

Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under figure 2–1, paragraph (32)(e) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation because promulgation of changes to drawbridge regulations have been found to not have a significant effect on the environment. A written "Categorical Exclusion Determination" is not required for this final rule.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.599 is revised to read as follows:

§ 117.599 Fort Point Channel.

The draw of the Northern Avenue Bridge, mile 0.1, at Boston, shall operate as follows:

(a) From May 1 through October 31, the draw shall open on signal from 7 a.m. to 11 p.m. From 11 p.m. to 7 a.m. the draw shall open on signal if at least a two-hour advance notice is given by calling the number posted at the bridge.

(b) From November 1 through April 30, the draw shall open on signal from 7 a.m. to 3 p.m. From 3 p.m. to 7 a.m. the draw shall open on signal if at least a twenty-four hours advance notice is given by calling the number posted at the bridge.

Dated: January 31 2001.

G.N. Naccara,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 01–4096 Filed 2–16–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–01–001]

Drawbridge Operating Regulation; Arroyo Colorado, TX

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation in 33 CFR 117.951 governing the operation of the FM 106, vertical lift span bridge across Arroyo Colorado, mile 22.2 at Rio Hondo, Texas. This deviation allows the Texas Department of Transportation to close the bridge to navigation from 7 a.m. on February 20, 2001 through 7 p.m. on February 25, 2001 for maintenance.

DATES: This deviation is effective from 7 a.m. on Tuesday, February 20, 2001 to 7 p.m. on Sunday, February 25, 2001.

ADDRESSES: Unless otherwise indicated, documents referred to in this notice are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Commander (obc), 501 Magazine Street, New Orleans, Louisiana, 70130–3396. The Bridge Administration Branch maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Phil Johnson, Bridge Administration Branch, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: The FM 106 vertical lift span bridge across Arroyo Colorado, mile 22.2, at Rio Hondo, Cameron County, Texas, has a vertical clearance of 27 feet above high water in the closed-to-navigation position and 73 feet above high water in the open-to-navigation position. Navigation on the waterway consists primarily of tugs with tows transporting concrete, petroleum products and fertilizer. Presently, the draw of the bridge opens on signal if at least 12 hours notice is given. The Texas Department of Transportation requested a temporary deviation from the normal operation of the drawbridge in order to accommodate the maintenance work, which involves replacing the drive motors and upgrading the operating system computer. This maintenance is necessary for the continued operation of the bridge.

This deviation allows the lift span of the FM 106 drawbridge across Arroyo Colorado, mile 22.2 at Rio Hondo, Texas to remain closed to navigation from 7 a.m. on February 20, 2001 until 7 p.m. on February 25, 2001.

Dated: February 7, 2001.

Paul J. Pluta,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 01–4138 Filed 2–16–01; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301094; FRL–6761–1]

RIN 2070–AB78

Flutolanil, N-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the fungicide flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide and metabolites converted to 2-(trifluoromethyl) benzoic acid, calculated as flutolanil in or on rice grain, rice straw, rice hulls, rice bran, potatoes, and potato, wet peel. Aventis 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 February 20, 2001. Objections and requests for hearings, identified by docket control number OPP-301094, must be received by EPA on or before April 23, 2001.

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-301094 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:

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/fedrgrstr/>. 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-301094. 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 January 24, 2000 (65 FR 3690) (FRL-6486-8), 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 pesticide petitions (PP 6F4693 and 4F4380) for

tolerances by Aventis Crop Science, 2 TW Alexander Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by the registrant Aventis, then known as AgrEvo USA Company and located at 2711 Centerville Rd, Wilmington, DE, 19808. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.484 be amended by establishing tolerances for residues of the fungicide flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide and its metabolites converted to 2-(trifluoromethyl) benzoic acid, calculated as flutolanil, in or on the raw agricultural commodities potatoes at 0.20 part per million (ppm), potato waste (wet) at 0.4 ppm, rice, grain at 2.0 ppm, rice, straw at 12.0 ppm, and in or on the processed food commodities rice, hulls at 7.0 ppm, and rice, bran at 3.0 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) 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 flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl) benzamide and its metabolites converted to 2-(trifluoromethyl) benzoic acid, calculated as flutolanil in or on the raw agricultural commodities potatoes at 0.20 ppm, rice, grain at 7.0 ppm, rice, straw at 10.0 ppm, and in or on the

