ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0018; FRL–8080–7]

Endothall; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of endothall and its monomethyl ester in or on fish. Cerexagri, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 16, 2006. Objections and requests for hearings must be received on or before October 16, 2006, 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–2005–0018. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joanne Miller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2005–0018 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 16, 2006.

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 your copies, identified by docket ID number EPA–HQ–OPP–2005–0018, 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 Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket'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 telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of February 11, 2005 (70 FR 7260) (FRL–7696–9), 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 9F6015) by Cerexagri, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406. The petition requested that 40 CFR 180.293 be amended by establishing a tolerance for residues of the herbicide endothall, 7-oxabicyclo[2,2,1] heptane-2,3-dicarboxylic acid, in or on fish/shellfish at 0.25 parts per million (ppm). That notice included a summary of the petition prepared by Cerexagri, Inc., the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. On June 8, 2006, Cerexagri, Inc. submitted a revised petition to the Agency. The petition was requested establishing a tolerance for endothall in or on fish at 0.1 ppm.

The endothall tolerance under 40 CFR 180.293 is being revised per the Endothall RED, to be expressed in terms of endothall *per se* and its monomethyl ester. Tolerances that are currently established for residues in/on undelinted cotton seed, hops, potato, and rice grain and straw will not change in value.

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of endothall and its monomethyl ester on fish at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the toxic effects caused by endothall and its monomethyl ester 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.epa.gov/oppsrrd1/REDs/endothall_red.pd.*

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at *http://www.epa.gov/pesticides/health/human.htm.*

A summary of the toxicological endpoints for endothall and its monomethyl ester used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ENDOTHALL AND ITS MONOMETHYL ESTER FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA Safety Factor (SF) and LOC for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13–50 years of age)			An appropriate endpoint attributable to a single dose was not available from any study, including the prenatal developmental toxicity study in rats. An acute reference dose (RfD) was not established.
Chronic Dietary (All populations)	LOAEL= 2 milligrams/kilogram (mg/kg)/day UF = 300 Chronic RfD = 0.007 mg/kg/day	FQPA SF = 1 Chronic population adjusted dose (cPAD) = chronic RfD ÷ FQPA SF = 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) (Residential)	Offspring NOAEL = 9.4 mg/kg/day	Residential LOC for Margin of Exposure (MOE) = 100 Occupational = Not Applicable (N.A.)	Rat 2–generation reproduction study LOAEL 60 mg/kg/day based on decreased pup body weight (both sexes) on Day 0 F_1 and F_2 generations
Intermediate-Term Incidental Oral (1 to 6 months) (Residential)	LOAEL= 2 mg/kg/day	Residential LOC for MOE = 300 Occupational = N.A.	Rat 2–generation reproduction study LOAEL 2 mg/kg/day based on proliferative lesions of the gastric epithelium (both sexes)

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR ENDOTHALL AND ITS MONOMETHYL ESTER FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA Safety Factor (SF) and LOC for Risk Assessment	Study and Toxicological Effects
Short-Term Dermal (1 to 30 days) (Residential)			No dermal assessments were conducted, since endothall is a severe dermal irritant and repeated dermal exposure is highly unlikely to occur.
Intermediate-Term Dermal (1 to 6 months) (Residential)			No dermal assessments were conducted, since endothall is a severe dermal irritant and repeated dermal exposure is highly unlikely to occur.
Long-Term Dermal (>6 months)	N.A. No exposure under use pattern	Residential N.A. Occupational N.A.	N.A.
Short-Term Inhalation (1 to 30 days)	Offspring NOAEL = 9.4 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Rat 2–generation reproduction study LOAEL 60 mg/kg/day based on decreased pup body weight (both sexes) on Day 0 F_1 and F_2 generations
Intermediate-Term Inhalation (1 to 6 months) and Long-Term Inhalation (>6 months)	LOAEL= 2 mg/kg/day	Residential LOC for MOE = 300 Occupational LOC for MOE = 300	Rat 2–generation reproduction study LOAEL 2 mg/kg/day based on proliferative lesions of the gastric epithelium (both sexes)
Cancer (oral, dermal, inhalation)	N.A.	N.A.	Chronic/Onco Rat Negative for carcinogenicity Carcinogenicity Mice Negative for carcinogenicity Not likely carcinogenic to humans

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.293) for the residues of endothall, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from endothall and its monomethyl ester 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 one–day or single exposure.

No such effects were identified in the toxicological studies for endothall and its monomethyl ester; therefore, a quantitative acute dietary exposure assessment is unnecessary. In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the United States Department of Agricultural (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: No toxicological endpoint was identified for acute oral exposure. Therefore no acute dietary exposure assessment was performed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID™, which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide CSFII, and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: For the chronic analyses, tolerance-level residues were assumed for all food commodities with current or proposed endothall tolerances, and it was assumed that all the crops included in the analysis were treated. Percent Crop Treated (PCT) and/or anticipated residues were not used in the chronic risk assessment.

iii. *Cancer.* Endothall is considered not likely to be carcinogenic to humans.

2. *Dietary exposure from drinking water.* This assessment assumes an endothall concentration of 100 parts per billion (ppb) as the average concentration in drinking water. This concentration is the Maximum Contaminant Level (MCL) for endothall. Actual monitoring data for endothall suggest the average concentration of endothall in drinking water are well below the MCL. Monitoring data for finished water are available from the National Contaminant Occurrence Database (NCOD) for both surface water and ground water. Detectable residues of endothall were found in only 7 of 27,494 or 0.025% of ground water samples and 8 of 5,112 or 0.15% of surface water samples. Although these few values are above the established Maximum Contaminant Level (MCL) for endothall of 100 ppb, greater than 99% of ground water and surface water samples contained concentration below the limit of detections (10 ppb). Using this data the mean concentration of endothall would be expected to be 10 ppb in both ground water and surface water. Although the MCL is likely to overestimate average (i.e., chronic) residues of endothall in drinking water,

EPA believes it provides a reasonable high-end estimate of potential drinking water concentrations from the aquatic uses of endothall. Consequently, the MCL of 100 ppb was used in the dietary risk assessment.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of endothall and its monomethyl ester for acute exposures are estimated to be 7.1 ppb for surface water and 0.086 ppb for ground water. The EECs for chronic exposures are estimated to be 2.5 ppb for surface water and 0.086 ppb for ground water. The EECs for chronic exposures (cancer) are estimated to be 2.4 ppb for surface water and 0.086 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Endothall and its monomethyl ester is currently registered for use on the following residential non-dietary sites: Ponds and garden pools. The risk assessment was conducted using the following residential exposure assumptions: Homeowners may potentially be exposed to endothall by applying home-use formulations. There is potential for exposure to adults and children from incidental oral and dermal exposure during recreational activities in public waters treated with endothall.

As a result, risk assessments were completed for both residential handlers and post-application scenarios. Residential applications are only expected to occur over short-periods of time. For residential post-application exposures, exposures on the day of application after an application to a public water body are of the greatest concern. The Agency identified incidental oral exposure (from swallowing water while swimming) and the potential for dermal irritation while swimming as possible post-application exposure scenarios. The Agency conducted an assessment, using the SWIM modeling program, to assess incidental exposures. Risks were calculated using MOEs, where and MOE greater than or equal to 100 is below EPA's LOC.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to endothall and its monomethyl ester and any other substances and endothall and its monomethyl ester does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that endothall and its monomethyl ester has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. There is not a concern for prenatal and/or postnatal toxicity resulting from exposure to endothall in rats (rabbit- not yet determined). There was no quantitative or qualitative evidence of increased susceptibility following prenatal exposure to rats in the developmental toxicity study and prenatal/postnatal exposure to rats in the 2–generation reproduction study. Due to the lack of a prenatal developmental study in rabbits, susceptibility could not be ascertained in a second (non-rodent) species.

There are no concerns for residual uncertainty for prenatal toxicity in the available developmental study, or the 2–generation rat toxicity study. In evaluating the toxicological database for endothall, the primary effects are the point of entry effects (i.e., dermal). In addition, the weight of evidence suggests that endothall will be of no developmental concern. The rabbit developmental study is being required as a confirmatory study.

3. *Conclusion*. Based on the above data base (which is considered adequate), no special FQPA safety factor (i.e. 1X) is required since there are no residual uncertainties for prenatal toxicity. In deriving uncertainty for use in the risk assessment, the conventional 10x factor for interspecies extrapolation and 10x for intraspecies extrapolation were used for all scenarios. The data base was complete enough and there was no evidence of prenatal or postnatal susceptibility in the studies submitted and evaluated to date. Therefore, the FQPA 10X factor was reduced to 1X. The exposure scenarios in which the hazard value was based on a LOAEL (intermediate term inhalation for both occupational and residential settings) an additional UF of 3X was used to approximate a NOAEL.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Due to the lack of an acute Rfd and acute dietary exposure/risk, an acute aggregate risk assessment was not performed.

2. *Chronic risk*. There are no long term residential uses of endothall. Aggregated chronic exposures to endothall through food plus drinking water were calculated in DEEM™. The results for directly treated crops, irrigated crops and drinking water from aquatic uses of endothall were 33% of the cPAD (0.002297 mg/kg/day) for the general population. The most highly exposed population subgroup was infants at 103% cPAD (0.007234 mg/kg/day). This risk estimate is the result of conservative assumptions (using the MCL of 100 ppb, likely to overestimate chronic residues of endothall in drinking waters).

3. *Short-term risk*. A risk assessment for aggregate exposures (food + drinking water + residential) was conducted for the short term exposure scenario because residential uses of endothall are expected to be only episodic. Food

exposures are based on treated crops and irrigated crops. Drinking water exposures are based on aquatic uses of endothall. Although endothall has terrestrial uses, as well as aquatic uses, the aquatic uses result in the highest estimates of potential drinking water exposures. Residential handler exposures for adults are based on granular applications of endothall with a belly grinder to lakes or ponds. Residential post-application exposures for adults and children are based on swimming.

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. The Agency notes the handler scenario aggregated for adults is the exposure scenario resulting in the lowest MOE (highest risk estimate) for residential handlers. 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 310, for children, it is 250. The MOEs are not a risk concern. Therefore, there are no short term aggregate (food + drinking water + residential) risk concerns for endothall.

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO ENDOTHALL AND ITS MONOMETHYL ESTER

Population	Short Term Scenario					
	Target Aggregate MOE[1]	MOE food + water[2]	Residential			Aggregate MOE (food + water and residential)[5]
			MOE oral[3]	MOE dermal	MOE inhalation[4]	
Child (3–5 years old)	100	2,770	280	N.A.	N.A.	250
Adults (50+ years old)	100	4,250	900	N.A.	470	310

[1] Target MOE of 100 based on using UF of 10X for interspecies extrapolation and 10X for intraspecies variability.
[2] MOE food + water, which incorporated the dietary exposures for treated crops, irrigated crops and aquatic uses, = (short-term oral NOAEL)/(chronic dietary exposure). Short-term NOAEL = 9.4 mg/kg/day from the 2–generation reproduction rat study, chronic dietary (food+ water) exposure = 0.003395, Children 3–5 years old, and 0.002211, Adults 50+ years old.
[3] MOE oral = (short-term oral NOAEL)/(Oral postapplication exposure of Swimmers) Short-term NOAEL = 9.4 mg/kg/day from the 2–generation reproduction rat study, Oral daily postapplication exposure of swimmers = 0.0341 mg/kg/day, Children 6–10 years old; 0.0107 mg/kg/day, Adults (see Table 6.3.2.2).
[4] MOE inhalation = [(inhalation NOAEL)/(high-end inhalation residential handler exposure)] Short-term inhalation NOAEL = 9.4 mg/kg/day from the 2–generation reproduction rat study.
[5] Aggregate MOE (food + water and residential) = 1÷[[(1÷MOE food+ water) + (1÷MOE oral) + (1÷MOE dermal) + (1÷MOE inhalation)]]

4. *Intermediate-term risk*. Due to the episodic residential use of Endothall, no intermediate term aggregate (dietary + residential) risk assessment was performed.

5. *Aggregate cancer risk for U.S. population*. Endothall is considered not likely to be carcinogenic 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, and to infants and children from aggregate exposure to endothall and its monomethyl ester residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An improved high performance liquid chromotography-mass spectrometry detection (HPLC-MSD) method has been submitted as a confirmatory enforcement method for plants and fish. A gas chromatography method with microcoulometric nitrogen detection is listed as Method I in the Pesticide Analytical Manual (PAM, Volume II) for the determination of endothall residues in/on crop commodities.

Adequate enforcement methodology (specify method; example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No International tolerances have been set for endothall.

C. Response to Comments

Public comments were received from B. Sachau who objected to the proposed tolerances because of the amounts of pesticides already consumed and carried by the American population. She further indicated that testing conducted on animals have absolutely no validity and are cruel to the test animals. B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to endothall, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has responded to B. Sachau's generalized comments on numerous previous occasions.

V. Conclusion

Therefore, the tolerance is established for combined residues of endothall, 7-oxabicyclo[2,2,1] heptane-2,3-dicarboxylic acid and its monomethyl ester, in or on fish at 0.1 ppm, and the endothall tolerance in 40 CFR 180.293 is revised to be expressed in terms of endothall *per se* and its monomethyl ester.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any

special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 3, 2006.

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 180.293, paragraph (a)(1) is amended by revising the introductory text and alphabetically adding the commodity ''fish'' to the table to read as follows:

§ 180.293 Endothall; tolerances for residues.

(a) *General.* (1) Tolerances are established for combined residues of Endothall, 7-oxabicyclo [2, 2, 1] heptane-2, 3-dicarboxylic acid and its monomethyl ester in or on the following raw agricultural commodities:

Commodity	Parts per million
* * *	* *
Fish	0.1
* * *	* *

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 302 and 355

[EPA–HQ–SFUND–2002–0010; EPA–HQ–SFUND–2002–0011; FRL–8210–5]

RIN 2050–AE12

Reportable Quantity Adjustments for Carbamates and Carbamate-Related Hazardous Waste Streams; Reportable Quantity Adjustment for Inorganic Chemical Manufacturing Process Waste (K178)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule promulgates adjustments to the reportable quantities under the Comprehensive Environmental Response, Compensation and Liability Act for 28 individual carbamates and five carbamate-related hazardous waste streams and for the inorganic chemical manufacturing process waste K178 from their statutory one-pound reportable quantities. All of the substances are listed as hazardous wastes under the Resource Conservation and Recovery Act, and as hazardous substances under the Comprehensive Environmental Response, Compensation and Liability Act.

DATES: This final rule is effective on September 15, 2006.

ADDRESSES: EPA has established two dockets for this action under Docket ID No. EPA–HQ–SFUND–2002–0010 and EPA–HQ–SFUND–2002–0011. All documents in the dockets are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose