paragraphs (a)(1) and (a)(2) to read as follows:

§ 1955.3 General policy.

(a) * * *

(1) Whenever the Assistant Secretary determines that under § 1902.2(b) of this chapter a State has not substantially completed the developmental steps of its plan at the end of three years from the date of commencement of operations, a withdrawal proceeding shall be instituted. Examples of a lack of substantial completion of developmental steps include but are not limited to the following:

* * * * *

(2) Whenever the Assistant Secretary determines that there is no longer a reasonable expectation that a State plan will meet the criteria of § 1902.3 of this chapter involving the completion of developmental steps within the three year period immediately following commencement of operations, a withdrawal proceeding shall be instituted. Examples of a lack of reasonable expectation include but are not limited to the following:

* * * * *

[FR Doc. 02–24284 Filed 9–24–02; 8:45 am]

BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0216; FRL–7200–5]

Tolylfluanid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an import tolerance for residues of tolylfluanid in or on imported apple, grape, hop, and tomato. Bayer Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective September 25, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0216, must be received on or before November 25, 2002.

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 ID number OPP–2002–0216 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 20460–0001; telephone number: (703) 308–9354; 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:

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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. 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 ID number OPP–2002–0216. 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 August 11, 1997 (62 FR 42980) (FRL–5736–1), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 7E4825) by Bayer Corporation, 8400 Hawthorn Rd., Kansas City, MO 64120. This notice included a summary of the petition prepared by Bayer Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.584 be amended by establishing an import tolerance for residues of the fungicide tolylfluanid, (1,1-dichloro-N-[(dimethylamino)-sulfonyl]-1-fluoro-N-(4-methylphenyl) methanesulfenamide), in or on apple at 5.0 parts per million (ppm), grape at 5.0 ppm, hop at 30 ppm, and tomato at 1.0 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) of the 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 the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see 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) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of tolylfluanid in or on apple at 5.0 ppm, grape at 11 ppm, hop at 30 ppm, and tomato at 2.0 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 tolylfluanid are discussed in Table 1 of this unit 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 rodents (rat)	NOAEL = 20.1 milligram/kilogram/day (mg/kg/day) male (M) LOAEL = 108 mg/kg/day, based on changes in clinical blood chemistry associated with the liver and thyroid (M) NOAEL = 131 mg/kg/day female (F) LOAEL = 736.1 mg/kg/day, based on changes in clinical blood chemistry associated with the liver and thyroid and decreased body weights (F) Acceptable/guideline
870.3150	90-Day oral toxicity in nonrodents (dog)	NOAEL = 23.1/25 mg/kg/day (F/M) LOAEL = 67.2/69.4 (F/M) mg/kg/day, based on decreased body weight gains and changes in liver structure and function in both sexes Unacceptable/guideline
870.3700	Prenatal developmental in rodents (rat)	Maternal NOAEL = not determined LOAEL = 100 mg/kg/day, based on decreased body weight gains and food consumption. Developmental NOAEL = 1,000 mg/kg/day highest dose tested (HDT) LOAEL > 1,000 mg/kg/day Acceptable/guideline
870.3700	Prenatal developmental in rodents (rat)	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day, based on dose-related decreased body weight gains during the dosing interval. Developmental NOAEL > 1,000 mg/kg/day (HDT) LOAEL = not identified Acceptable/guideline
870.3700	Prenatal developmental in nonrodents (rabbit)	Maternal NOAEL = 25 mg/kg/day LOAEL = 70 mg/kg/day, based on evidence of hepatotoxicity (increased glutamate dehydrogenase (GLDH) and triglyceride levels and gross and microscopic liver pathology) and decreased food consumption and equivocal decreases in body weight gain. Developmental NOAEL = 25 mg/kg/day LOAEL= 70 mg/kg/day, based on increased malformations (arthrogryposis of front extremities and small orbital cavity/folded retina) and variations (floating rib and accelerated ossification). Acceptable/guideline

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

Guideline No.	Study Type	Results
870.3800	2-Generation reproduction and fertility effects (rat)	Parental/systemic NOAEL = 7.9–10.5 mg/kg/day LOAEL = 57.5–78.0 mg/kg/day, based on decreased body weights, body weight gains, and liver weights in the P females Reproductive NOAEL = 7.9–10.5 mg/kg/day LOAEL = 57.5–78.0 mg/kg/day, based on reduced litter size Offspring NOAEL = 7.9–10.5 mg/kg/day LOAEL = 57.5–78.0 mg/kg/day, based on decreased pup weights, increased pup deaths and related pup viability indices Acceptable/guideline
870.3800	2-Generation reproduction and fertility effects (rat)	Parental/systemic NOAEL not established LOAEL = 15.9–21.5 mg/kg/day, based on hardened crania of P generation animals Reproductive NOAEL not established LOAEL = 15.9–21.5 mg/kg/day, based on increased clinical signs of toxicity Offspring NOAEL > 15.9–21.5 mg/kg/day (HDT) LOAEL not established Unacceptable/guideline
870.3800	2-Generation reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 20.1–26.3 mg/kg/day LOAEL = 83.4–109.5 mg/kg/day, based on decreased body weights and body weight gains Reproductive NOAEL = 83.4 - 109.5 mg/kg/day LOAEL = 335.6–492.4 mg/kg/day, based on decreased mean litter size Offspring NOAEL = 20.1–26.3 mg/kg/day LOAEL = 83.4–109.5 mg/kg/day, based on decreased pup weights Acceptable/guideline
870.3800	2-Generation reproduction and fertility effects (rat)	Parental/Systemic NOAEL = 75 mg/kg/day LOAEL = 375 mg/kg/day, based on decreased body weights and body weight gains for both generations Reproductive NOAEL > 375 mg/kg/day (HDT) LOAEL not established Offspring NOAEL = 75 mg/kg/day LOAEL = 375 mg/kg/day, based on decreased survival and reduced body weights during lactation Acceptable/guideline
870.4300	Combined chronic toxicity/carcinogenicity rodents (rat)	NOAEL = 18.1/21.1 mg/kg/day (M/F) LOAEL = 90.1/105.2 mg/kg/day (M/F), based on skeletal changes Evidence of thyroid follicular cell adenomas and/or carcinomas in high-dose males and females Acceptable/guideline
870.4300	Combined chronic toxicity/carcinogenicity rodents (rat)	NOAEL = 20/20 mg/kg/day (M/F) LOAEL = 80/110 mg/kg/day (M/F), based on bone hyperostosis in males and females Evidence of thyroid follicular cell adenomas and/or carcinomas in high-dose males and females Acceptable/guideline
870.4200	Carcinogenicity rodents (mouse)	NOAEL = 76.3/123.9 mg/kg/day (M/F) LOAEL = 375.8/610.8 mg/kg/day (M/F), based on skeletal, liver, and kidney changes No evidence of carcinogenicity Acceptable/guideline
870.4100	Chronic toxicity (dog)	NOAEL = 12.5 mg/kg/day LOAEL = 62.5 mg/kg/day (M), based on decreased body weight gains Acceptable/guideline
870.5100 Technical	Bacterial gene mutation assay	Tolylfluanid was cytotoxic to all strains at ≥ 8 μg/plate ± S9 and precipitated from solutions in all strains at 5,000 μg/plate ± S9. There were no reproducible, dose-related differences in the number of revertant colonies in any strain or dose over the background. Positive controls induced appropriate response. Acceptable/guideline

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

Guideline No.	Study Type	Results
870.5100 Metabolite—WAK 5815	Bacterial gene mutation assay	There was no evidence of toxicity or significant increase in mutant colonies over background in any of strains tested in either the initial or repeat mutagenicity assays. Positive controls induced appropriate response. Acceptable/guideline
870.5100 Metabolite—WAK 6550	Bacterial gene mutation assay	There were no reproducible, dose-related differences in the number of revertant colonies in any strain or dose over the background. Positive controls induced appropriate response. Acceptable/guideline
870.5100 Metabolite—WAK 6676	Bacterial gene mutation assay	There was no evidence of toxicity or significant increase in the mutant colonies over background in any strain tested. Positive controls induced the appropriate responses in the corresponding strains and in the solvent controls were consistent with the expected ranges of revertant colonies for the strains used. Acceptable/guideline
870.5100 Metabolite—WAK 6698	Bacterial gene mutation assay	Metabolite was cytotoxic at doses ≥158 μg/plate in the initial assay and 1,581 μg/plate in the repeat assay. There was no evidence of a significant increase in mutant colonies over background in any strains tested in the initial or repeat mutagenicity assays. Positive controls induced appropriate response. Acceptable/guideline
870.5100 Technical	Bacterial gene mutation assay	Tolylfluanid was tested to cytotoxic concentrations. Tolylfluanid showed no evidence of inducing methionine revertants in *Saccharomyces cerevisiae* strains ± S9. However, one of the tests (S211∞) was inadequate or inconsistent. Further, in the S9 activated assays, the positive controls did not elicit an adequate response, negating the test with S9 for both strains. Unacceptable/guideline
870.5300 Metabolite— WAK 6698	*In vitro* mammalian cell gene mutation assay	The compound was tested up to cytotoxic concentrations in two independent assays (± S9). In the initial test concentrations ranged from 50 to 1,000 μg/mL ± S9. In the repeat assay concentrations ranged from 100 to 800 μg/mL -S9 and 200 to 700 μg/mL + S9. Tolylfluanid metabolite was negative for inducing forward mutations at the TK locus in mouse L5178Y ± S9. Positive control methyl methanosulfonate and 3-methylcholanthrene induced appropriate responses. Acceptable/guideline
870.5300 Technical	*In vitro* mammalian cell gene mutation assay	These dose levels were selected based on a preliminary cytotoxicity study conducted at 0.5 to 250 μg/mL ± S9. Tolylfluanid has been judged to be non-mutagenic ± S9. Positive controls induced appropriate response ± S9. Acceptable/guideline
870.5300 Technical	*In vitro* mammalian cell gene mutation assay	Cultures were tested to cytotoxic concentrations. Tolylfluanid has been judged to be non-mutagenic ± S9. Positive controls induced appropriate response ± S9. Acceptable/guideline
870.5300 Technical	*In vitro* mammalian cell gene mutation assay	The compound was tested up to cytotoxic concentrations (± S9). Tolylfluanid was positive for inducing forward mutations at the TK locus in mouse L5178Y ± S9. Positive control ethylmethane sulfonate and 3-methylcholanthrene induced appropriate responses. Colony sizing was not performed. Acceptable/guideline
Non-Guideline Technical	Mouse spot test	F1 pups from female C57B1/6J mice exposed by oral gavage to tolylfluanid (98.4%) at concentration of 0; 1,750; 3,500; and 7,000 mg/kg did not show difference in incidence in relative spots between the treated and controls. Systemic toxicity was observed in dams at all doses. Mortality was observed at all doses; however treatment did not affect reproductive parameters nor there was difference in litter size. Positive controls showed a clear increase in spots in the progeny. Acceptable/non-guideline

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

Guideline No.	Study Type	Results
870.5375 Technical	*In vitro* mammalian cell gene mutation assay	The test was conducted up to cytotoxic levels ± S9. Tolylfluanid was weakly clastogenic in Chinese hamster V79 cells in the presence of S9 activation. Positive control mitomycin and cyclophosphamide induced appropriate responses. Acceptable/guideline
870.5375 Technical	*In vitro* mammalian cell gene mutation assay	Cytotoxicity was observed at concentrations 1 to 10 μg/milliliter (mL) -S9 and 5 to 10 μg/mL +S9. Over the ranges tested clastogenic effects included increased incidences of metaphases with aberrations including gaps, metaphases excluding gaps, metaphases with exchanges, and metaphases with polyploidy were observed. Tolyfluanid is clastogenic both in the presence and in the absence of S9 activation. Positive control mitomycin and endoxan induced appropriate responses. Acceptable/guideline
870.5380 Technical	*In vitro* mammalian spermatogonia chromosomal aberration test	No mortality or clinical signs were observed at either dose. No statistically significant increases in the frequency of chromosomal aberrations in spermatogonia were observed. Unacceptable/guideline
870.5380 Technical	*In vitro* mammalian spermatogonia chromosomal aberration test	Clinical signs of toxicity and cytotoxicity to target cells were seen at 5,000 mg/kg/day. Tolylfluanid did not induce chromosomal aberrations in spermatogonia at any dose. Positive controls did not produce strong positive results. Therefore, sensitivity of assay is questionable and the findings of the study are equivocal. Unacceptable/guideline
870.5385 Technical	Mammalian bone marrow chromosomal aberration test	3/10 animals died but exhibited no clinical signs. No cytotoxicity was observed at the dose tested. Positive controls induced appropriate response. Inadequate sampling time and no indication of test material present at target site; therefore, data not valid for regulatory purposes. Unacceptable/guideline
870.5385 Technical	Mammalian bone marrow chromosomal aberration test	3/10 of 10 animals died but no clinical signs of toxicity were observed at the dose tested. Test results were erratic. Positive controls induced appropriate response. Inadequate study since test samples were not analyzed and doses were not high enough to produce toxicity. Unacceptable/guideline
870.5395 Technical	Mammalian erythrocyte micronucleus assay	No clinical signs of toxicity was observed and was not toxic to the target tissue. Treatment with tolylfluanid did not induce micronucleated polychromatic erythrocytes. Inadequate methods and methodology. Unacceptable/guideline
870.5450 Technical	Dominant lethal assay (mice)	Did not induce variations in any dominant lethal parameters nor any reduced fertility. Inadequate study. No positive control data Unacceptable but upgradable with receipt of positive control data
870.5915 Technical	*In vivo* sister chromatid exchange assay	Mortality at 500 mg/kg and above. Tolylfluanid did not induce sister chromatid exchange at any dose level. Positive control cyclophosphamide responded appropriately. Acceptable/guideline
870.5500 Technical	Other genotoxic effects unscheduled DNA synthesis (UDS) in mammalian cells	Tolylfluanid did not induce UDS up to 15.0 μg/mL. The 17.5 and 20 μg/mL doses were highly toxic. The positive control 2-acetylaminofluorene responded appropriately. Acceptable/guideline
870.6200	Acute neurotoxicity screening battery (rat)	NOAEL = 50 mg/kg in females LOAEL = 150 mg/kg/day based on functional observation battery (FOB) effects and decreased motor and locomotor activity in females NOAEL = 2,000 mg/kg/day (M)—limit dose LOAEL = not established (M) Acceptable/guideline