processed food commodities potato, wet peel at 0.3 ppm, rice, hulls at 25.0 ppm, and rice bran at 10.0 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 flutolanil 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
870.1100	Acute Oral	LD ₅₀ > 10 g/kg, acute toxicity category IV
870.1200	Acute Dermal	LD ₅₀ > 2 g/kg, acute toxicity category III
870.1300	Acute Inhalation	LC ₅₀ > 5.98 mg/L (4 hours), acute toxicity category IV
870.2400	Primary Eye Irritation	Minimal irritation, acute toxicity category IV
870.2500	Primary dermal Irritation	Not a dermal irritant, acute toxicity category IV
870.2600	Dermal Sensitization	Not a dermal sensitizer
870.3100	90-Day oral toxicity rats - diet	NOAEL = 37 mg/kg/day LOAEL = 299 mg/kg/day based on increased absolute and relative liver weights (males and females) and slight decrease in body weights (males).
870.3150	90-Day oral toxicity in nonrodents (dog)	NOAEL = 80 mg/kg/day, LOAEL = 400 mg/kg/day based on enlarged livers and increased severity of glycogen deposition in both males and females.
870.3200	21-Day dermal toxicity - rat	NOAEL = 1,000 mg/kg/day (limit dose) LOAEL > 1,000 mg/kg/day
870.3250	90-Day dermal toxicity	Not available
870.3465	90-Day inhalation toxicity	Not available
870.3700a	Prenatal developmental in rat, oral gavage	Maternal NOAEL ≥ 1,000 mg/kg/day, LOAEL > 1,000 mg/kg/day, Developmental NOAEL ≥ 1,000 mg/kg/day, LOAEL > 1,000 mg/kg/day.
870.3700b	Prenatal developmental in rabbit, oral gavage	Maternal NOAEL ≥ 1,000 mg/kg/day, LOAEL > 1,000 mg/kg/day, Developmental NOAEL ≥ 1,000 mg/kg/day, LOAEL > 1,000 mg/kg/day.
870.3800	Reproduction and fertility effects in rat - 2 generation - diet	Parental/Systemic NOAEL ≥ 1,000 mg/kg/day, LOAEL > 1,000 mg/kg/day, Reproductive NOAEL ≥ 1,000 mg/kg/day, LOAEL > 1,000 mg/kg/day.
870.3800	Reproduction And Fertility Effects In Rat - 3 Generation - diet	Parental/Systemic NOAEL ≥ 661 mg/kg/day, LOAEL > 661 mg/kg/day, Reproductive NOAEL ≥ 661 mg/kg/day, LOAEL > 661 mg/kg/day.
870.4100a	Chronic toxicity rodents	See combined chronic/carcinogenicity study below.
870.4100b	Chronic toxicity - dogs - gelatin capsule	NOAEL = 50 mg/kg/day, LOAEL = 1250 mg/kg/day based on increase of clinical toxic signs (emesis, salivation, and soft stool), lower body weight gains and decreased food consumption.
870.4100a and 870.4200	Chronic/ Oncogenicity Rats - diet	Systemic NOAEL = 87 mg/kg/day, Systemic LOAEL = 460 mg/kg/day based on reduced body weight and body weight gains (males), decreased absolute and relative liver weights (males and females). Oncogenic NOAEL ≥ 586 mg/kg/day, no evidence of carcinogenicity.
870.4300	Carcinogenicity mice - diet	Systemic NOAEL = 735 (M) and 168 (F) mg/kg/day, Systemic LOAEL = 3333 (M) and 839 (F) mg/kg/day based on decreased body weight gains. Oncogenic NOAEL ≥ 3676 mg/kg/day, no evidence of carcinogenicity

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

Guideline No.	Study Type	Results
870.5375	Gene Mutation <i>In vitro</i> Chromosomal Aberration Assay in Cultured Mammalian Cell	Positive finding, flutolanil induced chromosomal aberrations in cultured Chinese hamster lung cells in the presence of metabolic activation (S9).
870.5100	Gene Mutation, Reverse Mutation Assay	Negative (with and without S-9 metabolic activator) at doses up to 25 mg/plate in the increase in revertant colonies using <i>Salmonella</i> strains TA98, TA10, TA1535, TA1537, and TA1538 and in the <i>E. Coli</i> WP2 <i>uvrA</i> strain.
870.5375	Gene Mutation in Cultured Mammalian Cells (Mouse Lymphoma Cells)	Negative (either in the presence or absence of S9 activation) for the induction of forward mutations at the TK+/- locus in L5178Y mouse lymphoma cells.
870.5385	Cytogenetics Mammalian Cells in Culture Cytogenetics Assay in Human Lymphocytes	Negative in the structural chromosome assay. There was no significant increase in the frequency of aberrations with any treatment levels, either with or without activation.
870.5395	Cytogenetics Mouse Micronucleus	Negative in the induction of micronuclei in the bone marrow erythrocytes of male and female mice.
870.5550	Other Genotoxicity Effects, In Vitro Unscheduled DNA Synthesis Assays in Primary Rat Hepatocytes	Negative in the induction of unscheduled DNA synthesis in primary rat hepatocytes.
870.6200a	Acute neurotoxicity screening battery	Not available
870.6200b	Subchronic neurotoxicity screening battery	Not available
870.6300	Developmental neurotoxicity	Not available
870.7485	Metabolism and pharmacokinetics - rat	Treatment was oral doses of 20 mg/kg/day for 14 days, and a single high dose of 1,000 mg/kg. The majority of the radioactivity excreted in urine had been excreted by 24 hours post-dose in all dose groups. There were no appreciable tissue levels of flutolanil at study termination (72 hours post-dose).
870.7600	Dermal penetration	Not available

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 intraspecies 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, as shown in following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUTOLANIL 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 general population including infants and children	None	No appropriate endpoint was identified in the oral toxicity studies including developmental toxicity studies in rats and rabbits.	None

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUTOLANIL 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
Chronic Dietary all population subgroups	NOAEL= 87 mg/kg/day UF = 100 Chronic RfD = 0.87 mg/kg/day	FQPA SF = 1 x cPAD = chronic RfD FQPA SF = 0.87 mg/kg/day.	2-year Chronic/Oncogenicity study in rats. LOAEL = 460 mg/kg/day based on decreases in body weight and body weight gain and increases in absolute and relative liver weights.
Short (1 to 7 days) -and Intermediate-(1 week to several months)- Term Dermal (Residential)	None	No appropriate endpoint was identified. No dermal or systemic toxicity was observed in a 21-day dermal study in rats. No maternal toxicity was observed in rats or rabbits in developmental toxicity studies.	None
Long-Term Dermal (several months to lifetime)	None	The current use pattern does not indicate long-term dermal exposure potential.	None
Inhalation (any time period)	Oral NOAEL= 87 mg/kg/day (inhalation absorption rate = 100%)	LOC ≥ 100	2-year Chronic/Oncogenicity study in rats. LOAEL = 460 mg/kg/day based on decreases in body weight and body weight gain and increases in absolute and relative liver weights
Cancer (oral, dermal, inhalation)	None	Based on the lack of evidence of carcinogenicity and mutagenicity in mouse and rat studies, flutolanil is classified as not likely to cause cancer.	None

* 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 180.484) for the residues of flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide and metabolites converted to 2-(trifluoromethyl) benzoic acid, calculated as flutolanil and its metabolites in or on the raw agricultural commodities peanuts, peanut meal, peanut hay; milk; fat; kidney; liver; meat and meat-by-product (mbyp) of cattle, goats, hogs, horses, and sheep; eggs; fat; meat; and mbyp of poultry. Time-limited tolerances, made permanent by today's rule, are established for residues of flutolanil and its metabolites in/on rice RACs.

Risk assessments were conducted by EPA to assess dietary exposures from flutolanil and its metabolites 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. A toxicological

endpoint for acute dietary toxicity was not selected for flutolanil. Therefore, a risk assessment for dietary food exposure was not conducted.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment 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. The following assumptions were made for the chronic exposure assessments: that residues would be present in or on treated crops at tolerance levels and that 100% of proposed and currently registered crops would be treated.

iii. *Cancer.* Flutolanil is unlikely to pose a carcinogenic hazard to humans. Therefore a cancer risk assessment was not conducted.

2. *Dietary exposure from drinking water.* Flutolanil resists all modes of abiotic and biotic degradation. Flutolanil is mobile in soil but was found in aquatic field dissipation studies to accumulate in the sediment fraction. Because flutolanil adsorbs at

low rates onto soil and exhibits a long half-life, the most important means of dissipation in surface water and also in ground water will most likely be dilution.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for flutolanil 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 physical characteristics of flutolanil.

The Agency used the First Approximation Rice Model to estimate pesticide concentrations in surface water after applying flutolanil on rice and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in groundwater. In general, EPA will use Generic Expected Environmental Concentrations (GENEEC) (a tier 1 model) before using Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) (a tier 2 model) for a screening-level assessment for surface water, but given the unique

hydrological issues arising from pesticide application to rice paddies, EPA used the First Approximation Rice Model rather than GENECC or PRZM/EXAMS for surface water estimates.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

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 %RfD or %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 flutolanil they are further discussed in the aggregate risk sections below.

Based on the First Approximation Rice Model and SCI-GROW model, the estimated environmental concentrations (EECs) of flutolanil for acute exposures are 3.8 parts per billion (ppb) for surface water and 0.34 ppb for ground water. The EECs for chronic exposures are 3.8 ppb for surface water and 0.34 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).

Flutolanil is currently registered for use on the following residential non-dietary sites: Turf grass. The risk assessment was conducted using the following residential exposure assumptions: There are non-occupational uses associated with flutolanil. Non-occupational handlers may mix, load and apply flutolanil products on turf grass. These exposures were assessed for inhalation risk. The MOEs for these scenarios range from 1.4×10^3 to 4.4×10^4 for handlers. Postapplication inhalation exposure following turf grass treatment is

considered negligible and was not assessed. Because certain flutolanil products are registered for use on residential lawns, postapplication exposure to infants may result from their hand-to-mouth activities on treated turf. The MOE's for these scenarios ranged from 6.7×10^2 to 1.4×10^3 . These MOEs are greater than the LOC of 100 and lie above the Agency's level of concern.

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 flutolanil 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, flutolanil 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 flutolanil 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.* 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.

2. *Prenatal and postnatal sensitivity.* Developmental toxicity studies in rat and rabbit and multigeneration reproductive studies in rat did not indicate any basis for concern about

prenatal and postnatal effects in infants and children.

3. *Conclusion.* There is a complete toxicity data base for flutolanil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures and the developmental and reproductive toxicity studies indicate no increased susceptibility of rat or rabbit fetuses to in utero or post-natal exposure. Accordingly, EPA determined that the 10X safety factor to protect infants and children should be removed.

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.* Acute aggregate risk is based upon the estimated risks from the combined exposures of food and drinking water sources. EPA did not recommend an acute dietary endpoint for flutolanil, therefore no acute

aggregate risk assessment was conducted and there is no expectation of acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to flutolanil from food will utilize < 1.0% of the cPAD for the U.S. population, 1.0% of the cPAD for infants less than one year old and < 1.0% of the cPAD for all other population subgroups.

Based on the use pattern, chronic residential exposure to residues of flutolanil is not expected. In addition, there is potential for chronic dietary exposure to flutolanil 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 cPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUTOLANIL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	DWLOC (ppb)
U.S. Population	0.87	< 1.0 %	3.8	0.34	3.0 x 10 ⁴
Infants less than one year old	0.87	1.0%	3.8	0.34	8.6 x 10 ³
Non-hispanic/non-white/non-black	0.87	< 1.0 %	3.8	0.34	3.0 x 10 ⁴
Females 13-50 (nursing)	0.87	< 1.0 %	3.8	0.34	2.6 x 10 ⁴

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).

Though residential exposure could occur with the use of flutolanil no toxicological effects have been identified for short-term dermal toxicity. Incidental oral exposure to adult residential handlers is expected to be insignificant and is therefore not assessed. Incidental oral exposure to infants eating treated turf is assessed below under intermediate-term aggregate risk.

4. *Intermediate-term risk.* Flutolanil is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for flutolanil.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1.3 x 10³ for the hand-to-mouth exposure of an infant following application of turf with a granular formulation of flutolanil and 6.4 X 10²

for the hand-to-mouth exposure of an infant following application with a wettable powder. These aggregate MOEs exceed 100, the Agency's maximum level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of flutolanil in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4:

TABLE 4.—AGGREGATE AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO FLUTOLANIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb) ground water
Infants < 1 year old, hand-to-mouth exposure to granular	1.3 x 10 ³	100	0.34	3.8	8.0 x 10 ³
Infants < 1 year old, hand-to-mouth exposure to wettable powder	6.4 x 10 ²	100	0.34	3.8	7.3 x 10 ³

5. *Aggregate cancer risk for U.S. population.* Flutolanil is classified as a "not likely" to be a human carcinogen considering the Proposed EPA Weight-of-the-Evidence Categories (August, 1999), based on the lack of evidence of carcinogenicity in male and female rats and mice up to the guideline limit dose and on the lack of mutagenicity in an acceptable battery of mutagenicity studies.

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 flutolanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed a residue analytical method for tolerance enforcement involving the transformation of flutolanil and its metabolites to 2-trifluoromethyl benzoic acid (2-TFBA). The organic extracts containing 2-TFBA are methylated with methyl iodide and residues are

quantified by gas chromatography utilizing a mass selective detector. The analytical method designated AU-9SR-04 has been independently validated. EPA review of the validation determined it to be adequate for enforcement purposes. Upon successful completion of the EPA validation process, this method will be forwarded to FDA for publication in a future version of the Pesticide Analytical Manual, Vol II (PAM II).

The method may be requested from: Calvin Furlow, PRRIB, 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 established or proposed Codex, Canadian or Mexican limits for residues of flutolanil in/on plant or animal commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances discussed in this petition review.

C. Conditions

Flutolanil will be conditionally registered for these uses subject to the following conditions:

1. Modification of the proposed enforcement method as directed by the Agency once the validation is completed.
2. Fortification recovery data for flutolanil and its metabolites from potato and radiovalidation data from all previously submitted metabolism studies.
3. Confirmatory method which is able to confirm that the residues determined in the primary method (proposed enforcement method (Method No. AU/95R/05), a common moiety method and determining all residues (parent plus metabolites) containing the 2-(trifluoromethyl) benzoic acid moiety) were derived from flutolanil.
4. Storage stability data for residues of flutolanil and representative metabolites in/on potatoes and potato processed commodities during frozen storage.
5. Storage stability data related to an already-submitted study concerning the uptake of residues in crops irrigated with water drained from treated rice fields, specifically for residues of flutolanil and representative metabolites in/on irrigated cotton, turnips, and soybeans for a period of up to 426 days.
6. An additional poultry feeding study in which the dose levels exceed those used in previously submitted studies.

V. Conclusion

Therefore, the tolerance is established for residues of flutolanil, *N*-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl)benzamide and metabolites converted to 2-(trifluoromethyl) benzoic acid, calculated as flutolanil, in or on the raw agricultural commodities potatoes at 0.20 part per million ppm, rice, grain at 7.0 ppm, rice, straw at 10.0 ppm, and in or on the processed food commodities potato, wet peel at 0.3 ppm, rice, hulls at 25.0 ppm, and rice bran at 10.0 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 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-301094 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 April 23, 2001.

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-301094, 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: December 15, 2000.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.484 is amended by alphabetically adding commodities to the table in paragraph (a)(1) to read as follows:

§ 180.484 Flutolanil, N-(3-(1-methylethoxy)phenyl)-2-(trifluoromethyl) benzamide; tolerances for residues.

(a)(1) *General.* * * *

Commodity	Parts per million
Potato	0.20
Potato, wet peel	0.30
Rice, bran	10.0
Rice, grain	7.0
Rice, hulls	25.0
Rice, straw	10.0

* * * * *

[FR Doc. 01-2047 Filed 2-16-01; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301096; FRL-6762-1]

RIN 2070-AB78

Dimethylpolysiloxane; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an existing exemption from the requirement of a tolerance for residues of dimethylpolysiloxane; when used as an inert ingredient in or on growing crops, and when applied to raw agricultural commodities after harvest. Wacker Silicones Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of dimethylpolysiloxane.

DATES: This regulation is effective February 20, 2001. Objections and requests for hearings, identified by docket control number OPP-301096, must be received by EPA on or before April 23, 2001.

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 VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301096 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone number; (703) 308-6379 and e-mail address: gairola.indira@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/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301096. 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 September 13, 2000 (65 FR 55240) (FRL-6738-2), 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 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 5E4430) by Wacker Silicones Corporation, 3301 Sutton Road, Adrian, Michigan 49221-9397. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c), be amended by revising an exemption from the requirement of a tolerance for residues of