

§ 558.550 [Amended]

17. Section 558.550 *Salinomycin* is amended in paragraphs (d)(1)(x)(c) and (d)(1)(xii)(c) by removing “053571” and by adding in its place “066104”.

18. Section 558.555 is amended by revising paragraph (a); by removing paragraph (c); by redesignating paragraph (b) as paragraph (c); in paragraph (d) by removing “000069” wherever it appears and by adding in its place “066104”; and by adding new paragraph (b) to read as follows:

§ 558.555 Semduramicin.

(a) *Specifications.* Type A medicated article containing 22.7 grams per pound (50 grams per kilogram) semduramicin sodium.

(b) *Approvals.* See No. 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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§ 558.625 [Amended]

19. Section 558.625 *Tylosin* is amended in paragraph (b)(25) by removing “000069” and by adding in its place “066104”.

§ 558.635 [Amended]

20. Section 558.635 *Virginiamycin* is amended in paragraph (a)(1) by removing “000069” and by adding in its place “066104”.

Dated: August 31, 2001.

Claire M. Lathers,

Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301164; FRL-6798-5]

RIN 2070-AB78

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 the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr in or on grass, forage and grass, hay and modifies the existing permanent tolerances for milk and for kidney of cattle, goat, hog, horse, and sheep. This action is in response to

EPA’s granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pastures and rangeland. This regulation establishes maximum permissible levels for residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr in these food commodities. The tolerances will expire and are revoked on June 30, 2003.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP-301164, must be received by EPA on or before November 16, 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 VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301164 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9367, and e-mail address: ertman.andrew@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 control number OPP-301164. 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 the combined residues of the herbicide fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and

conjugated, all expressed as fluroxypyr, in or on grass, forage at 120 part per million (ppm), grass, hay at 160 ppm, and modifying the permanent tolerances for milk from 0.1 ppm to 0.30 ppm and for kidney (cattle, goat, hog, horse, and sheep) from 0.5 ppm to 1.5 ppm. These tolerances will expire and are revoked on June 30, 2003. 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 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. . . ."

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such

emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fluroxypyr on Pastures and Rangeland and FFDCA Tolerances

Sericea lespedeza (also known as Chinese bush clover) is a perennial legume native to Asia that was introduced into the United States in 1896 for use as forage for livestock and as an erosion control plant. It was first recognized as a potential weed problem in southeast Kansas in the early 1980s. The Kansas Legislature made sericea lespedeza a statewide noxious weed effective July 1, 2000. It is the first federally listed crop to be declared a noxious weed.

While sericea lespedeza remains a relatively important forage crop in several southeastern states, it has become an invasive weed in tall grass and high plains prairie lands. Sericea aggressively competes with native prairie plants, and can result in a substantial reduction of native grasses and broadleaf plants. Researchers at Emporia State University (Emporia, Kansas) found that the number of grass and forb species in severely infested fields in east-central Kansas declined by 66% and 74% respectively. In a Kansas State University study, native grass production was reduced by as much as 80% when compared to non-infested areas. In addition, sericea lespedeza develops high tannin levels under the low rainfall conditions that exist in Kansas and becomes unpalatable to cattle as it matures. EPA has authorized under FIFRA section 18 the use of fluroxypyr on pastures and rangeland for control of sericea lespedeza in Kansas. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fluroxypyr in or on grass forage and hay and their associated commodities. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 2003, under FFDCA

section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on grass forage and hay and their associated commodities after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances is being approved under emergency conditions, EPA has not made any decisions about whether fluroxypyr meets EPA's registration requirements for use on pastures and rangeland or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of fluroxypyr by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Kansas to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fluroxypyr, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 fluroxypyr and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr, in or on grass, forage at 120 ppm, grass, hay at 160 ppm, and modifying the permanent tolerances for milk from 0.1 ppm to 0.30 ppm and for

kidney (cattle, goat, hog, horse, and sheep) from 0.5 ppm to 1.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. 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 level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently

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

TABLE 1. — SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUROXYPYR FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Endpoint/LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–50 years of age	Developmental NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1.0 mg/kg/day	FQPA SF = 3x aPAD = acute RfD FQPA SF = 0.33 mg/kg/day	Developmental rabbit Developmental LOAEL = 250 mg/kg/day, based on increased postimplantation loss.
Acute dietary general population including infants and children	A dose and endpoint were not selected for this population group because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose). A risk assessment is not required for this population subgroup.		
Chronic dietary all populations	NOAEL = 50 mg/kg/day UF = 100 Chronic RfD = 0.50 mg/kg/day	FQPA SF = 1X cPAD = cRfD = FQPA SF = 0.50 mg/kg/day	28–day dog range-finding feeding study LOAEL = 150 mg/kg/day based on histopathological lesions in the kidneys, decreased testes weights, and increased adrenal weights in both sexes.
Incidental, Oral: Short-term (1–7 days), Intermediate-term (1 week - several months), Long-term (several months - lifetime) (Residential)	Since there are no residential uses, toxicology endpoints were not proposed/selected for any exposure scenarios.		
Dermal ¹ and Inhalation ² , Short-term (1–7days) (Occupational/Residential)	Oral NOAEL= 100 mg/kg/day	LOC for MOE = 100 (Occupational)	Developmental rabbit study Developmental LOAEL = 250 mg/kg/day, based on increased postimplantation loss.
Dermal ¹ and Inhalation ² : Intermediate-term (1 week-several months) (Occupational/Residential)	Oral NOAEL= 100 mg/kg/day	LOC for MOE = 100 (Occupational)	Developmental rabbit study Developmental LOAEL = 250 mg/kg/day, based on increased postimplantation loss.

¹ Since an oral NOAEL was selected, a dermal absorption factor of 100% (default value) should be used in route-to-route extrapolation.

² Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) should be used in route-to-route extrapolation.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.535) for the combined residues of fluroxypyr, in or on a variety of raw agricultural commodities, including meat, milk, poultry and eggs. Risk assessments were conducted by EPA to assess dietary exposures from fluroxypyr in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: For the acute analysis, published and proposed tolerances level residues were used. Default concentration factors and 100% CT was assumed for all commodities.

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: For the chronic analysis, published and proposed tolerances level residues were used. Default concentration factors and 100% CT was assumed for all commodities.

iii. *Cancer.* The Agency has classified fluroxypyr as “not likely” to be a human carcinogen, therefore this risk assessment is not required.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fluroxypyr 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 fluroxypyr.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and

Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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 fluroxypyr they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of fluroxypyr for acute exposures are estimated to be 7.6 parts per billion (ppb) for surface water and 0.017 ppb for ground water. The EECs for chronic exposures are estimated to be 1.6 ppb for surface water and 0.017 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).

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

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” aggregate exposure 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 fluroxypyr 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, fluroxypyr 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 fluroxypyr 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).

C. 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. *Developmental toxicity studies.* In the developmental study in rats, the maternal (systemic) NOAEL was 125 milligrams/kilograms/day (mg/kg/day), based on clinical signs at the LOAEL of 250 mg/kg/day. The developmental (fetal) NOAEL was 250 mg/kg/day, based on reduced ossification at the LOAEL of 500 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 250 mg/kg/day, based on maternal deaths at the LOAEL of 400 mg/kg/day.

The developmental (pup) NOAEL was 125 mg/kg/day, based on increased postimplantation loss at the LOAEL of 250 mg/kg/day.

3. *Reproductive toxicity study.* In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was 100 mg/kg/day, based on increased kidney weights and kidney histopathology at the LOAEL of 500 mg/kg/day. The developmental (pup) NOAEL was 500 mg/kg/day, based on decreased body weight at the LOAEL of 1,000 mg/kg/day. The reproductive NOAEL was 1,000 mg/kg/day (HDT).

4. *Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for fluroxypyr is complete with respect to current data requirements. Based on the results of the rabbit developmental toxicity study for fluroxypyr there does appear to be an extra sensitivity for prenatal effects.

5. *Conclusion.* Based on the above, EPA concludes that reliable data support use of a 300 fold margin of exposure/uncertainty factor, rather than the standard 1,000 fold margin/factor, to protect infants and children.