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

Guideline No.	Study Type	Results
870.6200	Subchronic neurotoxicity screening battery (rat)	NOAEL = 25 mg/kg (F) LOAEL = 134 mg/kg based on decreased mean body weights in females. No treatment-related neurotoxicological effects were observed at any treatment level. Acceptable/guideline
870.7485	Metabolism and pharmacokinetics (rat)	In a metabolism study in rats, tolylfluanid was administered in single doses of 2 or 100 mg/kg of body weight, was readily absorbed and rapidly hydrolyzed within 48 hours. Absorption and excretion were independent of dose, sex, and pretreatment. About 86–100% of the dose was recovered in 48 hours, with 56–80% of the dose being excreted in urine, 12–36% in the feces, and ≤ 0.48% found in the carcass. Urinary metabolite common to both sexes were dimethylaminosulfonylamino-benzoic acid (RNH 0166; 46–78%), and 4-methylamino-benzoic acid (RNH 0416; 3–6%). Fecal compounds identified were unchanged tolylfluanid (1–19%), dimethylaminosulfotoluidid (DMST; 5–8%), RNH 0166 (3–12%), and RNH 0416 (< 1%). The data indicate that tolylfluanid hydrolyzed to DMST, which is then transformed to the major metabolite RNH 0166, which can be further demethylated to the minor metabolite, RNH 0416 (MRID No. 44285805). Acceptable/guideline
870.7485	Metabolism and pharmacokinetics (rat)	Series of metabolism studies showed that metabolic profile dependent upon label position. With [dichlorofluoromethyl-^{14}C]-tolylfluanid labeling major urinary metabolite was thiazolidine-2-thione-4carbonic acid resulting from cleavage of the side chain and accounted for 73–74% and 50–63%, respectively by IV and oral routes. Benzene ring label resulted in metabolite 4-(dimethylamino-sulfonylamino) benzoic acid which accounted for 90% of urinary metabolic activity and 70% of fecal radioactivity. The study with single oral dose of 2 or 20 mg/kg/day also supported the results of the main study (MRID No. 44285805).
Non-guideline	Non-guideline (rat) thyroid function	Thyroid-stimulating hormone levels significantly increased (168–425%) in high-dose males and females. Slightly increased T3 levels in males rats above 119.3 mg/kg/day Acceptable/nonguideline
Metabolite	Non-guideline (mice)*In vitro* investigation of TTCA goitrogenic properties	Tolylfluanid's metabolite TTCA was shown to reversibly inhibit thyroid peroxidase (TPO)-mediated reactions involved with the initial stages of thyroid hormone synthesis. This was shown by the dose-dependent decrease in formation of reactive iodine; the interference of the nonenzymatic and TPO-mediated iodination of L-tyrosine, and by TPO-mediated metabolism of TTCA. In the latter reaction, TTCA did not interfere with tyrosine iodination when the concentration in the reaction mixture fell below a certain concentration. Therefore, TTCA, unlike tolylfluanid, behaves as a goitrogenic compound with a potency approximately equal to propylthiouracil (PTU), a known thionamide inhibitor of initial thyroid hormone synthesis. Acceptable/nonguideline
Non-guideline	Non-guideline (rat) ^{32}P—post-labelling assay	In a ^{32}P—post-labelling assay for detection of adduct formation in lung, thyroid, and liver DNA in rats revealed that there was no evidence of DNA adduct formation in the liver, lung, or thyroid of rats exposed to tolylfluanid. Positive control 2-acetylaminofluorene (2-AAF) (liver, lung, and thyroid DNA adducts), benzidine (lung DNA adducts), 2-Thiourea (lung and thyroid DNA adducts), and dibenz[a,h]anthracene (DBA) (DNA adducts in the lungs) produced appropriate results. Acceptable/nonguideline

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 (SF) 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 SF.

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. In this case because it is an import tolerance only, there is only dietary risk.

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 tolylfluanid used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TOLYLFLUANID 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 = 25 UF[1] = 300 Acute RfD = aPAD = 0.083 mg/kg/day	1x	Prenatal developmental toxicity/rabbit LOAEL = 70 mg/kg/day based on increased malformations (arthrogryposis of front extremities and small orbital cavity/folded retina) and variations (floating ribs and accelerated ossification).
Acute dietary general population including infants and children	NOAEL = 50 UF[1] = 300 Acute RfD = aPAD = 0.17 mg/kg/day	1x	Acute oral neurotoxicity/rat LOAEL = 150 mg/kg/day based on FOB effects (pilorection, decreased activity, gait abnormalities, decreased body temperature, and/or decreased rearing).
Chronic dietary all populations	NOAEL= 7.9 UF[1] = 300 Chronic RfD = cPAD = 0.026 mg/kg/day	1x	2-Generation reproduction/rat LOAEL = 57.5 mg/kg/day based on decreased body weights, body weight gains, and liver weights.
Cancer	Classification: ''Likely to be carcinogenic to humans'' by the oral route, based on thyroid tumors in high-dose male and female rats. The FQPA SF Committee further recommended a linear low-dose extrapolation approach for the quantification of human cancer risk based on the thyroid tumors in rats. Q_1* = 1.59 x 10^{-3} based upon male rat thyroid adenomas and/or carcinomas combined.		

[1] UF (uncertainty factor), FQPA Safety Factor (SF), no-observed-adverse-effect-level (NOAEL), lowest-observed-adverse-effect-level (LOAEL), acute Population Adjusted Dose (aPAD), chronic Population Adjusted Dose (cPAD), reference dose (RfD).

* The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* This activity reflects the establishment of the first U.S. import tolerance for tolylfluanid on apple, grape, hop, and tomato without a U.S. registration. Since there are no other food or feed uses in the United States, the only exposure to occur is dietary.

Risk assessments were conducted by EPA to assess dietary exposures from tolylfluanid 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™7.76) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute Tier 2 (partially refined analysis) exposure assessments: An aPAD of 0.083 mg/kg/day was used for females between 13 and 50 years of age based on developmental toxicity in rabbits. An aPAD of 0.17 was used for the general U.S. population (including infants and children) based on acute neurotoxicity in rats. Anticipated residues were calculated based upon submitted field trial and livestock metabolism data for all proposed uses of tolylfluanid.

The resulting acute dietary exposure estimates do not exceed EPA's level of concern (<100% aPAD) at the 95th exposure percentile for females 13–50 years old (42% aPAD), the general U.S. population (31% of the aPAD) and all other population subgroups. The most

highly exposed population subgroup is infants (<1 year old, at 100% of the aPAD).

TABLE 3.—ACUTE DIETARY EXPOSURE TO TOLYLFLUANID

Population Subgroup	Acute Dietary[1]	
	Dietary Exposure (mg/kg/day)	% aPAD
U.S. Population (total)	0.051973	31
All Infants (< 1 year old)	0.169772	100
Children 1–6 years old	0.159553	94
Children 7–12 years old	0.063237	37
Females 13–50 years old	0.034529	20
Males 13–19 years old	0.023476	14
Males 20+ years old	0.030744	18
Seniors 55+ years old	0.033375	20

[1]Acute dietary endpoint of 0.083 mg/kg/day applies to females 13–50 years old only; acute dietary endpoint of 0.17 mg/kg/day applies to the general U.S. population (including infants and children).

The assessment of acute dietary exposure used the following conservative assumptions likely to generate upper-end estimates of the quantity of tolylfluanid and tolylfluanid residues ingested:

• No import consumption data were used in the assessment (i.e., the assessment assumes that all acute dietary exposure from the proposed commodities is from imported commodities).

• 100% crop treated (CT) was assumed for these imported commodities: All imported grape, apple, hop, and tomato were assumed to have been treated with tolylfluanid and to have tolylfluanid residues at the level of the tolerance.

