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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0613; FRL-9953-97]

Endothall; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of endothall in or on multiple commodities which are identified and discussed later in this document. United Phosphorus, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0613, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

B. How Can I Get Electronic Access to Other Related Information?

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

C. How Can I File an Objection or Hearing Request?

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in

40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0613 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0613, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75110) (FRL-9918-90), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8293) by United Phosphorus, Inc., 630 Freedom Business Center, Suite

402, King of Prussia, PA 19406. The petition requested that 40 CFR 180.293 be amended by amending tolerances for residues of the herbicide endothall, in or on cattle, fat from 0.01 to 0.05 parts per million (ppm); cattle, kidney from 0.20 to 0.06 ppm; cattle, liver from 0.10 to 0.05 ppm; cattle, meat from 0.03 to 0.05 ppm; goat, fat from 0.005 to 0.05 ppm; goat, kidney from 0.15 to 0.06 ppm; goat, meat from 0.015 to 0.05 ppm; hog, fat from 0.005 to 0.05 ppm; hog, kidney from 0.10 to 0.06 ppm; hog, meat from 0.01 to 0.05 ppm; milk from 0.03 to 0.01 ppm; poultry, fat from 0.015 to 0.05 ppm; poultry, meat from 0.015 to 0.05 ppm; poultry, meat byproducts from 0.2 to 0.05 ppm; sheep, fat from 0.005 to 0.05 ppm; sheep, kidney from 0.15 to 0.06 ppm; and sheep, meat from 0.015 to 0.05 ppm. That document referenced a summary of the petition prepared by United Phosphorus, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has adjusted the proposed tolerance for ruminant kidney from 0.06 to 0.05. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for endothall 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 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.

Endothall is a caustic chemical with toxicity being the result of a direct degenerative effect on tissue. By acute exposure, endothall is a skin sensitizer and an extreme irritant by the acute oral and ocular routes of administration. The most sensitive effect of endothall following oral administration is direct irritation of the gastrointestinal system. This effect was evident in several species and in several studies. The dog is particularly sensitive to endothall toxicity. Endothall caused gastric epithelial hyperplasia in dogs treated orally with endothall for 52 weeks (a no observed adverse effect level (NOAEL) was not determined). Besides gastric irritant effects, decreased body weight in the dog was also a sensitive effect following 13 weeks of

endothall administration. The decreased body weights were most likely attributable to the constant and direct irritation of the gastric lining. 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.

Proliferative lesions of the gastric epithelium were observed in F₁ parental male and female rats treated orally with endothall in a 2-generation reproduction study (a NOAEL for the parental effects was not identified). In a developmental rat study, pregnant rats exhibited decreased body weight and decreased body weight was also noted in a 90-day dietary study in the rat.

Dermally, endothall destroys the stratum corneum and then the underlying viable epidermis. In the 21-day dermal toxicity study, severe dermal effects were observed at the lowest dose tested. Available studies clearly demonstrate that local irritation (portal of entry effect) is the most sensitive and initial effect.

Acute inhalation toxicity of endothall is low; however, nasal and pulmonary toxicity were evident in the 5-day and 28-day inhalation toxicity studies in the rat including rales, labored respiration, pale lungs (gross necropsy), increased absolute and relative lung weights, subacute inflammation, alveolar proteinosis, and nasal hemorrhage inflammation, erosion, and ulceration.

Endothall does not cause pre-natal toxicity following in utero exposure to rats nor pre- and 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. The hazard data for endothall indicate no evidence of quantitative or qualitative

increased susceptibility of rat fetuses exposed in utero to endothall in the developmental toxicity studies. In addition, no evidence of quantitative or qualitative increased susceptibility of rat fetuses or neonates was observed in the 2-generation reproduction study.

