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

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

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

FR Doc. 00–24947 Filed 9–28–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301063; FRL–6744–8]

RIN 2070–AB78

Triallate,(S-2,3,3-trichloroallyl diisopropylthiocarbamate); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of the herbicide triallate (*S*-2,3,3, trichloroallyl diisopropylthiocarbamate) and its metabolite, TCPSA (2,3,3-trichloroprop-2-ene sulfonic acid) in or on sugar beet, root; sugar beet, top; and sugar beet, pulp. Monsanto requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000.Objections and requests for hearings, identified by docket control number OPP–301063, must be received by EPA on or before November 28, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301063 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins (PM 25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 305–5697; and e-mail address: Tompkins.Jim @epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically* .You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations, '' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register** —Environmental Documents.'' You can also go directly to the **Federal Register**listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301063. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 16, 1997 (62 FR 27027) (FRL–5717–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F2128) for tolerance by Monsanto, 600 13th St., NW., Suite 660, Washington, DC 20005. This notice included a summary of the petition prepared by Monsanto, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.314 be amended by establishing a tolerance for residues of the herbicide triallate, and its metabolite, TCPSA in or on sugar beet root at 0.01 part per million (ppm), sugar beet top at 0.5 ppm, and sugar beet pulp at 0.2 ppm

Section 408(b)(2)(A)(i) of the 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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for a tolerance for residues of the herbicide triallate and its metabolite, TCPSA in or on sugar beet root at 0.01 ppm, sugar beet top at 0.5 ppm, and sugar beet pulp at 0.2 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by triallate (*S*-2,3,3, trichloroallyl diisopropylthiocarbamate) are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity in rodents Rat	NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on decreased body weight in males and females, slight anemia in females (decreased red blood cells, hematocrit and hemoglobin) and histopathology of the kidney in males (tubular epithelial regeneration and nephropathy).
870.3200	21-Day dermal toxicity in rodents Rat	NOAEL = 500 mg/kg/day LOAEL = 3,000 mg/kg/day based on body weight gain decreases, relative kidney and liver weight increases, increased presence of basophillic tubules of the renal cortex, and alpha 2 -globulin inclusions in the proximal convoluted renal tubules in rats.
870.3465	Subchronic inhalation toxicity Rat	NOAEL = less than 2.62 mg/kg/day, not established LOAEL = 2.62 mg/kg/day based on histological changes in kidney (nephropathy and tubular epithelial regeneration).
870.3700	Prenatal developmental toxicity in rodents Rat	Maternal NOAEL = 10 mg/kg/day LOAEL = 30 mg/kg/day based on decreases in body weight gain and food consumption. Developmental NOAEL = 30 mg/kg/day LOAEL = 90 mg/kg/day based on decreased fetal body weight, external malformations (protruding tongue) and skeletal variations.
870.3700	Prenatal developmental toxicity in nonrodents Rabbit	Maternal NOAEL = 15 mg/kg/day LOAEL = 45 mg/kg/day based on clinical signs and decreases in body weight gain. Developmental NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day based on decreased fetal body weight and increased skeletal variations.
870.3800	Reproduction and fertility effects Rat	Parental/Systemic NOAEL = 7.5 mg/kg/day LOAEL = 30 mg/kg/day based on maternal mortality, increased incidences of chronic nephritis, head bobbing, circling movements and reduced body weight. Reproductive NOAEL = 7.5 mg/kg/day LOAEL = 30 mg/kg/day based on based on increased neonatal mortality during the F2b litter interval, reduced pup weights at birth during the F2b litter interval, reduced pup weights in late lactation for all litters, reduced pregnancy rate and shortened gestation length.
870.4100	Chronic toxicity Dog	NOAEL = 2.5 mg/kg/day LOAEL = 15.0 mg/kg/day based on increased alkaline phosphatase levels at all time intervals in male and female dogs.
870.4100	Chronic toxicity Dog	NOAEL = 1.5 mg/kg/day LOAEL = 5.0 mg/kg/day based on increased hemosiderin deposition in the spleen, increased serum alkaline phosphatase and increased liver weight in females.
870.4200	Combined chronic toxicity/carcinogenicity Rat	NOAEL = 2.5 mg/kg/day LOAEL = 12.5 mg/kg/day based on decreased survival (males and females), decreased body weight (males) and increased adrenal weight (males).

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

Guideline No.	Study Type	Results
		Evidence of carcinogenicity: Renal tubular adenomas in male rats.
870.4200	Combined chronic toxicity/carcinogenicity Mouse	NOAEL = (males) 3 mg/kg/day LOAEL = (males) 9 mg/kg/day based on increased absolute liver weight, increased incidence of altered foci of the liver and hematopoiesis in the spleen. NOAEL (females) = 37.5 mg/kg/day LOAEL (females) >37.5 mg/kg/day, not established
		Evidence of carcinogenicity: Increased incidence of hepatocellular carcinomas and hepatocellular adenomas (males).
870.4200	Combined chronic toxicity/carcinogenicity Hamster	NOAEL = (males) 50 ppm LOAEL = (males) 300 ppm based on decreased triglyceride levels (males and females)
870.5100	Gene Mutation in *Salmonella typhimurium*.	Positive. Triallate induced a mutagenic response in *Salmonella typhimurium*strains TA1535 and TA100 at noncytotoxic doses of 0.1 µg/plate and above -S9 activation and TA1535, TA98 and TA100 at 0.001 µg/plate and above +S9. In tester strains TA1537 and TA1538, there were no appreciable increases in revertant colonies of evidence of cytotoxicity at any dose. Mutagenesis was confirmed in a repeat test with Salmonella typhimurium strainTA1535 at dose levels of 1, 5, and 10 µg/plate +/- S9 activation.
870.5300	Gene Mutation/*In vitro* mammalian cell assay in mouse lymphoma cells Negative.	Negative. Triallate did not induce forward gene mutations at the thymidine kinase (TK+-) locus in L51784 mouse lymphoma cells at concentration of 0.005 to 0.04 µl/ml in the absence or presence of metabolic activation.
870.5300	Gene Mutation/*In vitro* mammalian cell assay in mouse lymphoma cells	Positive. Triallate induced forward gene mutations at the thymidine kinase (TK+/-) locus in L51784 mouse lymphoma cells. The frequency of gene mutations was greater than or equal to a two-fold increase and occurred at noncytotoxic concentrations of 60 µg/ml -S9 activation and 21 and 24 7mu;g/ml +S9 activation.
870.5385	Cytogenetics/*In vivo* hamster micronucleus assay	Negative. There was no evidence of either a clastogenic or aneugenic effect in male and female hamsters fed dietary concentrations of 0, 600, 2,000 or 6,000 ppm Triallate at any sacrifice time.
870.5395	Cytogenetics/*In vivo* mouse micronucleus assay	Negative. There was no evidence of either a clastogenic or aneugenic effect in male and female mice administered 70, 350, or 700 mg/kg Triallate at any sacrifice time.
870.5550	Other Mutagenic Mechanisms/*In vitro* unscheduled DNA synthesis in primary rat hepatocytes	Negative. Triallate did not induce a genotoxic effect in primary rat hepatocytes at concentrations of 5, 10, 50, 100, 500 and 1,000 µg/mL.
870.5550	Other Mutagenic Mechanisms/*In vivo In vitro* unscheduled DNA synthesis in primary rat hepatocytes	Negative. There was no evidence that Triallate induce either a cytotoxic or genotoxic response a any dose (50, 250 or 500 mg/kg) or sacrifice time (92 or 16 hours).
870.5900	Other Mutagenic Mechanisms/*In vitro* sister chromatid exchange in Chinese hamster ovary cells	Positive. Triallate induced significant increases in the number of sister chromatid exchanges per cell at concentrations of 1.6 x 10^{-5}M to 8.1 x 10^{-5}M -S9 activation and 0.8 x 10^{-5}M to 4.0 x 10^{-5}M +S9 activation after either a two or four hour exposure period, respectively. Repeat assays conducted for 30 hours at concentrations up to 40.4 x 10^{-5}M -S9 activation and for 2 hours at concentrations up to 12.1 x 10^{-5}M +S9 activation confirmed these findings.
870.6100	Acute delayed neurotoxicity Hen	Systemic NOAEL less than 312.5 mg/kg, not established LOAEL = 312.5 mg/kg based on acute, reversible clinical signs (muscle weakness/paralysis, salivation and involuntary neck movement). Triallate did not induce delayed peripheral neuropathy.
870.6200	Acute neurotoxicity screening battery Rat	NOAEL = 60 mg/kg

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

Guideline No.	Study Type	Results
		LOAEL = 300 mg/kg based on decreased body weight gain and alterations in motor activity.
870.6200	Subchronic neurotoxicity screening battery Rat	NOAEL = 6.38/8.14 mg/kg/day for male/female rats LOAEL = 32.9/38.9 mg/kg/day for male/female rats based on decreased body weights, body weight gains, food consumption and lesions (nerve fiber degeneration) in the central and peripheral nervous systems.
870.6200	Subchronic neurotoxicity screening battery Rat	Neurotoxic NOAEL = 134.32 mg/kg/day LOAEL = 223.79 mg/kg/day based on behavioral effects (histopathology for axonal degeneration was not conducted at this dose level). At 295 mg/kg/day, nuerohistopathological lesions occurred in both the central and peripheral nerves. Systemic NOAEL = 34.64 mg/kg/day LOAEL = 134.32 mg/kg/day based on decreased body weight and food consumption and food efficiency.
870.6300	Developmental neurotoxicity Rat	Maternal NOAEL = 30 mg/kg/day LOAEL = 60 mg/kg/day based on reductions in body weight gains and food consumption. Developmental Neurotoxicity NOAEL = 30 mg/kg/day LOAEL = 60 mg/kg/day based [on increased motor activity.
870.7485	Metabolism and pharmacokinetics Rat	General metabolism Analysis of whole body elimination in male and female rats indicated that 85% of the radiolabeled triallate was excreted within 24 hours of dosing. Most radioactivity was excreted in approximately equal amounts (42%) in the urine and feces of male rats after 10 days. Females excreted 51% in urine and 32% in feces after 10 days. Males and females retained about 0.4% of the dose in organs and tissues and approximately 2% in the remaining carcass. The distribution of radioactivity in both sexes indicated that the greatest amount of activity was found in the red blood cells followed by whole blood, spleen, kidney, liver and lung.
870.7485	Metabolism and pharmacokinetics Rat	General metabolism Seven metabolites, in concentrations of greater than one percent, were identified in rat urine; 2,3,3-trichloro-2-propenesulfinic acid (20-27%), *N*-acetyl-*S*-(2,2-dichloro-1-[methyl-sufonyl) methyl]ethenyl)-*L*-cysteine (6–11%), (E)-S-(2carboxy-2-chloroethenyl)-L-cysteine (4–5%), carbon dioxide (4%), 2,3,3-trichloro-propene sulfonic acid (3–5%), (E)-3-((carboxymethyl)thio)-2-chloro-2-propenoic acid (1–3%), and 1-((3,3,2-trichloro-2-propenyl)thio)-beta-*D*-glucuronic acid. The remaining metabolites were found at less than 1% of the administered dose.
Special studies	Assessment of the kidney for alpha 2μ globulins in the rat subchronic and chronic feeding studies	Data from this study is considered a preliminary indication that triallate may be classified as an alpha 2μ globulin type nephrotoxin. Additional data and analysis considered necessary for a more conclusive decision.

Several acute toxicology studies place technical triallate in acute toxicity category III for acute oral toxicity and primary eye irritation and in toxicity category IV for acute dermal toxicity, acute inhalation toxicity, and primary dermal irritation. Triallate is a skin sensitizer.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (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 lowest dose at which adverse effects of concern are identified (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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure '' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for triallate (*S*-2,3,3-trichloroallyl diisopropylthiocarbamate) used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIALLATE (S-2,3,3-TRICHLOROALLYL DIISOPROPYLTHIOCARBAMATE) FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age	NOAEL = 5 mg/kg/day, UF = 100, Acute RfD = 0.05 mg/kg/day	FQPA SF = 3, aPAD = acute RfD÷FQPA SF = 0.017 mg/kg/day	Developmental toxicity study -Rabbits Developmental LOAEL = 15 mg/kg/day based on decreased fetal body weight and increased skeletal variations.
Acute Dietary general population including infants and children	NOAEL = 60 mg/kg/day, UF = 100, Acute RfD = 0.60 mg/kg/day	FQPA SF = 1 aPAD = acute RfD÷ FQPA SF = 0.60 mg/kg/day	Acute Neurotoxicity-Rat LOAEL = 300 mg/kg/day based on decreased body weight and alterations in motor activity
Chronic Dietary all populations	NOAEL = 2.5 mg/kg/day, UF = 100, Chronic RfD = 0.025 mg/kg/day	FQPA SF = 1, cPAD = chronic RfD÷ FQPA SF = 0.025 mg/kg/day	Chronic Toxicity/Carcinogenicity-Rat LOAEL = 12.5 mg/kg/day based on decreased survival in males and females, decreased body weight in males, increased adrenal weight in males
Short- Term Dermal (1 to 7 days) (Residential)	oral study NOAEL= 5 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 100 (Residential)	Developmental Toxicity - Rabbit LOAEL = 15 mg/kg/day based on Increased skeletal malformations/variations
Intermediate-Term Dermal (1 week to several months) (Residential)	(oral) study NOAEL = 5 mg/kg/day (dermal absorption rate = 1%	LOC for MOE = 100 (Residential)	Developmental Toxicity-Rabbit LOAEL = 15 mg/kg/day based on Increased skeletal malformations/variations
Long-Term Dermal (several months to lifetime) (Residential)	Dermal (or oral) study NOAEL= none mg/kg/day (dermal absorption rate = none% when appropriate)	LOC for MOE = none (Residential)	none LOAEL = none mg/kg/day based on none Not identified, continuous exposure greater than 180 days not expected
Short-Term Inhalation (1 to 7 days) (Residential)	inhalation (or oral) study NOAEL= 5 mg/kg/day (inhalation absorption rate = 100%	LOC for MOE = 100 (Residential)	Developmental toxicity-Rabbit LOAEL = 15 mg/kg/day based on Increased skeletal malformations/variations
Intermediate-Term Inhalation (1 week to several months) (Residential)	inhalation (or oral) study NOAEL = 5 mg/kg/day (inhalation absorption rate = 100%	LOC for MOE = 100 (Residential)	Developmental toxicity-Rabbit LOAEL = 15 mg/kg/day based on Increased skeletal malformations/variations

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIALLATE (S-2,3,3-TRICHLOROALLYL DIISOPROPYLTHIOCARBAMATE) FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-Term Inhalation (several months to lifetime)(Residential)	inhalation (or oral) study NOAEL= none mg/kg/day (inhalation absorption rate = 100%	LOC for MOE = none (Residential)	none LOAEL = none mg/kg/day based on none Not identified, continuous exposure greater than 180 days not expected
Cancer (oral, dermal, inhalation)	....	....	Q*7.17 x 10^{-2}(mg/kg/day)$^{-1}$ Group C chemical-likely to be a human carcinogen

*The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.314(a)) for residues of the herbicide triallate (*S*-2,3,3, trichloroallyl diisopropylthiocarbamate), per se (parent only) in or on a variety of raw agricultural commodities; Barley, grain; Barley, straw; Lentils; Lentils, forage; Lentils, hay; Peas, forage; Peas, hay; Wheat, grain; and Wheat, straw. Under reregistration, the triallate tolerance expression will be revised in order to reflect the Agency's determination that triallate and its TCPSA metabolite 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. Tolerances are to be expressed as triallate for the combined residues of the herbicide triallate (*S*-2,3,3-*S*-2,3,3-trichloroallyl diisopropylthiocarbamate) and its metabolite TCPSA (2,3,3-trichloroprop-2-ene sulfonic acid) in or on the following commodities: Sugar Beet, root; Sugar Beet, top; and Sugar Beet, pulp. No tolerances have been established for processed food/feed or animal commodities. Risk assessments were conducted by EPA to assess dietary exposures from triallate (*S*-2,3,3-trichloroallyl diisopropylthiocarbamate) and its metabolite TCPSA in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. A probalistic (Monte Carlo) acute dietary analysis was conducted for triallate residues in food. This analysis is highly refined (Tier 3), and represents a realistic estimate of acute dietary exposure in food possible with current data, based on all uses supported through reregistration and the proposed used of triallate on sugar beets. The percent acute population adjusted doses (PADs) are significantly below the Agency's level of concern at the 99.9th percentile of exposure for the females 13+ subgroup (<2% aPAD) and for the general population (<1% aPAD). For acute dietary analyses, anticipated residues and percent of crop treated data were used. For the purposes of this assessment, residue field trial data were used for the acute anticipated residues calculations.

ii. *Chronic exposure* . In conducting the chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The chronic (non-cancer) dietary risk from exposure through food is <1% of the Agency's level of concern (<100% of the chronic PAD) for the general U.S. population and all subgroups. For chronic dietary analyses, anticipated residues and percent of crop treated data were used. For the purposes of this assessment, residue field trial data were used for the chronic anticipated residue calculations.

iii. *Cancer.* Triallate is classified as a Group C chemical (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 (Q_1*) approach was used to characterize human health risk. The unit risk, Q_1*based on the hepatocellular carcinomas in male mice, is 7.17 x 10^{-2}(mg/kg/day)$^{-1}$in human equivalents. The Agency generally considers risks in the range of 1 x 10^{-6}(1 in 1 million) or less as negligible risk for cancer dietary exposure. The results of this analysis indicate that the cancer dietary risk of 7.1 x $10^{-8}$from exposure through food, associated with the uses supported through reregistration and the proposed use of triallate on sugar beets, is below the Agency's level of concern for food alone.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that 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 such pesticide residue;

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if 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 percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

A routine chronic dietary exposure analysis for triallate and its metabolite (TCPSA) was based on percent crop treated (PCT) information as follows:

Acute Estimated Maximum	Chronic Weighted Average
Barley 13%	Barley 9%
Barley bran 13%	Barley bran 9%
Barley flour 13%	Barley flour 9%
Dry pea 30%	Dry pea 13%
Sugar beet dried pulp 21%.	Sugar beet dried pulp 21%
Sugar beet molasses 21%.	Sugar beet molasses 21%
Sugar beet root 21%	Sugar beet root 21%
Sugar beet tops 21%	Sugar beet tops 21%
Sugar beet sugar 21%	Sugar beet sugar 21%
Wheat bran 8%	Wheat bran 6%
Wheat flour 8%	Wheat flour 6%
Wheat grain 8%	Wheat grain 6%
Wheat mill by-products 8%.	Wheat mill by-products 6%
Wheat shorts 8%	Wheat shorts 6%

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, 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 information on the regional consumption of food to which triallate *S*-2,3,3-trichloroallyl diisopropylthiocarbamate may be applied in a particular area.

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

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) and the Pesticide Root Zone/EXposure Analysis Modeling System (PRZM/EXAMS) to produce estimates of pesticides in surface source drinking water. The Screening-concentration in ground water (SCI-GROW) model was used to estimate concentrations in shallow groundwater. The primary use of the models by the Agency is to screen out pesticides with low potential of reaching concentrations in drinking water exceeding human health levels of concern. EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The GENEEC model was designed to simulate runoff from a 10 hectare (ha) field into a static 1 ha small water body. It was originally designed to assess pesticide concentrations in aquatic environments for ecological risk assessments. The PRZM/EXAMS model scenario is designed as a refined screening model which incorporates a watershed scale assessment with a flow-through index reservoir. Additionally, the PRZM/EXAMS modeling incorporates a percent cropped area (PCA) to account for the extent of cropping area within a watershed. None of the models consider the impact of water treatment (mixing, dilution, or treatment) on pesticide concentrations in raw water. In cases where the screening model predictions exceed human health levels of concern, the Agency will require targeted monitoring studies to assess the actual pesticide concentrations in drinking water.

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

Based on the PRZM-EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of triallate and its metabolite TCPSA in surface water and ground water for acute exposures are estimated to be 9.452 parts per billion (ppb) for surface water and 0.21 ppb for ground water. The EECs for chronic (non-cancer) exposures are estimated to be 1.26 ppb for surface water and 0.21 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).

Triallate is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether triallate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, triallate 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 triallate 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. FFDCA section 408 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 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. Quantitatively, there is evidence of increased susceptibility in the prenatal developmental toxicity study in rabbits; developmental effects (decreased fetal body weight and increased incidence of malaligned sternebrae) were observed in the absence of maternal toxicity.

iii. *Conclusion*. There is a complete toxicity data base for triallate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures—EPA determined that some additional safety factor was needed to protect infants and children because the toxicity data indicated increased sensitivity to the young. The FQPA factor was reduced to 3x because the toxicology data base is complete; increased sensitivity was observed in only one species (rabbits); there is no quantitative or qualitative indication of increased susceptibility in the prenatal developmental toxicity study in rats, the 2-generation reproduction study in rats, or the developmental neurotoxicity in rats; adequate data are available or conservative modeling assumptions are used to assess dietary food and drinking water exposure; and there are currently no registered residential uses for triallate.

E. Aggregate Risks and Determination of Safety

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

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

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

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to triallate, and its metabolite, TCPSA will occupy <1% of the aPAD for the U.S. population, 1.8% of the aPAD for females 13 years and older, <1% of the aPAD for all infants (<1 year) and <1% of the aPAD for children (1-6 years). In addition, there is potential for acute dietary exposure to triallate and its metabolite TCPSA in drinking water.After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE ACUTE RISK ASSESSMENT FOR TRIALLATE AND ITS METABOLITE TCPSA

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S.Population	0.60	<1	9.4	0.21	21,000
Children (1-6 years)	0.60	<1	9.4	0.21	6,000
Females (13+ nursing)	0.017	1.8	9.4	0.21	500

2. *Chronic risk* . Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to triallate and its metabolite, TCPSA from food will utilize <1% of the cPAD for the U.S.

population, <1% of the cPAD for Non-nursing infants (<1 year old) and <1% of the cPAD for children (1-6 years old). There are no residential uses for triallate and its metabolite TCPSA that result in chronic residential exposure to triallate and its metabolite TCPSA, as shown in the following Table 4:

TABLE 4.—AGGREGATE CHRONIC RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRIALLATE AND ITS METABOLITE, TCPSA

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.025	<1	1.26	0.21	875
Females (13+, nursing)	0.025	<1	1.26	0.21	250
Children (1-6 years)	0.025	<1	1.26	0.21	750

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

Triallate is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

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

Triallate is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency generally considers risks in the range of 1×10^{-6}(1 in 1 million) or less as negligible risk for cancer. The results of this analysis indicate that the cancer dietary (food) risk estimate of 7.1×10^{-8}associated with the uses supported through reregistration and the proposed use on sugar beets is not of concern. The cancer DWLOC is 0.45 ppb. The Tier II (PRZM-EXAMS) estimated average concentration of triallate + TCPSA in surface water is 0.566 ppb (mean annual with 2 incorporation) and 1.26 ppb (mean annual with no incorporation). Concentrations in ground water are not expected to be higher than 0.21 ppb. The 36-year annual mean estimated concentrations in surface water exceed the DWLOCs for triallate + TCPSA in drinking water as a contribution to cancer aggregate exposure. However, the drinking water component is based on model predictions, which are generally conservative in estimating chemical concentrations in drinking water. To address this concern, the registrant initiated a 3-year surface drinking water monitoring study in June 1999 to measure raw and finished triallate + TCPSA concentrations at five surface drinking water collection locations. Interim results of the surface water monitoring study indicated that peak and mean exposure to total parent triallate and TCPSA at all five sites are below the cancer DWLOC (0.45 ppb). Additional monitoring data will be provided on a quarterly basis, with a final report of the study expected in late 2002. Based on the interim results of the surface water monitoring study, which indicated that peak and mean exposure to total parent triallate and TCPSA are below the cancer DWLOC (0.45 ppb), the aggregate cancer risk for the U.S. Population is expected to be less than 1×10^{-6}.

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 triallate and its metabolite (TCPSA) combined residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

In conjunction with the regional registration of triallate on sugar beets, the registrant has proposed a GC/ECD method (designated as Method RES-099-96, Version No. 2) for tolerance enforcement purposes. The method determines residues of triallate and its TCPSA metabolite. This method has been subjected to a successful independent laboratory validation. The method has also been validated in an Agency study at Beltsville, MD. The laboratory (Analytical Chemistry Branch, BEAD) verified the limits of quantitation (LOQs) to be 0.025 ppm triallate and 0.025 ppm TCPSA in/on sugar beet roots, and 0.05 ppm triallate and 0.20 ppm TCPSA in/on sugar beet foliage. The Beltsville report (7/28/98) also estimated the limits of detection (LODs) to be 0.001 ppm triallate and 0.004 ppm TCPSA in sugar beet root, and 0.005 ppm triallate and 0.04 ppm TCPSA in sugar beet top. The expected dietary burdens of triallate to beef/dairy cattle and poultry animals were recalculated following tolerance reassessment of livestock feed items. There is no reasonable expectation of finite residues (Category 3 of 40 CFR section 180.6); therefore, tolerances are not required for milk, eggs, and animal tissues.

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex MRLs for triallate; therefore, no questions of compatibility with U.S. tolerances exists.

C. Conditions

Completion of the 3-year surface drinking water study will be a condition of registration. Monitoring data will be provided on a quarterly basis, with a final report of the study expected in late 2002.

V. Conclusion

Therefore, the tolerance is established for the combined residues of the herbicide triallate (*S*-2,3,3, trichloroallyl diisopropylthiocarbamate) and its metabolite, TCPSA (2,3,3-Trichloroprop-2-ene sulfonic acid) in or on sugar beet, root, sugar beet, top, and sugar beet pulp.

VI. Objections and Hearing Requests

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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301063 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 28, 2000.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim @epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301063, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket @epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 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. 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: September 21, 2000.

James Jones,

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 180.314 is revised to read as follows:

§ 180.314 Triallate; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide (*S*-2,3,3-trichloroallyl diisopropylthiocarbamate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, straw	0.05
Lentils	0.05
Lentils, hay	0.05
Peas	0.05
Peas, forage	0.05
Peas, hay	0.05
Wheat, grain	0.05
Wheat, straw	0.05

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

(c) *Tolerances with regional registrations*. Tolerances are established for residues of the herbicide triallate (*S*-2,3,3-trichloroallyl diisopropylthiocarbamate) and its metabolite 2,3,3-trichloroprop-2-enesulfonic acid in or on the following food commodities:

Commodity	Parts per million
Sugar beet, pulp	0.2
Sugar beet, root	0.1
Sugar beet, top	0.5

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

[FR Doc. 00–24942 Filed 9–28–00; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301062; FRL–6747–9]

RIN 2070–AB78

Dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for residues of dimethomorph, (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2- propenyl]morpholine in or on dried hops cones, grapes, raisins, tomato fruit, and tomato paste. American Cyanamid Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301062, must be received by EPA on or before November 28, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301062 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9354; and e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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