inter- and intra-species variation and an additional 10X pursuant to FFDCA section 408(b)(2)(C).

The Agency does not have similar concerns regarding acute, short-term, and intermediate term risk assessments. First, the absence of a NOAEL only occurred in a chronic study. Second, reliable data show that the DIT is unlikely to result in a NOAEL for acute, short-term, or intermediate term effects that is lower than the NOAELs currently being used to assess the risk from such effects. EPA has required a Developmental Immunotoxicity Study (DIT) with dinotefuran based on the changes in the thymus weight in offspring in the reproduction study and in adult rats and dogs. There is, however, little evidence to support a direct effect of dinotefuran on immune function. This is because lymphoid organ weight changes can be secondary to generalized toxicity (e.g., reductions in body weight, body weight gain, and/or food efficiency). In the reproduction study, decreased thymus weights were seen in offspring in the presence of decreased body weight only at the Limit Dose (10,000 ppm). In the 1-year dog study, decrease in thymus weight was seen in the absence of other toxicity, however, no decrease in thymus weight was seen in the subchronic study in dogs which was conducted at higher doses (i.e., the results of the 1-year study was not supported by the results of the 90-day study).

Further, the only evidence on dinotefuran's potential immunological effect is found in studies with prolonged exposure. In the reproduction study, the effect of concern [i.e, decrease in thymus weight in only one generation (F2)] was seen only following approximately 13 weeks of exposure to the parental animals at close to the Limit Dose (1,000 mg/kg). Similarly, thymus effects in the chronic dog study were only observable after long-term exposures, but were not seen in the 90-day dog study.

Finally, it is clear that DIT study, which is performed in the rat, will have to be conducted at high doses (close to the Limit Dose) to elicit a potential single dose effect and this will result in a potential NOAEL higher than that currently used for various risk assessments. As noted, in the rat reproduction study, effects only occurred at doses close to the Limit Dose (1,000 mg/kg/day). The Limit Dose is the maximum dose recommended for testing in the Series 870 Health Effects Harmonized Test Guidelines; toxic effects occurring only at or near the Limit Dose are of less concern for human health since they may be specifically related to the high dose exposure and may not occur at the much lower doses to which humans are exposed. Additionally, in the acute neurotoxicity study in the rat, the LOAEL was 750 mg/kg/day in females and 1,500 mg/kg/day in males based on reductions in motor activity indicating that high doses are required to elicit Dinotefuran-induced toxicity in rats.

The NOAELs in the critical studies selected for acute dietary (125 mg/kg/day), short term incidental oral (33 mg/kg/day), and intermediate term incidental oral and dermal (22 mg/kg/day) exposure scenarios are lower than the offspring NOAEL (241 mg/kg/day) in the reproduction study. Therefore, EPA is confident that the doses selected for these risk assessments will address the concerns for the thymus weight changes seen in the offspring in the reproduction study and will not underestimate the potential risk from exposure to dinotefuran.

The Agency believes there are reliable data showing that the regulatory endpoints are protective of children despite the need for a developmental neuorotoxicity study. Developmental neurotoxicity data received and reviewed for other compounds in this chemical class (neonicotinoids) including thiacloprid, clothianidin, and imidacloprid, indicate that the results of the required DNT study will not likely impact the regulatory doses selected for dinotefuran.

In addition, the acute and chronic dietary food exposure assessment utilized proposed 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, the dietary drinking water assessment (Tier 1 estimates) uses values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. Finally, the residential assessment for children's postapplication exposures is based upon

maximum application rates in conjunction with chemical-specific study data and are not expected to underestimate risk.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to dinotefuran will occupy 0.68% of the aPAD for the U.S. population, 0.76% of the aPAD for females 13 years and older, 0.21% of the aPAD for infants <1 year old, and 0.76% of the aPAD for children 3 to 5 years old. In addition, there is potential for acute dietary exposure to dinotefuran in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3.

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO DINOTEFURAN

Population/Subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	1.25	0.68	75.78	5.06	43,000
All infants (< 1 year old)	1.25	0.21	75.78	5.06	12,000
Children (3-5 years old)	1.25	0.76	75.78	5.06	12,000
Females (13-49 years old)	1.25	0.76	75.78	5.06	37,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to dinotefuran from food will utilize 8.6% of the cPAD for the U.S. population, 4.4% of the cPAD for infants <1 year old, 8.6% of the cPAD for children 3-5 years old and 9.4% of the cPAD for females 13-49 years old. In addition, there is potential for chronic dietary exposure to dinotefuran in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DINOTEFURAN

Population/Subgroup	cPAD (mg/kg/day)	%cPAD (FOOD)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.02	8.6	20.97	5.06	640
All infants (< 1 year old)	0.02	4.4	20.97	5.06	190
Children (3-5 years old)	0.02	8.6	20.97	5.06	180
Females (13-49 years old)	0.02	9.4	20.97	5.06	550

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

Dinotefuran is proposed for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures. For dinotefuran, short-term and intermediate-term aggregate risk assessments based on exposure from oral, inhalation, and dermal routes were considered.