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: Human Health Risk Assessment in Support of Registration Review, and the Petition to Re-evaluate Tolerances for Livestock, and Remove the Restriction that Prohibits Livestock from Drinking Treated Water” in docket ID number EPA-HQ-OPP-2014-0613.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a

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

A summary of the toxicological endpoints for endothall used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Endothall for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary	An appropriate endpoint attributable to a single dose was not available from any study. An acute RfD was not established.		
Chronic dietary (All populations)	LOAEL= 2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF UF _L = 3x	Chronic RfD = 0.007 mg/kg/day cPAD = 0.007 mg/kg/day	Rat 2-generation reproduction study LOAEL = 2 mg/kg/day based on proliferative lesions of the gastric epithelium (both sexes)
Short-term Incidental oral (1 to 30 days)	Offspring NOAEL= 9.4 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100 Occupational = N/A	Rat 2-generation reproduction study LOAEL = 60 mg/kg/day based on decreased pup body weight (both sexes) on Day 0 in F ₁ and F ₂ generations
Short-term Inhalation (1 to 30 days)	NOAEL = 0.001 mg/L Residential HEC = 0.00049 mg/L (HED = 0.0143 mg/kg/day) Inhalation (or oral) study	Residential LOC for MOE = 30	Subchronic inhalation toxicity study (MRID 47872201). Residential acute scenario: LOAEL = 0.005 mg/L based on clinical signs (rales and labored respiration)

	NOAEL= 0.001mg/L mg/kg/day (inhalation absorption rate = 100%) UF _A = 3x UF _H = 10x FQPA SF = 1x		observed acutely (0-1 hr postdosing and prior to next exposure).
Cancer (Oral, dermal, inhalation)	Classified as a "Not Likely" human carcinogen.		

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

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 such effects were identified in the toxicological studies for endothall; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA), conducted from 2003-2008. As to residue levels in food, average residue values have been used for all crops. The residue and processing data used

in this assessment are from residue field trials and processing studies designed to produce maximum residues for the purpose of setting tolerances. All treatments in the field trials with irrigated crops were performed by overhead irrigation (i.e. are sprayed on the crops). The processing data available were translated to the important processed commodities of all crops. Where data were not available, DEEM default processing factors were used.

Anticipated residues of meat, milk, poultry, and eggs have been estimated by using the maximum or average residues in feed stuffs as well as the maximum allowed 5 ppm concentration of endosulfan in livestock drinking water. Tolerance level residues were used for finfish and shellfish.

EPA used average percent crop treated (PCT) data for alfalfa, cotton, and potato, the crops to which endosulfan is directly applied, as well as PCT data for irrigated crops.

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

iv. *Anticipated residue and 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 estimated the PCT for existing uses as follows for irrigated crops: Apple 78%, fresh market apple 84%, processing apple 49%, apple juice 22%, canned apple 55%, barley for grain 40%, corn for grain 21%, dry beans 35%, grape 97%, fresh market grape 99%, processed grape 96%, green peas 42%, oats for grain 8%, peanut for nuts 34%, rice 100%, sorghum for grain 19%, soybean for beans 12%, strawberry 92%, fresh market strawberry 90%, processed strawberry 100%, sugarbeet for sugar 37%, sugarcane for sugar 54%, watermelon 38%, wheat for grain 13%. For direct uses of endothall, PCT estimates used include alfalfa 1%, cotton 1%, and potatoes 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 to 7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for

that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

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

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for endosulfan in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of endosulfan. Further information regarding EPA drinking water

models used in pesticide exposure assessment can be found at

<http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Simple First-Order Degradation the estimated drinking water concentrations (EDWCs) of endosulfan for chronic exposures for non-cancer assessments are estimated to be 31 ppb for surface water and ground water. This represents a conservative estimate of high-end chronic exposure from endosulfan from the use most likely to generate the highest exposures (treatment of a reservoir).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

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).

Endosulfan is currently registered for the following uses that could result in residential exposures: aquatic applications. EPA assessed residential exposure using the following assumptions: There are no registered residential uses resulting in residential handler exposure to endosulfan.

Therefore, a quantitative residential handler exposure assessment was not performed.

Residential post-application exposure/risk estimates were assessed for certain scenarios. The scenarios, routes of exposure and lifestages assessed include inhalation exposure during recreational swimming (both adults and children 3 to < 6 years old) and ingestion of water during recreational swimming (both adults and children 3 to < 6 years old.) The assessment of these lifestages is health protective for the exposures and risk estimates for any other potentially exposed lifestages. Further information regarding EPA standard assumptions and

generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found 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 Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of quantitative or qualitative increased susceptibility following prenatal exposure to rats or rabbits in developmental toxicity studies, and pre- and post-natal exposure to rats in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all scenarios except the chronic dietary assessment. For the assessment of risk following chronic dietary exposure, the FQPA Safety Factor for increased susceptibility to infants and children is reduced to 3X because a lowest observed adverse effect level (LOAEL) established in the 2-generation reproduction study was used for assessing chronic dietary risks. Since a LOAEL was used, a 3X FQPA Safety Factor in the form of UF_L is retained for chronic exposure scenarios. A 3X factor (as opposed to a 10X) was determined to be adequate since the severity of the lesions observed at the LOAEL were minimal to mild, and therefore the true NOAEL for this study is likely to be very near the LOAEL value. For assessments other than the chronic dietary assessment, the FQPA safety factor was reduced to 1X for the following reasons:

- i. The toxicity database is complete.
- ii. There are no concerns for neurotoxicity, and thus no need to retain the 10X for the lack of a developmental neurotoxicity study.
- iii. There is no indication of increased susceptibility of rats or rabbits in utero and/or postnatal exposure in the developmental and reproductive toxicity studies;
- iv. There are no residual uncertainties identified in the exposure databases. The residential post-application exposure assessments are based upon the 2012 Residential Standard Operating Procedures (SOPs). These assessments of exposure are not likely to underestimate exposure to endothall. There is no residual uncertainty in the exposure database for endothall with respect to dietary exposure. An adequate database with respect to both the

nature and magnitude of residues expected in food has been provided. The chronic dietary food exposure assessment is conservative as field trial data along with 100% of crop treated assumptions for some commodities, and default processing factors for some commodities were used. Also, conservative modeled drinking water estimates of exposure were included in the assessments which are likely to exaggerate actual exposures from drinking water. 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 dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. 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 90% of the cPAD for children 1 to 2 years of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of endothall is not expected.

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

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 result in aggregate MOEs of 1,200 for adults and 210 for children. Because EPA's level of concern for endothall is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term exposure is not expected to result from the residential uses of endothall. 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.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, endothall is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to endothall residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (GC with microcoulometric nitrogen detection for plants, Method KP-245R0 for livestock, and Method KP-218R0 for fish and plants) is available to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for endothall.

C. Revisions to Petitioned-For Tolerances

The registrant requested modification of tolerances for all livestock commodities at the LOQ of the enforcement method (0.01 ppm for milk, 0.05 ppm for the remaining commodities) with the exception of ruminant kidney for which a tolerance of 0.06 ppm was proposed based on residues of 0.051 ppm observed in the cow feeding study. Based on available data and calculations of anticipated residues, EPA has determined that 0.05 ppm would be sufficient cover residues for all meat, poultry, and egg commodities, including ruminant kidney.