Inclusion of additional data, such as %CT/import consumption data and/or monitoring data (including metabolites of concern), could be made in order to refine the acute dietary exposure assessment.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments:

A cPAD of 0.026 mg/kg/day was used based on the 2-generation rat reproduction study. All dietary exposure from the proposed commodities is from imported commodities. Import share data generated within the Agency were used in the assessment to estimate what proportion of the grape, apple, hop, and tomato consumed in the United States are imported. Modified DEEM™ processing factors based on the results of processing studies were used for raisins and apple and grape juice/juice concentrates. Default DEEM™ processing factors were used for all other processed commodities. Anticipated residues calculations were used based upon submitted field trial and livestock metabolism data.

TABLE 4.—CHRONIC EXPOSURE TO TOLYLFLUANID

Population Subgroup	Chronic Dietary[1]	
	Dietary Exposure (mg/kg/day)	% aPAD
U.S. Population (total)	0.000780	3
All Infants (< 1 year old)	0.003397	13
Children 1–6 years old	0.003638	14
Children 7–12 years old	0.001029	4
Females 13–50 years old	0.000399	2
Males 13–19 years old	0.000342	1
Males 20+ years old	0.000340	1
Seniors 55+ years old	0.000333	1

[1]Chronic dietary endpoint of 0.026 mg/kg/day applies to general U.S. population and all population subgroups.

The assessment of chronic dietary exposure for the general U.S. population and all population subgroups (including infants and children) used the following conservative assumptions to generate upper-end estimates of the quantity of tolylfluanid and tolylfluanid residues ingested:

• 100% CT was assumed for these imported commodities: All imported grape, apple, hop, and tomato were assumed to have been treated with tolylfluanid and to have tolylfluanid residues at the level of the tolerance.

• The calculated ARs (parent and additional metabolites of concern not in tolerance expression) are based on field trial data, submitted by the registrant to support tolerances. Field trial residue data are generally considered by the Agency as an upper-end or a worst case scenario of possible residues and are more suited to the requirements of tolerance setting, because it requires highest rates of application and shortest PHI, than to the requirements of dietary exposure assessment (when a more realistic estimate is desired).

The chronic dietary exposure estimates do not exceed EPA's level of concern (<100% cPAD) for the general U.S. population (3% cPAD) and all population subgroups. The most highly exposed population subgroup is children 1–6 years old at 14% of the cPAD.

iii. *Cancer*. A partially refined, cancer dietary exposure assessment was conducted for the general U.S. population using the same assumptions as were used in the chronic risk assessment (listed in the preceding section). Import share data generated within the Agency were used in the assessment to estimate what proportion of the grape, apple, hop, and tomato consumed in the United States are imported. Modified DEEM™ processing factors based on the results of processing studies were used for raisins and apple and grape juice/juice concentrates. Default DEEM™ processing factors were used for all other processed commodities The cancer risk estimate is 1.2×10^{-6} for the general U.S. population.

For cancer dietary risk estimates, the Agency is generally concerned with cancer risks that exceed the range of 1×10^{-6}. The following conservative assumptions were used in the cancer dietary exposure assessment:

• The percent import consumption information used for apple, grape and tomato commodities assume that 100% of these imported commodities are treated with tolylfluanid.

• The calculated ARs are based on field trial data, submitted by the registrant to support tolerances. Field trial residue data are generally considered by the Agency as providing an upper-end scenario of possible residues and are more suited to the requirements of tolerance setting, because it requires highest rates of application and shortest PHI, than to the requirements of dietary exposure

assessment (when a more realistic estimate is desired).

With additional refinements to the dietary exposure assessment (i.e., country-specific percent import consumption data and/or monitoring data (including metabolites of concern) the Agency expects the estimated cancer risk to be significantly lower.

iv. *Anticipated residue and %CT*.

Section 408(b)(2)(E) of the 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 chemicals that have been measured in food. Adequate reliable information was not available on the fraction of imported grape, apple, hop, and tomato which were treated with tolylfluanid, therefore the Agency assumed that all these commodities were treated (100% CT). In addition, the Agency must provide for periodic evaluation of any estimates used. As required by section 408(b)(2)(E) of the FFDCA, 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) of the FFDCA 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 %CT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on %CT. The Agency used %CT information as follows:

Since the tolerances being established are for imported commodities only and a petition for domestic use of tolyfluanid is not currently pending with EPA, the Agency analyzed the amount of imported apple, grape, hop, and tomato, relative to domestic production, and derived a ''percent crop imported'' figure for each commodity. The Agency based this analysis on import and domestic production data available from the USDA for the years 1995 through 1999. The proportion of imports relative to domestic production for each of the commodities are as follows: Fresh apple—5.6%; apple juice—56.4%; canned apple—0.1%; fresh grape—0.2%, grape juice—43.4%; fresh tomato—16.4%; and processed tomato—4.1%. The Agency's analysis assumed 100% for hop. Tolylfluanid is currently only registered for use in a small number of European countries, however, the estimates stated in this unit reflect total imports of these commodities into the United States, not just imports from Europe. Therefore, the values used in the Agency's risk assessment assume that all imported commodities contain residues of tolyfluanid. These assumptions fulfill Condition 1 by overestimating the portion of imported apple, grape, hop, and tomato with tolylfluanid residues. 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.

2. *Dietary exposure from drinking water*. Residues in drinking water are not expected to result as a consequence of establishing an import tolerance for tolylfluanid residues in or on apple, grape, hop, and tomato. Tolylfluanid is not registered for use in the United States. Therefore, exposure through drinking water is unlikely.

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). Tolylfluanid 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) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether tolylfluanid 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, tolylfluanid 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 tolylfluanid 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. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional 10-fold 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure in the prenatal developmental study in rats. Although there is qualitative evidence of increased susceptibility in the prenatal developmental study in rabbits and in the 2-generation reproduction study in rats, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of tolylfluanid.

3. *Conclusion*. There is a complete toxicity data base for tolylfluanid and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The RfDs established are protective of pre-/post-natal toxicity following acute and chronic exposures. The Agency therefore concluded that no Special FQPA FS is necessary to protect the safety of infants and children in assessing tolylfluanid exposure and

risks. However, a FQPA factor in the form of data base UF (UF_{DB}) of 3x was applied to the acute RfDs and chronic RfDs to account for the comparative thyroid assay (adult versus young animals) data requirement. 3X is adequate in this case since the observed thyroid hormone changes that necessitated the additional study occurred at a dose level more than three-fold higher than the dose levels (based on developmental and reproductive toxicity) used as the basis for endpoints for risk assessment. Thus, use of an additional 3X FQPA SF will provide at least a 10X margin of safety regarding the effects for which there is some uncertainty and for which additional data is required.

TABLE 5.—ADDITIONAL FQPA SAFETY FACTOR

	LOAEL to NOAEL (UF_L)	Subchronic to Chronic (UF_S)	Incomplete Data base (UF_{DB})	Special FQPA Safety Factor (Hazard and Exposure)
Magnitude of factor	1X	1X	3X	1X
Rationale for the factor	No LOAEL to NOAEL extrapolations performed	No subchronic to chronic extrapolations performed	Lack of comparative thyroid assay (adult versus young animals)	No residual uncertainties regarding pre- or post-natal toxicity or completeness of the toxicity or exposure data bases
Endpoints to which the factor is applied	Not applicable (NA)	NA	All dietary exposure scenarios	NA

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to tolylfluanid will occupy 31% of the aPAD for the U.S. population, 20% of the aPAD for females 13 years and older, 100% of the aPAD for infants < 1year old, and 94% of the aPAD for children between 7 and 12 years old. In addition, there is no potential for acute dietary exposure to tolylfluanid in drinking water. Although this risk assessment projects that infants under 1 year of age will receive the maximum safe exposure, for the reasons detailed in this unit, this assessment is likely to substantially overstate risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to tolylfluanid from food will utilize 3% of the cPAD for the U.S. population, 13% of the cPAD for infants < 1 year old, and 14% of the cPAD for children between 1 and 6 years old. There are no residential uses for tolylfluanid that result in chronic residential exposure to tolylfluanid.

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). Tolylfluanid is not registered for use on any sites that would result in residential exposure. Therefore, a short-term aggregate risk was not performed.

4. *Intermediate-term risk.* Tolylfluanid is not registered for use on any sites that would result in residential exposure. Therefore, an intermediate-term aggregate risk was not performed.

5. *Aggregate cancer risk for U.S. population.* The cancer risk estimate for the general U.S. population from tolylfluanid is 1.2×10^{-6}. In general, the Agency's level of concern for cancer exposure is for risks in the range of 1×10^{-6} and this risk estimate is comfortably with this range. Moreover, several conservative assumptions were included in the assessment (enumerated in Unit III.C.1., Dietary exposure from food and feed uses). With additional refinements to the dietary exposure assessment (i.e., country-specific percent import consumption data and/or monitoring data (including metabolites of concern), the Agency expects the cancer risk to be substantially lower.