However, for short-term aggregate exposure assessment, oral and inhalation risk estimates cannot be combined due to the different bases of their endpoints; i.e., neurotoxicity for oral and decrease in body weight for inhalation. 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, a short-term aggregate risk assessment cannot be performed for dinotefuran. However, an intermediate-term aggregate risk assessment was performed as a screening level assessment, which will apply to short-term aggregate risk.

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

Dinotefuran is proposed for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for dinotefuran. An intermediate-term aggregate risk assessment was performed as a screening level assessment for adults and children.

The child subgroup with the highest estimated chronic dietary exposure (children 3-5 years old) was used to calculate the intermediate-term aggregate risk, including chronic dietary (food and drinking water) and residential dermal and oral exposures. All acceptable MOEs must be identical for all MOEs to be included in the intermediate-term risk assessment. Based on the toxicity endpoint information, all acceptable MOEs are 100, and an oral endpoint for hand-to-mouth residential exposure was identified. In this case, the chronic dietary endpoint (NOAEL) was used to incorporate dietary (food and water), and residential exposures in the aggregate risk assessment. An intermediate-term residential exposure scenario was identified and includes dermal and oral exposure routes. To complete the aggregate intermediate-term exposure and risk assessment, chronic dietary (food and drinking water) and residential dermal and oral exposures must be included.

For children's combined exposure on turf, the total residential MOE was estimated to be 590. The average (chronic) dietary exposure for the highest exposed child subgroup (children 3-5 years old) was estimated to be 0.0017 mg/kg/day. The aggregate risk assessment for intermediate-term exposure to children is summarized in the following Table 5.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE OF CHILDREN TO DINOTEFURAN.

Population	NOAEL/ mg/kg/ day	Target MOE[1]	Max Exposure[2]/ mg/kg/ day	Average Food Exposure mg/kg/ day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]	Max Water Exposure[5] mg/kg/day	Ground Water EEC[6] µg/L	Surface Water EEC[6] µg/L	Intermediate-Term DWLOC[7] µg/L
Children 3-5 yrs old	22	100	0.22	0.0017	0.037227	565	0.181	20.97	5.06	1,810

[1] The target MOE of 100 is based on the standard inter-species and intra-species safety factors, 10x for intra-species variability and 10x for inter-species extrapolation.
[2] Maximum exposure (mg/kg/day) = NOAEL/Target MOE.
[3] Residential exposure to children playing on treated lawns (combined dermal + oral hand-to-mouth + oral object-to-mouth + oral soil ingestion).
[4] Aggregate MOE = NOAEL/(Avg. Food Exposure + Residential Exposure).
[5] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure).
[6] The use site producing the highest level was used; i.e. turf.
[7] DWLOC (µg/L) = Maximum water exposure (mg/kg/day) x body weight (10 kg) Water exposure (1L) x 10^3 mg/µg.

Compared with the EECs, the aggregate intermediate-term DWLOC does not exceed Agency's level of concern for the subgroup population of children 3-5 years old.

For adults, the worst case intermediate-term aggregate risk assessment includes the following scenarios: (1) Dermal and inhalation exposures to residential handlers (i.e. M/L/A of liquids to lawns by hose-end sprayers); (2) dermal post-application exposures on treated lawns; and (3) oral dietary exposures (i.e. food + drinking water). Based on the toxicity endpoint information, the acceptable MOEs are not all identical. The intermediate-term inhalation endpoint has a UF/MOE of 1,000, because a NOAEL was not reached and a LOAEL was used instead, while the assessments for incorporating food, water and dermal exposures have UFs/MOEs of 100. In this case, the aggregate risk index (ARI) method was used to calculate DWLOC values for the adult aggregate intermediate-term risk assessment.

The highest estimated average (chronic) dietary exposure occurred with females 13-49 years old (i.e. 0.0019 mg/kg/day). The adult residential combined risks from dermal (ARI = 17) and inhalation (ARI = 970) exposures to residential handlers; and dermal postapplication exposures (ARI = 12) on treated lawns were assessed and combined. The aggregate risk assessment for intermediate-term exposure to adults is summarized in following Table 6.

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE OF ADULTS TO DINOTEFURAN.

Polulation	Target ARI[1]	ARI Food[2]	Residential ARIs[3]			Max Water Exposure ARI[4]	Ground Water EEC[5] µg/L	Surface Water EEC[5] µg/L	Inter-mediate-Term DWLOC[6] µg/L
			Applicators		Post-application Dermal Exposure				
			Dermal Exposure	Inhalation Exposure					
Females 14-49 years old	1	116	17	970	12	1.18	20.97	5.06	5,600

[1] ARI (Aggregate Risk Index) = $MOE_{calculated}/MOE_{acceptable}$
[2] ARI_{Food} = 22 / 0.0019 / 100 = 116
[3.] $ARI_{dermal} = MOE_{calculated}/100$ and, $ARI_{inhal} = MOE_{inhal}/1{,}000$
[4.] ARI Water = 1/1/1- (1/$ARI_{Residential\ aplicator\ dermal}$) + (1/$ARI_{Residential\ applicator\ inhalation}$) + (1/ARI Post-application dermal)
[5.] The use site producing the highest level was used; i.e. turf.
[6.] DWLOC (µg/L) = [Maximum water exposure (mg/kg/day) x body weight (60 kg)] / [Water exposure (2 L) x 10^{-3} mg/µg]; where Maximum water exposure = NOAEL (22) / ARI Water (1.18) x 100 = 0.1866 mg/kg/day.

Compared with the EEC, the aggregate intermediate-term DWLOC does not exceed Agency's level of concern for the subgroup population of females 13-49 years old.

5. *Aggregate cancer risk for U.S. population*. Dinotefuran is not expected to pose a cancer risk.

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, and to infants and children from aggregate exposure to dinotefuran residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography/Ultraviolet for the determination of residues of dinotefuran per se in lettuce, and High Performance Liquid Chromatography/Mass Spectrometry and High Performance Liquid Chromatography/Mass Spectrometry/Mass Spectrometry method for the determination of dinotefuran metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea] in lettuce) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits for residues of dinotefuran in/on plant or livestock commodities.

V. Conclusion

Therefore, the tolerance is established for combined residues of dinotefuran, *N*-methyl-*N'*-nitro-*N*-[tetrahydro-3-furanyl)methyl]guanidine and its metabolites DN [1-methyl-3-[tetrahydro-3-furylmethyl]guanidine and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran, in or on vegetable, leafy, except Brassica, group 4 at 5.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0155 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 on or before November 16, 2004.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk, Environmental Protection Agency, 1099 14th Street NW., Suite 350, Washington DC 20005, (telephone number (202) 564–6255). The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0155, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide

Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 9, 2004.

James Jones,

Director, 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 added to subpart C to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

(a) *General*. Tolerances are established for the combined residues of Dinotefuran, *N*-methyl-*N'*-nitro-*N*-(tetrahydro-3-furanyl)methyl)guanidine and its metabolites DN 1-mehyl-3-(tetrahydro-3-furylmethyl)guanidine and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran.

Commodity	Parts per million
Vegetable, leafy, except Brassica, group 4	5.0

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 04–20981 Filed 9–16–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0277; FRL–7679–4]

Thifensulfuron Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of thifensulfuron methyl in or on canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed. E. I. DuPont de Nemours & Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, this regulatory action is part of the tolerancere assessment requirements of section 408 (q) of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U. S. C. 346a (q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required to reassess 100% of the tolerances in existence on August 2, 1996, by August 2006. This regulatory action will count for 10 reassessments toward the August 2006 deadline.

DATES: This regulation is effective September 17, 2004. Objections and requests for hearings must be received on or before November 16, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0277. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides 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 and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm/*.

II. Background and Statutory Findings

In the **Federal Register** of July 7, 2004 (69 FR 40920) (FRL–7364–7), 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 0F6152) by E.I. DuPont de Nemours and Company, DuPont Agricultural Products, Barley Mill Plaza, Wilmington, DE 19880–0038. The petition requested that 40 CFR 180.439 be amended by establishing a tolerance for residues of the herbicide thifensulfuron methyl, (methyl-3-[[[[(4-methoxy-6-methyl-1, 3, 5, -triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate), in or on imazethapyr tolerant canola seed at 0.02 parts per million (ppm), cotton seed at 0.02 ppm, cotton gin trash at 0.02 ppm, and CDC triffid flax at 0.02 ppm. That notice included a summary of the petition prepared by E. I. DuPont de Nemours & Company, the registrant. There were no comments received in response to the notice of filing.

During the course of the review the Agency decided to correct the Company address and correct the listings for the commodities canola, cotton gin trash, cottonseed, and flax. The company address is changed to DuPont Crop Protection, Stine-Haskell Research Center, Newark, DE 19714. The listing of the commodities imazethapyr tolerant canola, cotton seed, cotton gin trash, and Crop Development Center (CDC) triffid flax are corrected to read canola, seed; cotton, gin byproducts; cotton, undelinted seed; and flax, seed; respectively.

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