D. 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 + chronic non-dietary, non-occupational 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 US EPA Office of Water are used to calculate DWLOCs: 2Liter/70 kilogram (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 ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to fluroxypyr 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 fluroxypyr on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to fluroxypyr will occupy 1.5% of the aPAD for females 13-50 years old, the only population sub-group of concern. A dose and endpoint were not selected for the U.S. population, including infants and children because there were no effects observed in oral toxicology studies including maternal toxicity in the developmental toxicity studies in rats and rabbits that are attributable to a single exposure (dose). Therefore, a risk assessment is not required for this population subgroup.

In addition, despite the potential for acute dietary exposure to fluroxypyr in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of fluroxypyr in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2. — AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUROXYPYR

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13-50 years old)	0.33	1.5	7.6	0.017	9,700

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fluroxypyr from food will utilize 0.6% of the cPAD for the U.S. population, 0.9% of the cPAD for all infants < 1 year old and 2.1% of the

cPAD for children 1-6 years old. There are no residential uses for fluroxypyr that result in chronic residential exposure to fluroxypyr. In addition, despite the potential for chronic dietary exposure to fluroxypyr in drinking water, after calculating DWLOCs and

comparing them to conservative model estimated environmental concentrations of fluroxypyr in 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 FLUROXYPYR

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population (48 contiguous states)	0.50	0.6	1.6	0.017	17,000
All infants (< 1 year old)	0.50	0.9	1.6	0.017	5,000
Children (1-6 years old)	0.50	2.1	1.6	0.017	4,900

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

Population Subgroup	cPAD mg/ kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children (7–12 years old)	0.50	1.1	1.6	0.017	4,900
Females (13–50 years old)	0.50	0.4	1.6	0.017	15,000
Males (13–19 years old)	0.50	0.7	1.6	0.017	17,000
Males (20+ years old)	0.50	0.4	1.6	0.017	17,000
Seniors (55+ years old)	0.50	0.4	1.6	0.017	17,000

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).

Fluroxypyr is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

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

Fluroxypyr is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified fluroxypyr as “not likely” to be a human carcinogen, therefore this risk assessment is not required.

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 fluroxypyr residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. 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 CODEX, Canadian, or Mexican Maximum Residue Limits (MRLs) for fluroxypyr on grass.

VI. Conclusion

Therefore, tolerances are established for the combined residues of fluroxypyr 1-methylheptyl ester and its metabolite fluroxypyr, free and conjugated, all expressed as fluroxypyr, in or on grass, forage at 120 part per million (ppm), grass, hay at 160 ppm, and the permanent tolerances are modified for milk from 0.1 ppm to 0.30 ppm and for kidney (cattle, goat, hog, horse, and sheep) from 0.5 ppm to 1.5 ppm.

VII. 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-301164 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 16, 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 VII.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 the docket control number OPP-301164, 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 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).

VIII. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDC section 408. 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 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 FIFRA section 18 exemption under FFDC section 408, such as the tolerances 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 FFDC section 408(n)(4). 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.

IX. 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: August 30, 2001.

James Jones,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.535 is amended by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

* * * * *
(b)* * *

Commodity	Parts per million	Expiration/Revocation Date
Grass, forage	120	6/30/03
Grass hay	160	6/30/03
Kidney, cattle	1.5	6/30/03
Kidney, goat	1.5	6/30/03
Kidney, hog	1.5	6/30/03
Kidney, horse	1.5	6/30/03
Kidney, sheep	1.5	6/30/03
Milk	0.30	6/30/03

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301168; FRL-6800-9]

RIN 2070-AB78

Clethodim; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of clethodim in or on green onion, leaf lettuce, Brassica, head and stem, subgroup, flax seed, flax meal, mustard seed, canola seed, and canola meal. The Interregional Research Project Number-4 (IR-4) and Valent U.S.A. Corporation requested these tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This final rule establishes permanent tolerances for clethodim and as part of that process the Agency has reassessed existing tolerances. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. All permanent tolerances for clethodim that existed on August 2,

1996 were previously reassessed in the **Federal Register** of April 8, 1998 (63 FR 17101) (FRL-5784-9). Consequently, regarding the actions in this final rule, no tolerance reassessments are counted toward the August 2002 review deadline of FFDCA section 408(q).

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings, identified by docket control number OPP-301168, must be received by EPA on or before November 16, 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-301168 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; and e-mail address: brothers.shaja@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