D. International Trade Considerations

In this rulemaking, EPA is reducing the existing tolerances for cattle, goat, hog, and sheep kidney; cattle, liver; poultry, meat byproducts to 0.05 ppm and for milk to 0.01 ppm. The petitioner requested these reductions. EPA has determined that the reduction is appropriate based on available data and residue levels resulting from registered use patterns. In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures Agreement, EPA notified the WTO of the request to revise these tolerances. In this action, EPA is allowing the existing higher tolerances to remain in effect for 6 months following the publication of this rule in order to allow a reasonable interval for producers in the exporting countries to adapt to the requirements of these modified tolerances. On *[insert date 6 months after date of publication in the **Federal Register**]*, those existing higher tolerances will expire, and the new reduced tolerances for ruminant kidney, cattle, liver and poultry, meat byproducts and milk will remain to cover residues of endosulfan on those commodities. Before that date, residues of endosulfan on those commodities would be permitted up to the higher tolerance levels; after that date, residues of endosulfan on ruminant kidney, cattle, liver and poultry, meat byproducts and milk will need to comply with the new lower tolerance levels. This reduction in tolerance is not

discriminatory; the same food safety standard contained in the FFDCa applies equally to domestically produced and imported foods.

V. Conclusion

Therefore, tolerances are amended for residues of endosulfan, in or on cattle, fat from 0.01 to 0.05 parts per million (ppm); cattle, kidney from 0.20 to 0.05 ppm; cattle, liver from 0.10 to 0.05 ppm; cattle, meat from 0.03 to 0.05 ppm; goat, fat from 0.005 to 0.05 ppm; goat, kidney from 0.15 to 0.05 ppm; goat, meat from 0.015 to 0.05 ppm; hog, fat from 0.005 to 0.05 ppm; hog, kidney from 0.10 to 0.05 ppm; hog, meat from 0.01 to 0.05 ppm; milk from 0.03 to 0.01 ppm; poultry, fat from 0.015 to 0.05 ppm; poultry, meat from 0.015 to 0.05 ppm; poultry, meat byproducts from 0.2 to 0.05 ppm; sheep, fat from 0.005 to 0.05 ppm; sheep, kidney from 0.15 to 0.05 ppm; and sheep, meat from 0.015 to 0.05 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action 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 action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: October 13, 2016.

Michael Goodis,
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. Amend the table in § 180.293 paragraph (d) as follows:

a. Revise the entries for “Cattle, fat”, “Cattle, meat”, “Goat, fat”, “Goat, meat”, “Hog, fat”, “Hog, meat”, “Poultry, fat”, “Poultry, meat”, “Sheep, fat, and “Sheep, meat”;

b. Add alphabetically footnotes for the entries “Cattle, kidney¹”, “Cattle, liver¹”, “Goat, kidney¹”, “Hog, kidney¹”, “Milk”, “Poultry, meat byproducts¹”, and “Sheep, kidney¹”; and

c. Add alphabetically the entries for “Cattle, kidney”, “Cattle, liver”, “Goat, kidney”, “Hog, kidney”, “Milk”, “Poultry, meat byproducts”, and “Sheep, kidney”.

The revisions and additions read as follows:

§ 180.293 Endothall; tolerances for residues.

* * * * *

(d) * * *

Commodity	Parts per million
* * * * *	* * * * *
Cattle, fat	0.05
Cattle, kidney ¹	0.20
Cattle, kidney	0.05
Cattle, liver ¹	0.10
Cattle, liver	0.05
Cattle, meat	0.05
* * * * *	* * * * *
Goat, fat	0.05
Goat, kidney ¹	0.15
Goat, kidney	0.05
* * * * *	* * * * *
Goat, meat	0.05

	* * * * *
Hog, fat	0.05
Hog, kidney ¹	0.10
Hog, kidney	0.05
	* * * * *
Hog, meat	0.05
Milk ¹	0.03
Milk	0.01
	* * * * *
Poultry, fat	0.05
	* * * * *
Poultry, meat	0.05
Poultry, meat byproducts ¹	0.20
Poultry, meat byproducts	0.05
	* * * * *
Sheep, fat	0.05
Sheep, kidney ¹	0.15
Sheep, kidney	0.05
	* * * * *
Sheep, meat	0.05
	* * * * *

¹ This tolerance expires on *[insert date six months after date of publication]*.