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 tolylfluanid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

For tolylfluanid in/on apple, grape, hop, and tomato, the submitted independent laboratory validation (ILV) using a gas chromatograph (GC)/thermal ionization detector (TID) procedure designated as Method 00441 and entitled *Determination of Tolylfluanid in/on Various Raw Agricultural and Processed Commodities* has been received and the method has been forwarded to the Agency's laboratory for validation. The petitioner will be required to make any modifications or revisions to the proposed method resulting from EPA's validation.

The petitioners submitted the multiresidue data concerning the recovery of tolylfluanid residues using the Food and Drug Administration (FDA) MRM protocols (PAM Vol. I) and following modified cleanup procedures. These results indicate that tolylfluanid is likely to be recovered through FDA MRM Protocols D and E. The results have been forwarded to the FDA for inclusion in the Pesticide Analytical Method Volume I.

Prior to publication and upon request, the method will be available from the Analytical Chemistry Branch (ACB), BEAD (75053), Environmental Science Center, 701 Mapes Rd., Ft. George C. Meade, MD 20755–5350. Contact Francis D. Griffith, Jr., telephone number: (410) 305–2905; e-mail address: *griffith.francis@epa.gov*. The analytical standards are also available from the EPA National Standard Repository at the same location.

Based on the proposed uses, a residue enforcement method for livestock commodities is not necessary at this time.

B. International Residue Limits

There are no Canadian or Mexican MRLs established for tolylfluanid residues in/on crop commodities. The Codex Alimentarius Commission has established MRLs for tolylfluanid residues in/on various commodities, including currant at 5 ppm, gherkin at 2 ppm, lettuce head at 1 ppm, pome

fruits at 5 ppm, strawberry at 3 ppm, and tomato at 2 ppm. The Codex MRLs are expressed in terms of tolylfluanid per se. Although the submitted residue data support the proposed tolerance of 1.0 ppm on tomato, the Agency is establishing this tolerance at 2.0 ppm in order to harmonize with the current Codex MRL.

V. Conclusion

Therefore, the tolerance is established for residues of tolylfluanid, (1,1-dichloro-N-[(dimethylamino)-sulfonyl]-1-fluoro-N-(4-methylphenyl)methanesulfenamide), in or on apple at 5 ppm, grape at 11 ppm, hop at 30 ppm, and tomato at 2 ppm.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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 ID number OPP–2002–0216 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 25, 2002.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 20460–0001.

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 20460–0001.

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 ID number OPP–2002–0216, 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 20460–0001. 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 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 section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any

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

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 13, 2002.

James Jones,

Acting Director, 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), 346(a) and 371.

2. Section 180.584 is added to subpart C to read as follows:

§ 180.584 Tolylfluanid, tolerances for residues.

(a) *General.* Tolerances are established for residues of tolylfluanid, 1,1-dichloro-N-[(dimethylamino)-sulfonyl]-1-fluoro-N-(4-methylphenyl)methanesulfenamide in or on the following commodities.

Commodity	Parts per million
Apple[1]	5.0
Grape[1]	11
Hop[1]	30
Tomato[1]	2.0

[1] No U.S. registration as of August 31, 2002.

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

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

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

[FR Doc. 02–24094 Filed 9–24–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0234; FRL–7198–3]

Fluroxypyr 1-methylheptyl ester; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of fluroxypyr [1-methylheptyl ester 1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid] in or on sorghum, grain at 0.035 parts per million (ppm); sorghum, forage at 2.0 ppm; and sorghum, grain, stover at 4.0 ppm. This action is in connection with a crisis exemption declared by the state of Kansas under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on sorghum. This regulation establishes maximum permissible levels for residues of fluroxypyr 1-methylheptyl ester and its metabolite, all expressed as fluroxypyr in these food commodities. The tolerances will expire and are revoked on December 31, 2005.

DATES: This regulation is effective September 25, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0234, must be received on or before November 25, 2002.

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 VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0234 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9364; e-mail address: *sec–18–Mailbox@epamail.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 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/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0234. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the herbicide fluroxypyr 1-methylheptyl ester, [1-methylheptyl ((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetate] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy)acetic acid], in or on sorghum, grain at 0.035 ppm; sorghum, forage at 2.0 ppm; and sorghum, grain, stover at 4.0 ppm. These tolerances will expire and are revoked on December 31, 2005. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical