

excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Field and External Affairs Division, (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460-0001; telephone number: (703) 305-6304; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under the **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>.

II. What Does this Technical Amendment Do?

In the **Federal Register** of October 24, 2007 (72 FR 60251) (FRL-8116-2), EPA issued a Final Rule which, among other things, redesignated 40 CFR part 158 as 40 CFR part 161. The regulations in redesignated part 161 were intended to apply to, and are applicable only to antimicrobial pesticides as was shown in the redesignation table. This technical amendment is issued to clarify the applicability of part 161, clear up any confusion among the users of the regulations in 40 CFR parts 158 and 161, and to correct the part heading for part 161 to show applicability to antimicrobial pesticides. The data requirements for conventional, biochemical, and microbial pesticides are set forth in 40 CFR part 158.

III. Why is this Technical Amendment Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause

for making today’s technical amendment final without prior proposal and opportunity for comment, because EPA is not making any substantive changes to the regulations and is merely clarifying the applicability of existing regulations to avoid confusion. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

The appropriate statutory and Executive Order reviews were included in the October 24, 2007 Final Rule.

V. 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 161

Environmental protection, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 12, 2009.

Debra Edwards,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR part 161 is amended as follows:

PART 161—[AMENDED]

■ 1. The authority citation for part 161 continues to read as follows:

Authority: 7 U.S.C. 136—136y.

■ 2. Revise the heading for part 161 to read as follows:

PART 161—DATA REQUIREMENTS FOR REGISTRATION OF ANTIMICROBIAL PESTICIDES

[FR Doc. E9-14620 Filed 6-23-09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0386; FRL-8421-2]

Triallate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of triallate and its metabolite TCPSA in or on bermudagrass, hay under 40 CFR 180.314(a). Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 24, 2009. Objections and requests for hearings must be received on or before August 24, 2009, 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-2008-0386. 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: Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5704; e-mail address: walters.vickie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural

producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

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

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

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

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–2008–0386 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 August 24, 2009.

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–2008–0386 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 June 13, 2008 (73 FR 33817) (FRL–8367–3), 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 8F7334) by the Gowan Company, 370 South Main St., Yuma, AZ 85364. The petition requested that 40 CFR 180.314 be amended by establishing tolerances for residues of the herbicide triallate, (S-2,3,4-trichloroallyl diisopropylthiocarbamate), in or on Bermudagrass hay at 0.2 parts per million (ppm). That notice referenced a summary of the petition prepared by Gowan Company, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

The Gowan Company has requested an amendment to a Section 3 registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to register a new use on Bermuda grass for grass grown for seed or hay. The petitioner has requested a tolerance for Bermuda grass, hay to support registration of the new use. This petition was filed in conjunction with Gowan’s requested amendment to its FIFRA registration.

Based upon review of the data supporting the petition, EPA has determined that the correct commodity name and numerical value for the tolerance proposed in this petition is Bermudagrass, hay at 0.3 ppm. EPA has also assigned the proposed tolerance in this petition to paragraph 40 CFR

180.314(a), is correcting the tolerance expression to read: “Tolerances are established for residues of the herbicide (S-2,3,4-trichloroallyl diisopropylthiocarbamate) and its metabolite 2,3,3-trichloroprop-2-enesulfonic acid (TCPSA) in or on the following food commodity Bermudagrass, hay at 0.3 ppm.” 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 the petitioned-for tolerances for residues of triallate and its metabolite TCPSA in/on bermudagrass, hay at 0.3 ppm. EPA’s assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered 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.

Triallate has a low order of acute toxicity via oral, dermal, and inhalation routes. Triallate is neurotoxic in rats

based on the acute neurotoxicity study, the subchronic neurotoxicity study, the rat multi-generation reproduction study, and the developmental neurotoxicity study. In subchronic studies in rats, the major target organ appears to be the kidney. Following chronic exposure, systemic toxicity in dogs is limited to an increase in liver weight in both sexes, increases in serum alkaline phosphatase in both sexes, and increases in hemosiderin in the spleen. Toxicity in mice included increased absolute liver weight, increased incidence of altered foci of the liver and hematopoiesis in the spleen. In rats, systemic toxicity was manifested as decreased survival in both sexes, decreased body weight and increased adrenal weight in males. In high dose males from the chronic toxicity/carcinogenicity study, the only treatment-related finding at interim sacrifice was linear papillary mineralization. The only treatment-related effect noted in male Syrian hamsters was decreased serum triglycerides.

There was no increased susceptibility to the offspring of rats following *in utero* exposure in the prenatal developmental toxicity study in rats, the 2-generation reproduction study in rats, or the developmental neurotoxicity study in rats. However, there is evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits. Triallate has been classified as a possible human carcinogen based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice and increased incidence of renal tubular cell adenomas in rats. A linear low-dose approach is used to quantify cancer risk to humans. The existing toxicological data for triallate do not show any significant effects on immunological organs or functions.

The Agency has determined that only triallate and its metabolite TCPSA should be regulated and assessed for dietary exposure in plant commodities. The Agency decided to regulate on the TCPSA metabolite because it is present at more than 10% of the total radioactive residue (TRR) in the plant metabolism studies, and in the absence of toxicological data for this metabolite, the same toxicity as the parent compound, triallate is assumed.

Specific information on the studies received and the nature of the adverse effects caused by triallate and its metabolite TCPSA 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

Triallate: Risk Assessment for Proposed New Use of Triallate as Pre-Emergence Herbicide for Bermuda grass, Case # 824883, pages 32–42 in docket ID number EPA–HQ–OPP–2008–0386 identified as document EPA–HQ–OPP–2008–0386–0003.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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

A summary of the toxicological endpoints for triallate and TCPSA used for human risk assessment can be found at <http://www.regulations.gov> in document *Triallate: Risk Assessment for Proposed New Use of Triallate as Pre-Emergence Herbicide for Bermuda grass, Case # 824883*, pages 32–42 in docket ID number EPA–HQ–OPP–2008–0386

identified as document EPA–HQ–OPP–2008–0386–0003.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to triallate and its metabolite TCPSA, EPA considered exposure under the petitioned-for tolerances as well as all existing triallate tolerances in 40 CFR 180.314. EPA assessed dietary exposures from triallate and TCPSA in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) insert 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used field trial data, empirical processing factors and 100 percent crop treated (PCT) for all commodities. Anticipated residues (AR) were used. All commodities with the exception of succulent peas were blended commodities; therefore, average field trial values were used for these commodities. The acute AR for succulent peas is the highest field trial residue. PCT data were not used.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA insert 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used field trial data, empirical processing factors and 100 PCT for all commodities. AR were used. All commodities with the exception of succulent peas were blended commodities; therefore, average field trial values were used for these commodities. The chronic AR for succulent peas is the average field trial residue. PCT data were not used.

iii. *Cancer.* To assess cancer risk, EPA used the same assessment as for chronic exposure.

iv. *Anticipated residue information.* Section 08(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.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for triallate and TCPSA in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of triallate and TCPSA. 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 Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of triallate and TCPSA for acute exposures are estimated to be 9.45 parts per billion (ppb) for surface water and 0.21 ppb for ground water.

The estimated EDWCs of triallate and TCPSA for chronic exposures for non-cancer assessments are estimated to be 1.26 ppb for surface water and 0.21 ppb for ground water.

The estimated EDWCs of triallate and TCPSA for chronic exposures for cancer assessments are estimated to be 1.26 ppb for surface water and 0.21 ppb for ground water.

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

For acute dietary risk assessment, the water concentration value of 9.45 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 1.26 ppb was used to assess the contribution to drinking water.

For cancer dietary risk assessment, the water concentration of value 1.26 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Triallate and its metabolite TCPSA are not registered for any specific use patterns that would result in residential exposure.

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 found in 2001 that although studies suggest that the thiocarbamate pesticides (including triallate) share a common metabolic profile and a common toxic effect (neuropathology of the sciatic nerve), insufficient information exists to establish a common mechanism of toxicity for this effect. For the purposes of this tolerance action, therefore, EPA has assumed that triallate does not have a common mechanism of toxicity with other substances. For more information regarding the common mechanism determination for triallate and the other thiocarbamate pesticides see <http://www.epa.gov/oppsrrd/cumulative/thiocarbamate.pdf>.

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.* A Degree of Concern analysis was performed for triallate and TCPSA because the rabbit developmental study provided evidence of increased susceptibility in the fetus. The purpose of the Degree of Concern analysis was:

i. To determine the level of concern for the effects observed when considered in the context of all available toxicity data; and

ii. Identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment.

In the case of triallate and TCPSA, there was no increased susceptibility to the offspring of rats following *in utero* exposure in the prenatal developmental

toxicity study in rats, in the 2-generation reproduction study in rats, or in the developmental neurotoxicity study in rats. However there was evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits. Fetal effects include decreased body weight and increased skeletal variations at 15 mg/kg/day. However, the rabbit developmental study identified a NOAEL of 5 mg/kg/day for fetal effects, and this NOAEL was selected as the point of departure for the acute dietary risk assessment. The point of departure for chronic dietary exposure (2.5 mg/kg/day) is lower than the NOAEL for fetal effects (observed at 15 mg/kg/day) and is protective of this endpoint, thus there are no residual concerns.

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. That decision is based on the following findings:

i. The toxicity database for triallate and its metabolite is adequate for addressing the sensitivity of infant and children to triallate exposure. The toxicity database for triallate is complete with the exception of an immunotoxicity study. The existing subchronic and chronic studies did not indicate that the immune system will be affected by triallate based on hematology, lymphoid organ weights, and histopathology measurements. The effects seen in the chronic study in dogs and the chronic toxicity study in mice in the spleen are related to hematology, but not related to immunotoxicity—they're just manifested in the spleen as well as in other organs. They do not increase concern for immunotoxicity in any way. Thus, the residual concerns for immunotoxicity are low.

ii. No quantitative or qualitative increased susceptibility was demonstrated in the fetuses in the prenatal developmental study in rats following *in utero* exposure, in the offspring in the developmental neurotoxicity study in rats, as well as in the offspring in the 2-generational reproduction study in rats following *in utero* and/or postnatal exposure to triallate.

iii. Although there was some increased susceptibility in the rabbit developmental toxicity study (where the developmental NOAEL of 5 mg/kg/day was lower than the maternal NOAEL of 15 mg/kg/day), the dose response for this effect has been adequately characterized (see discussion in Unit III.D.2) and the fetal NOAEL was selected as a point of departure for the acute dietary risk assessment. The point

of departure for the chronic dietary assessment (2.5 mg/kg/day) is lower than the NOAEL for fetal effects (observed at 15 mg/kg/day). Thus, these assessments are protective of potential adverse effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, and reliable data from field trial studies and food processing studies. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to triallate and TCPSA in drinking water. There are no residential uses for triallate, therefore no residential exposure is expected from the use of triallate. These assessments will not underestimate the exposure and risks posed by triallate and its metabolite TCPSA.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to triallate and TCPSA will occupy <1% of the aPAD for (all infants <1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to triallate and TCPSA from food and water will utilize <1% of the cPAD for (all infants <1 year old) the population group receiving the greatest exposure. There are no residential uses for triallate and TCPSA.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus average exposure to food and water

(considered to be a background exposure level).

Triallate and its metabolite TCPSA are not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to triallate and TCPSA through food and water and will not be greater than the chronic aggregate risk.

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

Triallate and its metabolite TCPSA are not registered for any use patterns that would result in intermediate-term residential exposure. Therefore, the intermediate-term aggregate risk is the sum of the risk from exposure to triallate and TCPSA through food and water, which has already been addressed, and will not be greater than the chronic aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for cancer exposure, EPA has determined that the estimated dietary exposure for the general U.S. population corresponded to a cancer risk of 3×10^{-7} for food and drinking water, which is less than the range of 1 in 1 million (1×10^{-6}), the EPA level of concern.

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 residues of triallate and its metabolite TCPSA.

IV. Other Considerations

A. Analytical Enforcement Methodology

Two analytical methods are available for enforcement of tolerances. They include the current PAM VOL. II method (gas chromatography with electron capture detection (GC/ECD) designated as method A and another GC/ECD method (designated as Method RES-099-96, Version 2) which may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no Canadian, Mexican or Codex MRLs established for triallate and its metabolite TCPSA for Bermudagrass, hay, the tolerance established by this rule. Therefore, there are no issues regarding compatibility with respect to

the tolerance established for bermudagrass, hay in this rule.

C. Revisions to Petitioned-For Tolerances

Based on residue trial data submitted to the Agency, EPA determined that the proposed tolerance of 0.2 ppm for Bermudagrass, hay was too low. The residue trial data support the establishment of a tolerance of 0.3 ppm on Bermudagrass, hay expressed in the terms of triallate and its metabolite TCPSA.

V. Conclusion

Therefore, tolerances are established for residues of triallate, S-2,3,4-trichloroallyl diisopropylthiocarbamate and its metabolite 2,3,3-trichloroprop-2-enesulfonic acid (TCPSA), in or on the following food commodity: Bermudagrass, hay at 0.3 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: June 12, 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. Paragraph (a) of §180.314 is revised to read as follows:

§180.314 Triallate; tolerances for residues.

(a) *General.* Tolerances are established for residues of triallate, S-2,3,4-trichloroallyl diisopropylthiocarbamate and its metabolite 2,3,3-trichloroprop-2-enesulfonic acid (TCPSA) in or on the following food commodity:

Commodity	Parts per million
Bermudagrass, hay	0.3

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0007; FRL-8417-5]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation increases the tolerance for residues of glyphosate in or on cotton, gin byproducts. Cheminova, Inc requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 24, 2009. Objections and requests for hearings must be received on or before August 24, 2009, 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-2009-0007. 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: Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5704; e-mail address: walters.vickie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>.

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