

entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

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

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: December 8, 2009.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

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

2. Section 180.463 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.463 Quinclorac; tolerances for residues.**

(a) \* \* \*

| Commodity           | Parts per million |
|---------------------|-------------------|
| * * *               | * *               |
| Grass, forage ..... | 150               |
| Grass, hay .....    | 130               |

| Commodity | Parts per million |
|-----------|-------------------|
| * * *     | * *               |

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2008-0730; FRL-8804-8]

**Endothall; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for indirect or inadvertent combined residues of endothall in or on multiple commodities identified and discussed elsewhere in this document. The Interregional Research Project Number 4 (IR-4) in cooperation with the registrant, United Phosphorus, Inc., 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-2008-0730. 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 (7505P), 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](mailto: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 Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods & Guidelines" on the left-side navigation menu.

*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-2008-0730 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-2008-0730, 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 December 3, 2008 (73 FR 73644) (FRL-8386-9), 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 8E7419) by the IR-4, IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.293 be amended by establishing tolerances for combined residues of the herbicide endothall, mono (*N,N*-dimethylalkylamine) salt of endothall, and the dipotassium salt of endothall, in or on Vegetable Root, and Tuber Group 1 at 2 ppm (parts per million); Vegetable, Leaves of Root and Tuber, Group 2 at 3.5 ppm; Vegetable, Bulb, Group 3-07 at 2 ppm; Vegetable, Leafy, except Brassica, Group 4 at 3.5 ppm; Vegetable, Brassica, Leafy, Group 5 at 0.1 ppm; Turnip, greens at 0.1 ppm; Vegetable, Legume, Group 6 at 3 ppm; Vegetable, Fruiting, Group 8 at 0.05 ppm; Okra at 0.05 ppm; Vegetable, Cucurbit, Group 9 at 1.1 ppm; Fruit,

Citrus, Group 10 at 0.05 ppm; Fruit, Pome, Group 11 at 0.05 ppm; Fruit, Stone, Group 12 at 0.25 ppm; Berry and Small Fruit Group 13-07 at 0.6 ppm; Nut, Tree, Group 14, at 0.05 ppm; Pistachio at 0.05 ppm; Almond, hulls at 10 ppm; Grain, Cereal, Group 15 at 2.5 ppm; Grain, Cereal, Forage, Fodder and Hay, Group 16, forage at 3.5 ppm, Grain, Cereal, Forage, Fodder and Hay, Group 16, hay at 5 ppm, Grain, Cereal, Forage, Fodder and Hay, Group 16, stover at 11 ppm, Grain, Cereal, Forage, Fodder and Hay, Group 16, straw at 6 ppm, Grain, aspirated fractions at 24 ppm; Grass, Forage, Fodder, and Hay, Group 17, forage at 3 ppm, Grass, Forage, Fodder and Hay, hay at 19 ppm; Nongrass Animal Feed, Group 18 forage at 3.5 ppm, Nongrass Animal Feed, Group 18 hay at 8 ppm; Grape at 0.9 ppm, Peppermint, tops at 7 ppm, Spearmint, tops at 7 ppm; and Rice, grain at 1.7 ppm and Rice, straw at 4.5 ppm. That notice referenced a summary of the petition prepared by United Phosphorus, Inc., the registrant, on behalf of IR-4 which is available to the public in the docket, <http://www.regulations.gov>. This petition for tolerances was filed in conjunction with an application under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") for use of endothall in irrigation water and thus the broad request for tolerances. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition as well as the proposed use to irrigation canals, EPA has determined that virtually all crops as well as most food and feed commodities could potentially be exposed to residues in endothall-laden irrigation water with EPA approval of this use. In consideration of these factors, the Agency is revising the proposed tolerances to include inadvertent endothall residues on any food commodities not otherwise listed at 5.0 ppm and any feed commodities not otherwise listed at 10.0 ppm. Additionally, based on the residue data submitted, EPA has revised proposed tolerance levels for certain food and feed commodities. Finally, EPA is not establishing certain petitioned-for tolerances after determining they are not needed. The reasons for these changes are explained in Unit IV.D.

## 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 including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with endothall 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.

Endothall is a caustic chemical with toxicity being the result of a direct degenerative effect on tissue. By acute dermal application and inhalation exposure, it has mild toxicity. Dermal, it destroys the stratum corneum and then the underlying viable epidermis. Endothall is a skin sensitizer. Endothall is an extreme irritant by the acute oral, and ocular routes of administration. Orally, endothall attacks the digestive tract. In the eye irritation study, endothall was shown to be extremely irritating to the eye and was also lethal to 4 of 6 rabbits tested.

In the 21-day dermal rat study, systemic toxicity (hematology and clinical chemistry alterations) were noted at a dose level that was one order of magnitude greater than that causing dermal irritation. Available studies clearly demonstrate that local irritation (portal of entry effect) is the most sensitive and initial effect, occurring at

dose levels lower than those associated with systemic toxicity. In dogs, gastric irritation developed at a dose level that was one order of magnitude lower than doses associated with clinical signs of toxicity (subdued behavior, poor condition, thin appearance and distended abdomen). In the rat, gastric irritation was noted at a dose level that was 1 to 2 orders of magnitude lower than doses resulting in kidney lesions. Besides gastric irritant effects, decreased body weight was also a sensitive effect following endothall administration. The decreased body weights were most likely attributable to the constant and direct irritation of the gastric lining. In a developmental rat study, pregnant rats exhibited decreased body weight and decreased body weight was noted in a 90-day dietary study in the rat. Body weight loss occurred in dogs following a 13 week oral treatment with endothall.

Endothall does not cause prenatal toxicity following *in utero* exposure to rats nor prenatal or postnatal toxicity following exposures to rats for 2-generations. In the developmental mouse study, there was severe maternal toxicity (i.e., greater than 30% mortality) at the highest dose tested; at this dose level, a slight increase in vertebral and rib malformations was observed in the offspring indicating that these effects were most likely secondary to severe maternal toxicity.

Available studies showed no evidence of neurotoxicity and do not indicate potential immunotoxicity. Endothall does not belong to the class of compounds (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be toxic to the immune system. Endothall is classified as "not likely to be carcinogenic to humans" based on lack of evidence of carcinogenicity in mice or rats. It has no mutagenic potential.

Specific information on the studies received and the nature of the adverse effects caused by endothall as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document "Endothall: Revised Human Health Risk Assessment for the Section 3 Registration Action to Support a New Use of Endothall in Irrigation Canals with No Required Holding Period before that Water Can Be Used on Crops," dated 11/09/2009, page 16 in docket ID number EPA-HQ-OPP-2008-0730-0004.

### 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-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for endothall used for human risk assessment can be found at <http://www.regulations.gov> in document entitled; "Endothall: Revised Human Health Risk Assessment for the Section 3 Registration Action to Support a New Use of Endothall in Irrigation Canals with No Required Holding Period before that Water Can Be Used on Crops," dated 11/09/2009, page 21 in docket ID number EPA-HQ-OPP-2008-0730-0004.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to endothall, EPA considered exposure under the petitioned-for tolerances as well as all existing endothall tolerances in 40 CFR 180.293. EPA assessed dietary exposures from endothall 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.

No systemic toxicity resulting from a single exposure was identified. An acute Reference Dose (RfD) was not established for any population subgroup because an appropriate endpoint attributable to a single endothall dose was not available from any study, including the prenatal developmental toxicity study in the rat or the mouse. Therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID<sup>TM</sup>, Version 2.03 which incorporates consumption data from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII).

Analyses were performed to support the use of endothall in irrigation canals with no holding period before the water may be used on crops. The resulting chronic exposure assessment for food is refined, using average residues from the field trials, and estimating residues in meat, milk, poultry and eggs (MMPE), and using average residues in the livestock feeds. The exposure estimate also includes an adjustment for the percent of the harvested crop that has been irrigated for some crops. Despite this refinement, the results remain very conservative for several reasons. First, the field residue trials were performed under highly conservative conditions. Second, the manner of taking percent of the crop irrigated into consideration was very conservative. For most commodities EPA assumed 100% of the crop would be irrigated. For the remaining crops, EPA used two different methods to estimate the percent of the crop that was irrigated. Where EPA had reliable data on the percent of a crop that is irrigated, EPA assumed that percentage of that crop is irrigated with endothall-treated water (i.e., assuming that 100% of irrigation water is treated

with endothall). Where EPA did not have adequate data on the percent of a crop that is irrigated, EPA assumed that all crops grown in the western U.S. are irrigated with endothall-treated water. Endothall is unlikely to be used in treatment of irrigation water outside of the western U.S. This is a very conservative assumption because all of the crops grown in the western U.S. are not irrigated.

The average residue values used in the dietary exposure assessment were taken from 18 sets of field trials submitted by IR-4. Processing factors were taken from the appropriate processing studies submitted with these field trials. Because this assessment needed to cover all possible crops that might be irrigated in the U.S., the appropriate crop residues and processing studies were translated within each extant crop group, and in addition appropriate residue values were translated to other orphan crops outside of those crop groups as needed. For similar reasons appropriate processing factors were sometimes translated to similarly processed commodities. DEEM default concentration factors were used for any applicable processed commodities where no applicable processing factors could reasonably be translated, but default factors did exist. For certain crops no formal default values have been established, so the processing factors for these crops were left at 1.0, to be consistent with other contemporary assessments.

iii. *Cancer*. Endothall is considered "not likely to be carcinogenic to humans" based on lack of evidence of carcinogenicity in mice and rat studies. Endothall showed no mutagenic potential based on results from *in vitro* mammalian cell gene mutation assay in Chinese hamster ovary (CHO) cells and bacterial gene mutation assay (*Salmonella typhimurium*). Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are

required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Apple, fresh market 78%, apple, processing 44%, apple, juice 49%, apple, canned 14%, barley 36%, corn 19%, dry edible beans 32%, grape, fresh market 99%, grape, processing 94%, green peas 11%, oats 7%, peanuts 42%, sorghum 15%, soybeans 9%, sugarbeets 37%, sugarcane 54%, strawberry, fresh market 89% and wheat 14%, and watermelon 39%.

EPA is establishing tolerances on multiple commodities to support the application of the aquatic herbicide endothall to be used in irrigation canals without a holding period. For a new agricultural pesticide use, EPA typically estimates PCT by comparison with the amount of use of other pesticides for the same crop or site. That approach is inappropriate for the new use for endothall, because the use is on irrigation canals rather than crops and EPA does not have data on the frequency of use of aquatic herbicides on irrigation canals.

Instead, EPA has estimated PCT for endothall by estimating the percent crop irrigated which serves as an upperbound for crops that may be exposed to endothall in irrigation water. EPA used two methods to estimate percent crop irrigated. The preferred method, used where reliable data on irrigated production are available, is an estimate of the share of total production that is irrigated. Estimates from this method are provided for barley, corn, dry edible beans, oats, peanuts, rice,

sorghum, soybeans, sugarbeets, sugarcane, and wheat. Where data on irrigated production are not available, EPA estimated the percent crop irrigated by determining the percentage of U.S. production of a crop that is grown in 17 western states where endothall may be used. The 17 western states are Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming. These states are the states where large scale water projects predominate, and where other chemicals are used in canals for weed control. These types of irrigation projects are relatively rare in other parts of the country.

Use of these estimates in the exposure assessment is conservative, because it is the equivalent of assuming 100% of irrigated crops have irrigated with water from endothall-treated canals. In fact, even in areas with surface water delivery systems, all irrigation canals may not be treated with endothall. Additionally, some crops, even in the heavily irrigated areas of the West, are not irrigated, such as dryland grain production.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which endothall may be applied in a particular area.

2. *Dietary exposure from drinking water*. The maximum potential exposure of endothall in drinking water sources is expected to result from the direct application of endothall to drinking water reservoirs to control aquatic

weeds. EPA assumed that the entire reservoir would be treated at the maximum rates, with no more than 10% of the reservoir treated at one time as stated on the label, so that 10 treatments were applied 7 days apart to treat the entire reservoir. Since the label specified that the community water system (CWS) could not supply treated drinking water unless the endothall residues were below 0.1 ppm (100 µg/L), EPA assumed 100 µg/L (0.1 ppm) as the acute (peak) exposure and the constant exposure during the treatment period and then modeled residue decline by degradation after the final treatment. This resulted in a chronic (annual average) concentration of 31 µg/L (0.031 ppm) for endothall. This represents the likely high-end chronic exposure from endothall from the use expected to generate the highest exposures (treatment of a reservoir).

Additional information on the drinking water exposure assessment can be found at <http://www.regulations.gov> in document entitled; "Drinking Water Assessment for the IR-4 Tolerance Petition for the Use of Endothall-treated Irrigation Water on a Variety of Crops," dated 9/09/2009 in docket ID number EPA-HQ-OPP-2008-0730.

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).

Endothall is currently registered for the following uses that could result in residential exposures. There is a potential for exposure from registered uses in residential for homeowners who apply endothall products to control aquatic weeds and algae in ponds and garden pools. There is also a potential for exposure to adults and children from contacting water treated with endothall through swimming, wading, water skiing, etc. The Agency conducted risk assessments for both residential handler and post-application scenarios.

For residential handlers, exposure scenarios are only considered to be short-term in nature due to the episodic uses associated with homeowner products. In ponds and garden pools use patterns and under current product labeling, two likely residential exposure scenarios exist including; 1) loading/ applying granules with a bellygrinder and 2) applying granules by hand. The quantitative exposure/risk assessment developed for residential handlers is based on these two scenarios.

In residential post-application scenarios, exposures to adults and children may be expected following

applications of endothall to ponds and lakes. Only short-term exposures are expected since these scenarios are expected to be only episodic.

Of the possible post-application exposures, swimming in treated water is considered by EPA to be worse-case and is used as a surrogate for all other possible post-application exposures, such as wading, water skiing, etc. The Agency considered residential post-application exposure for different segments of the population using the Swimmer Exposure Assessment Model (SWIMODEL). Details on the SWIMODEL used in this assessment may be found at: <http://www.epa.gov/oppad001/swimodel.htm>.

Risks were calculated using the MOE approach, where a MOE of >100 is considered a level that does not pose a 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."

EPA has not found endothall to share a common mechanism of toxicity with any other substances, and endothall does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that endothall 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.* There is no quantitative or qualitative evidence of increased susceptibility following prenatal exposure to rats in the developmental toxicity study. Endothall does not cause prenatal toxicity following *in utero* exposure to rats nor prenatal or postnatal toxicity following exposures to rats for 2-generations reproduction studies. Due to high mortality observed in a range finding study in rabbits even at low doses, a developmental toxicity study in this species was not conducted (i.e., acute direct irritative effects of the chemical could interfere with developmental toxicity in this susceptible species). A developmental toxicity study in mice showed no evidence for enhanced susceptibility in this species.

EPA concluded that there is not a concern for prenatal and/or postnatal toxicity resulting from exposure to endothall in rats. In the developmental mouse study, there was severe maternal toxicity (i.e., greater than 30% mortality) at the highest dose tested; at this dose level, a slight increase in vertebral and rib malformations was observed in the offspring indicating that these effects were likely secondary to severe maternal toxicity.

3. *Conclusion.* For chronic and intermediate-term risk assessments, EPA is retaining an additional safety factor for the protection of infants and children because it is relying on a LOAEL in the 2-generation reproduction study in assessing the risk of endothall. For short-term risk assessments, EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. Based on the following factors, EPA has determined that an additional factor of 3X will be safe for infants and children for chronic and intermediate-term risk assessments and that a 1X factor will be safe for short-term risk assessments:

i. Despite the fact that a NOAEL was not identified in the 2-generation reproduction study for chronic and intermediate-term effects and EPA is relying on a LOAEL from that study, a 3X factor (as opposed to a 10X) was determined to be adequate because: The gastric lesions (most sensitive effect) are due to the direct irritant properties of endothall (i.e., portal effects) and not as a result of frank systemic toxicity; the severity of the lesions were minimal to mild; and there was no apparent dose-response for this effect.

Therefore, EPA is confident that the POD for chronic dietary and intermediate inhalation exposure risks will not underestimate risks following exposure to endothall. A NOAEL for short-term effects was identified in the 2-generation reproduction study and is being used as the POD for assessing short-term risks of endothall.

ii. The toxicity database for endothall is complete except for acute and subchronic neurotoxicity studies and immunotoxicity testing. Recent changes to 40 CFR part 158 make these studies (OPPTS Guideline 870.7800) required for pesticide registration; however, the available data for endothall do not show potential for neurotoxicity or immunotoxicity. Although neurotoxicity studies have not yet been submitted, there are no concerns for neurotoxicity. The EPA does not expect that these studies will demonstrate a potential neurotoxic effect that is more sensitive than direct local irritation (the most sensitive effect identified in the data base). The available acute subchronic and chronic studies showed no evidence of neurotoxicity. However, irritation was identified as the initial and most sensitive effect. In the absence of specific immunotoxicity studies, EPA has evaluated the available endothall toxicity database to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. The available studies do not indicate potential immunotoxicity, and endothall does not belong to the class of compounds (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be toxic to the immune system. Based on the available data, the required immunotoxicity study is not expected to provide a POD lower than that currently used (i.e., direct local irritation - the most sensitive effect) for overall risk assessments. Consequently, the EPA believes the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the FQPA, and an additional database uncertainty factor does not need to be applied.

iii. There is no indication that endothall is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. There is no evidence that endothall results in increased susceptibility in *in utero* rats or mice in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

v. There are no residual uncertainties identified in the exposure databases.

While the chronic dietary exposure estimates are refined (average field trial residues and adjustment of the percent of the harvested crop that has been irrigated) the results are very conservative because the field trials were performed under highly conservative conditions, and it was assumed that 100% of all irrigation canals in the U.S. are treated at the maximum rate for endothall. Further, it was assumed that this maximally treated water is applied to the crops on the day of harvest, and all consumers are chronically exposed to simultaneous inadvertent residues of endothall through all possible food and water sources. For most commodities EPA assumed 100% of the crop would be irrigated. For the remaining crops, EPA used two different methods to estimate the percent of the crop that was irrigated which were very conservative estimates. Therefore, the estimated dietary exposure (food and drinking water) will not underestimate the potential risks for infants and children. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to endothall in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by endothall.

#### *E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, endothall is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to endothall from food and water will utilize 84% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. The general U.S. population subgroup was exposed at a maximum of 32% of the cPAD.

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).

Endothall 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 endothall.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures aggregated result in aggregate MOEs. For adults, estimated dietary exposures via food and drinking water were combined with inhalation exposures during application to a pond or lake and potential post-application exposures during swimming. For children, estimated dietary exposures via food and drinking water were combined with potential post-application exposures during swimming. The short term aggregate risk estimate (MOE) for adults is 290, and for children, it is 240. The LOC for short-term exposures is for MOEs < 100. Therefore, there are no short term aggregate (food + drinking water + residential) risk concerns for endothall.

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).

Endothall is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for endothall.

5. *Aggregate cancer risk for U.S. population.* Endothall is considered not likely to be carcinogenic to humans. EPA does not expect endothall 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, or to infants and children from aggregate exposure to endothall residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography (GC) with microcoulometric nitrogen detection) is listed as Method I in the Pesticide Analytical Manual (PAM, Volume II) for the determination of endothall residues (total common moiety) in plant commodities, with a limit of quantitation (LOQ) of 0.1 ppm. A second liquid chromatography/mass spectrometry (LC/MS) method (Method No. KP218R0) is also available for determining residues of endothall and its monomethyl ester in fish and in plant commodities. The LOQ is 0.05 ppm for fish, and range from 0.01–0.10 ppm for plant commodities.

##### B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits for endothall on plant or animal commodities.

##### C. Revisions to Petitioned-For Tolerances

The Agency revised the proposed tolerance levels for the following commodities: Almond, hulls from 10 to 15 ppm; animal feed, nongrass, group 18, forage from 3.5 to 4.0 ppm; animal feed, nongrass, group 18, hay from 8.0 to 10.0 ppm; fruit, stone, group 12 from 0.25 to 0.3 ppm; grain, aspirated fractions from 24.0 to 35.0 ppm; grain, cereal, group 15, except corn from 1.9 to 4.0 ppm; grape from 0.9 to 1.0 ppm; grass, forage, fodder, and hay group 17, forage from 3.0 to 3.5 ppm; grass, forage, fodder, and hay group 17, hay from 19.0 to 18.0 ppm; peppermint, tops from 7.0 to 5.0 ppm; spearmint, tops from 7.0 to 5.0 ppm; vegetable, bulb, group 3 at 2.0 to bulb, group 3-07 at 0.5 ppm; vegetable, cucurbit, group 9 from 1.1 to 1.5 ppm; vegetable, leafy, except brassica, group 4 from 3.5 to 2.0 ppm; vegetable, leaves of root and tuber, group 2 from 3.5 to 3.0 ppm; and vegetable, root and tuber, group 1 from 2.0 to 1.0 ppm. For proposed tolerances for cereal, forage, fodder and straw, group 16, stover at 11.0 ppm; and cereal,

forage, fodder and straw, group 16, except stover at 6.0 ppm, the Agency established a single tolerance for both as “grain, cereal, forage, fodder and straw, group 16” at 10 ppm.

The Agency revised the tolerance levels based on available data on maximum endothall residues in subject crop and/or representative crop including analysis of the residue field trial data using the Agency’s Tolerance Spreadsheet in accordance with the Agency’s Guidance for Setting Pesticide Tolerances Based on Field Trial Data.

Using the same resources and procedures, the Agency established tolerances for the following additional commodities: Apple, wet pomace at 0.15 ppm; beet, sugar, molasses at 1.5 ppm; cattle, fat at 0.01 ppm; cattle, kidney at 0.20 ppm; cattle, liver at 0.1; cattle, meat at 0.03 ppm; corn, field, grain at 0.07 ppm; corn, pop, grain at 0.07 ppm; egg at 0.05 ppm; feed commodities not otherwise listed at 10.0 ppm; food commodities not otherwise listed at 5.0 ppm; goat, fat at 0.005; goat, kidney at 0.15 ppm; goat, fat at 0.015 ppm; goat, liver at 0.05 ppm; goat meat at 0.015 ppm; grape, raisin at 5.0 ppm; herb and spice, group 19 at 5.0 ppm; hog, fat at 0.005; hog, liver at 0.05; hog, kidney at 0.10; hog, meat at .01 ppm; milk at 0.03 ppm; pea and bean, succulent shelled, subgroup 6B; pea and bean, dried shelled, subgroup, 6C at 0.2 ppm; poultry, fat at 0.015 ppm; poultry, liver at 0.05 ppm; poultry, meat byproducts at 0.20 ppm; poultry, meat at 0.015 ppm; rice, hull at 8.0 ppm; sheep, fat at 0.005 ppm; sheep, kidney at 0.15 ppm; sheep, liver 0.05; sheep, meat 0.015 ppm; soybean, hulls at 0.5 ppm; soybean, seed at 0.2 ppm; tomato, paste at 0.1 ppm; tomato, puree at 0.1 ppm; brassica, head and stem subgroup 5A at 0.1 ppm; brassica, leafy, group 5B at 2.0 ppm; vegetable, foliage of legume group 7 at 4.0 ppm; vegetable, legume, edible, podded, subgroup 6A; and wheat, milled byproducts at 5.0 ppm. Some of these tolerances are being added because processing data indicated that residues in the processed food may exceed the raw commodity tolerance (grape, raisin; wheat, milled byproducts). The other tolerances are being added because use of an aquatic herbicide such as endothall in irrigation water may theoretically result in residues in these crops. The available data support these tolerances.

EPA has also determined that individual tolerances are not necessary for certain petitioned-for commodities. Proposed tolerances for cereal, forage, fodder and straw, group 16, hay; cereal, forage, fodder and straw, group 16, straw; and cereal, forage, fodder and

straw, group 16, forage are combined into forage, hay and straw and, therefore individual tolerances are not required. Proposed tolerances for rice, grain and rice, straw are not needed as these commodities are covered by the tolerances for cereal grains and cereal grain straw. The Agency rejected a proposed tolerance for vegetable, legume group 6 and established separate tolerances for soybeans and the various legume subgroups including vegetable, legume, edible podded, subgroups 6A; pea and bean, succulent shelled, subgroup 6B; and pea and bean, dried shelled, subgroup 6C. Likewise, tolerances were established for brassica, head and stem subgroup 5A and brassica, leafy, group 5B in place of a proposed tolerance for vegetable, brassica, group 5.

The Agency established a tolerance for cattle, fat; cattle meat; cattle liver and cattle kidney based upon calculations for dairy cattle using metabolism data even though no tolerance was proposed by IR-4 for cattle meat products. Tolerances were also established for cereal, forage, fodder and straw, group 16.

No tolerance was petitioned for on corn, field, grain or corn, pop, grain. However, a 0.7 ppm tolerance is established for each based on tolerance spreadsheet for corn grain. Also, a tolerance is established for corn, sweet, kernel plus cob with husks removed at 0.3 ppm based on maximum residues in sweet corn K+CWHR of 0.17 ppm based on available data.

Additionally, the Agency has determined that the tolerances should be established in § 180.293(d) for direct and inadvertent residues and the tolerance expression should read: Tolerances are established for the indirect or inadvertent combined residues of the herbicide, endothall (7-oxabicyclo[2.2.1] heptane-2,3-dicarboxylic acid) in potable water from use of its potassium, sodium, di-*N,N*-dimethylalkylamine, and mono-*N,N*-dimethylalkylamine salts.

#### V. Conclusion

Therefore, tolerances are established for the indirect or inadvertent combined residues of endothall (7-oxabicyclo[2.2.1] heptane-2,3-dicarboxylic acid) in water, potable from use of its potassium, sodium, di-*N,N*-dimethylalkylamine, and mono-*N,N*-dimethylalkylamine salts as algicides or herbicides to control aquatic plants in canals, lakes, ponds, and other potable water sources that may lead to endothall residues in or on almond, hulls at 15.0 ppm; animal feed, nongrass, group 18, forage at 4.0 ppm;

animal feed, nongrass, group 18, hay at 10 ppm; apple, wet pomace at 0.15 ppm; beet, sugar at 1.5 ppm; bushberry subgroup 13-07B at 0.6 ppm; caneberry subgroup 13-07A at 0.6 ppm; cattle, fat at 0.01 ppm; cattle, kidney at 0.20 ppm; cattle, liver at 0.10 ppm; cattle, meat at 0.03 ppm; grain, cereal, forage, fodder and straw, group 16 at 10.0 ppm; corn, field, grain at 0.07 ppm; corn, pop, grain at 0.07 ppm; corn, sweet, kernel plus cob with husks removed at 0.3 ppm; citrus, dried pulp at 0.1 ppm; egg at 0.05 ppm; feed commodities not otherwise listed at 10.0 ppm; food commodities not otherwise listed at 5.0 ppm; fruit, citrus group 10 at 0.05 ppm; fruit, pome, group 11 at 0.05 ppm; fruit, stone, group 12 at 0.3 ppm; goat, fat at 0.005 ppm; goat, kidney at 0.15 ppm; goat, liver at 0.05 ppm; goat, meat at 0.015 ppm; grain, aspirated fractions at 35.0 ppm; grain, cereal, group 15, except corn at 35.0 ppm; grape at 1.0 ppm; grape, raisin at 5.0 ppm; grass, forage, fodder, and hay group 17, forage at 3.5 ppm; grass, forage, fodder, and hay group 17, hay at 18.0 ppm; herb and spice, group 19 at 5.0 ppm; hog, fat at 0.005 ppm; hog, liver at 0.05 ppm; hog, kidney at 0.10 ppm; hog, meat at 0.01 ppm; milk at 0.03 ppm; nut, tree, group 14 at 0.05 ppm; okra at 0.05 ppm; pea and bean, succulent shelled, subgroup 6B at 2.0 ppm; pea and bean, dried shelled, subgroup 6C at 0.2 ppm; peppermint, tops at 5.0 ppm; pistachio at 0.05 ppm; poultry, fat at 0.015 ppm; poultry, liver at 0.05 ppm; poultry, meat byproducts at 0.28 ppm; poultry, meat at 0.15 ppm; rice, hull at 8.0 ppm; sheep, fat at 0.005 ppm; sheep, kidney at 0.15 ppm; sheep, liver at 0.05 ppm; sheep, meat at 0.015 ppm; soybean hulls at 0.5 ppm; soybean, seed at 0.2 ppm; tomato, paste at 0.1 ppm; tomato, puree at 0.1 ppm; brassica, head and stem subgroup 5A at 0.1 ppm; brassica, leafy, group 5B at 2.0 ppm; vegetable, bulb, group 3-07 at 0.5 ppm; vegetable, cucurbit, group 9 at 1.5 ppm; vegetable, foliage of legume, group 7 at 4.0 ppm; vegetable, fruiting, group 8 at 0.05 ppm; vegetable, leafy, except brassica, group 4 at 2.0 ppm; vegetable, leaves of root and tuber, group 2 at 3.0 ppm; vegetable, legume, edible, podded, subgroup 6A at 2.0 ppm; vegetable, root and tuber, group 1 at 1.0 ppm; and wheat, milled byproduct at 5.0 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) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995

(NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

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

**List of Subjects in 40 CFR Part 180**

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

Dated: December 11, 2009.

**Daniel J. Rosenblatt,**

*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 180.293 is amended by revising paragraph (d) to read as follows:

**§ 180.293 Endothall; Tolerances for residues.**

\* \* \* \* \*

(d) *Indirect or inadvertent residues.*

Tolerances are established for the indirect or inadvertent combined residues of the herbicide, endothall (7-oxabicyclo[2.2.1] heptane-2,3-dicarboxylic acid) in potable water from use of its potassium, sodium, di-N, N-dimethylalkylamine, and mono-N, N-dimethylalkylamine salts as algicides or herbicides to control aquatic plants in canals, lakes, ponds, and other potable water sources that may lead to endothall residues in or on the following commodities:

| Commodity                                     | Parts per million |
|---|-------------------|
| Almond, hulls .....                           | 15.0              |
| Animal feed, nongrass, group 18, forage ..... | 4.0               |
| Animal feed, nongrass, group 18, hay .....    | 10                |
| Apple, wet pomace .....                       | 0.15              |



| Commodity  | Parts per million | Commodity  | Parts per million |
|--|-------------------|--|-------------------|
| Beet, sugar, molasses ....                             | 1.5               | Vegetable, cucurbit, group 9 .....                   | 1.5               |
| Brassica, head and stem subgroup 5A .....              | 0.1               | Vegetable, foliage of legume, group 7 .....          | 4.0               |
| Brassica, leafy, subgroup 5B .....                     | 2.0               | Vegetable, fruiting, group 8 .....                   | 0.05              |
| Bushberry subgroup 13-07B .....                        | 0.6               | Vegetable, leafy, except brassica, group 4 .....     | 2.0               |
| Caneberry subgroup 13-07A .....                        | 0.6               | Vegetable, leaves of root and tuber, group 2 .....   | 3.0               |
| Cattle, fat .....                                      | 0.01              | Vegetable, legume, edible, podded, subgroup 6A ..... | 2.0               |
| Cattle, kidney .....                                   | 0.20              | Vegetable, root and tuber, group 1 .....             | 1.0               |
| Cattle, liver .....                                    | 0.10              | Wheat, milled byproducts                             | 5.0               |
| 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               |  |                   |

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](mailto: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

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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