§ 685.200 [Amended]

■ 24. Section 685.200 is amended by:
■ A. In paragraph (a)(1)(iv)(C)(2), removing the words ''requirement in paragraph (a)(1)(iv)(A)(1)'' and adding, in their place, the words ''requirements in paragraphs (a)(1)(iv)(A)(*1*) and (*2*)''.
■ B. In paragraph (a)(1)(iv)(C)(*3*), removing the words ''neither the prior loan nor the Direct Loan that the borrower receives may'' and adding, in their place, the words ''the loan that has been conditionally discharged prior to a final determination of total and permanent disability cannot''.

§ 685.203 [Amended]

■ 25. Section 685.203(b) is amended by removing the words ''Federal Unsubsidized Stafford/Ford Loan Program'' and adding, in their place, the words ''Federal Unsubsidized Stafford Loan Program''.

§ 685.205 [Amended]

■ 26. Section 685.205(b)(3) is amended by adding the words ''without the Secretary's knowledge'' after the word ''repayment''.

■ 27. Section 685.207 is amended by revising paragraph (f) to read as follows:

§ 685.207 Obligation to repay.

* * * * *

(f) *Determining the date on which the grace period begins for a borrower in a correspondence program.* For a borrower of a Direct Subsidized or Direct Unsubsidized Loan who is a correspondence student, the grace period specified in paragraphs (b)(2) and (c)(2) of this section begins on the earliest of—

(1) The day after the borrower completes the program;

(2) The day after withdrawal as determined pursuant to 34 CFR 668.22; or

(3) 60 days following the last day for completing the program as established by the school.

§ 685.210 [Amended]

■ 28. Section 685.210(b)(1) is amended, in the second sentence, by removing the reference to ''§ 685.211(c)(3)(ii)'' and adding, in its place, the reference to ''§ 685.211(d)(3)(ii)''.

§ 685.220 [Amended]

■ 29. Section 685.220 is amended by:
■ A. In paragraph (b)(1), adding the word ''Subsidized'' after the word ''Federal''.
■ B. In paragraph (d)(1)(ii)(F), removing the reference to ''§ 685.209(d)(5)'' and adding, in its place, the reference to ''§ 685.209(c)(7)''.
■ C. In paragraph (h)(2), removing the reference to ''(d)(1)(ii)(E)'' and adding, in its place, the reference to ''(d)(1)(ii)(F)''.

§ 685.301 [Amended]

■ 30. Section 685.301 is amended by:
■ A. In paragraph (a)(4)(i), adding a period after''§ 685.203'' and removing the remainder of the sentence.
■ B. In paragraph (a)(7), removing the word ''student'' and adding, in its place, the word ''borrower''.

§ 685.302 [Removed and Reserved]

■ 31. Section 685.302 is removed and reserved.

§ 685.303 [Amended]

■ 32. Section 685.303 is amended in paragraph (b)(2)(i) by removing the words ''described in the promissory note'' and adding, in their place, the words ''for which the loan was intended''.

[FR Doc. 03–32062 Filed 12–30–03; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0377; FRL–7340–5]

Fluroxypyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluroxypyr in or on field corn, sweet corn, sorghum, range and pasture grass. Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective December 31, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0377, must be received on or before March 1, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703)305–6224; e-mail address: *miller.joanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., Agricultural workers; Greenhouse, nursery, and floriculture workers; Farmers.
- Animal production (NAICS 112), e.g., Cattle ranchers and farmers, Dairy cattle farmers, Livestock farmers.
- Food manufacturing (NAICS 311), e.g., Agricultural workers; Farmers; Greenhouse, nursery, and floriculture workers; Ranchers; Pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., Agricultural workers; Commercial applicators; Farmers; Greenhouse, nursery, and floriculture workers; Residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0377. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m.,

Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html/*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 14, 2003 (68 FR 25883) (FRL–7301–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 9F6050) by Dow AgroSciences LLC, 9330 Zionville Road, Indianapolis, IN 46268. That notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.535 be amended by establishing tolerances for combined residues of the herbicide fluroxypyr 1-methylheptyl ester [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy) acetic acid, 1-methylheptyl] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy) acetic acid], free and conjugated, all expressed as fluroxypyr, in or on the following raw agricultural commodities: Sweet corn at 0.02 parts per million (ppm) for kernels plus cob with husk removed, and forage and stover at 1.0 ppm. Tolerances for residues of fluroxypyr in or on field corn are being proposed in support of this registration as follows: grain, 0.02 ppm; forage, 1.0 ppm; and stover, 0.5 ppm. Tolerances for residues of fluroxypyr in or on sorghum as follows: Grain, 0.02 ppm; forage, 2.0 ppm; and stover, 4.0 ppm. Tolerances for residues of fluroxypyr in or on grasses as follows: Forage, 120 ppm; hay, 160 ppm; and grass silage, 100 ppm. Increased tolerances are also proposed for fluroxypyr in or on the following animal commodities: Milk of cattle, goats, hogs, horses and sheep at 0.3 ppm; and kidney of cattle, goats, hogs, horses and sheep at 1.5 ppm.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for tolerances for combined residues of fluroxypyr on or in field corn, grain at 0.02 ppm; field corn, forage at 1.0 ppm; field corn, stover at 0.5 ppm; on or in sweet corn, kernels plus cob with husks removed at 0.02 ppm; sweet corn, forage at 1.0 ppm; sweet corn, stover at 2.0 ppm; on or in sorghum, grain at 0.02 ppm; sorghum, forage at 2.0 ppm; sorghum, stover (fodder) at 4.0 ppm; on or in grass, forage at 120 ppm; grass, hay at 160 ppm; and a tolerance for combined residues of fluroxypyr on cattle, milk; goat, milk; hog, milk; horse, milk; and sheep, milk at 0.3 ppm; and on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 1.5 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 fluroxypyr are discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity—Rats	NOAEL = 700 milligram/kilogram/day (mg/kg/day) LOAEL = 1,000 mg/kg/day based on decreased body weight gain & testis weight (M), decreased brain weight (F), and increased kidney weight (M/F).
870.3100	90–Day oral toxicity—Mice	NOAEL = 1,342 mg/kg/day (Males)/ 1,748 mg/kg/day (Females) LOAEL not established.

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

Guideline No.	Study Type	Results
870.3200	21/28–Day dermal toxicity	NOAEL = 1,000 mg/kg/day LOAEL not established
870.3700	Prenatal developmental—Rodents	Maternal NOAEL = 300 mg/kg/day LOAEL = 600 mg/kg/day based on increased maternal deaths and decreased body weight gains and food consumption. Developmental NOAEL = 600 mg/kg/day LOAEL not established.
870.3700	Prenatal developmental—Nonrodents	Maternal NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased abortions. Developmental NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased abortions.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 100 mg/kg/day (Males) / 500 mg/kg/day (Females) LOAEL = 500 mg/kg/day (Males) / 1,000 mg/kg/day (Females), based on kidney effects (M&F) and increased deaths (F). Reproductive NOAEL = 750 mg/kg/day (Males) / 1,000 mg/kg/day (Females). LOAEL not established. Offspring NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on decreased pup weight and body weight gain and slightly lower survival.
870.4100	Chronic toxicity—Dogs	NOAEL = 150 mg/kg/day LOAEL not established.
870.4200	Carcinogenicity—Mice	NOAEL = 300 mg/kg/day (Males/Females) LOAEL = 1,000 mg/kg/day based on decreased body weight and body weight gain (M) and increased kidney lesions (F).(no) evidence of carcinogenicity
870.4300	Carcinogenicity—Rats	NOAEL = 100 mg/kg/day LOAEL = 500 mg/kg/day based on chronic progressive kidney glomerulonephropathy (M&F).(no) evidence of carcinogenicity
870.5100	Bacterial reverse mutation	Negative.
870.5300	*In vitro* mammalian cell gene mutation	Negative, but did not test a soluble dose.
870.5375	*In vitro* mammalian chromosome aberration (HL)	Negative.
870.5395	Mammalian micronucleus (mouse)	Negative.
870.7485	Metabolism and pharmacokinetics	Total recovery of the administered dose was 105%, with the principal route of excretion being expired $14CO_2$, which contained approximately 61% of the radioactivity for the fluroxypyr MHE. The urine contained approximately 30% and the feces contained 5% of the administered dose. At 48 hours post dose, approximately 7% of the administered dose was recovered in the blood, carcass, and skin. Approximately 52% of the administered dose was absorbed and expired as $14CO_2$ within 12 hours post dose, and an additional 18% of the administered dose was excreted in the urine within 12 hours post dose. Based on the percentage of dose in the expired $14CO_2$, urine, and tissues, approximately 90% of the dose was absorbed. Once absorbed, it was extensively metabolized and rapidly expired as $14CO_2$ and eliminated in the urine with a half-life of 6 hours. Peak plasma concentrations of 14C-radioactivity were attained by 7 hours post dose.

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.

Three other types of safety or uncertainty factors may be used: ''Traditional uncertainty factors;'' the

''special FQPA safety factor;'' and the ''default FQPA safety factor.'' By the term ''traditional uncertainty factor,'' EPA is referring to those additional uncertainty factors used prior to FQPA passage to account for database deficiencies. These traditional uncertainty factors have been incorporated by the FQPA into the additional safety factor for the protection of infants and children. The term ''special FQPA safety factor'' refers to those safety factors that are deemed necessary for the protection of infants and children primarily as a result of the FQPA. The ''default FQPA safety factor'' is the additional 10X safety factor that is mandated by the statute unless it is decided that there are reliable data to choose a different additional factor (potentially a traditional uncertainty factor or a special FQPA safety factor).

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 an UF of 100 to account for interspecies and intraspecies differences and any traditional uncertainty factors deemed appropriate (RfD = NOAEL/UF). Where a special FQPA safety factor or the default FQPA safety factor is used, 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 safety factor.

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk). An example of how such a probability risk is expressed would be to describe the risk as one in one hundred thousand (1×10^{-5}), one in a million (1×10^{-6}), or one in ten million (1×10^{-7}). 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 Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUROXYPYR FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional UF	Special FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary(All populations)	NOAEL = NA UF = NA Acute RfD = NA	FQPA SF = NA aPAD = acute RfD/ FQPA SF = NA	No appropriate endpoint to quantify single dose exposure.
Chronic Dietary(All populations)	NOAEL= 100 mg/kg/day UF = 100 Chronic RfD =1 mg/kg/day	FQPA SF = 1x cPAD =chronic RfD/ FQPA SF = 1 mg/kg/day	Chronic/Onco-Rat LOAEL = 100 mg/kg/day based on kidney effects.
Short-TermIncidental Oral (1-30 days)	NOAEL= 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Chronic/Onco-Rat LOAEL = 100 mg/kg/day based on kidney effects.
Intermediate-TermIncidental Oral (1- 6 months)	NOAEL= 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Chronic/Onco-Rat LOAEL = 100 mg/kg/day based on kidney effects.
Dermal(All durations)	Dermal (or oral) study NOAEL=NA	Residential LOC for MOE = NA Occupational LOC for MOE = NA	Quantification not required since 21-Day dermal rabbit NOAEL = 1,000 mg/kg/day and there is no developmental toxicity concern.
Inhalation(All durations)	Inhalation (or oral) study NOAEL= 100 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic/Onco-Rat LOAEL = 100 mg/kg/day based on kidney effects.
Cancer (oral, dermal, inhalation)	Classification: ''not likely'' human carcinogen		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

C. 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. Tolerances have also been established for the combined residues of fluroxypyr on meat and milk. 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.

No adverse effect attributable to a single exposure (dose) of fluroxypyr was observed in the oral toxicity studies. Therefore, EPA did not identify an acute dietary endpoint and a quantitative acute dietary assessment was not performed because no acute risk is expected.

ii. *Chronic exposure.* In conducting the chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID^T), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 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: 100% crop treated (PCT) and tolerance-level residues for fluroxypyr on all treated crops. This assessment was Tier I analysis. The exposures from fluroxypyr residues are below EPA's level of concern (<100% of the chronic population adjusted dose (cPAD)) for the general U.S. population (<1% of the cPAD) and all population subgroups.

iii. *Cancer.* Fluroxypyr is classified as ''not likely'' a human carcinogen and there was no concern for its mutagenicity potential.

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 used the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), a Tier 2 model, to estimate pesticide concentrations in surface water. PRZM/EXAMS incorporates an index reservoir environment and includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin. The Tier 1 Screening Concentration In Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water.

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 screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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), which are the model estimates of a pesticide's concentration in water. EECs derived from these models are used 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 in Unit III.E.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of fluroxypyr for acute exposures are estimated to be 32.9 parts per billion (ppb) for surface water and 0.04 ppb for ground water. The EECs for chronic exposures are estimated to be 3.3 ppb for surface water and 0.062 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 currently registered for use on the following residential non-dietary sites: Residential turfgrass and recreational sites such as golf courses and sports fields. The risk assessment was conducted using the following residential exposure assumptions: Adults and children may be exposed to fluroxypyr residues from dermal contact with turf during postapplication activities. Toddlers may receive short- and intermediate-term oral exposure from incidental ingestion during postapplication activities. Residential handlers may receive short-term dermal and inhalation exposure to fluroxypyr when mixing, loading and applying the formulations.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether fluroxypyr has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluroxypyr and any other substances and 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 policy statements released by EPA's OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative/*.

D. Safety Factor for Infants and Children

1.*In general.* Section 408 of FFDCA 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 based on reliable data that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in

calculating a dose level that poses no appreciable risk to humans. In applying this provision, EPA either retains the default value of 10 X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional safety factor value based on the use of traditional uncertainty factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased susceptibility of rat or rabbit fetuses following in utero exposure in the developmental studies with fluroxypyr. There is no evidence of increased susceptibility of rats in the reproduction study with fluroxypyr. EPA concluded there are no residual uncertainties for prenatal and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for fluroxypyr and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed and instead, a different additional safety factor of 1X should be used. The FQPA factor is removed because: There is no evidence (quantitative/qualitative) of increased susceptibility following in utero exposure to the acid and the ester of fluroxypyr in rats and rabbits, or following pre and/or postnatal exposure to the acid of fluroxypyr in rats; there are no concerns or residual uncertainties for pre- and/or post-natal toxicity; there is no evidence of neurotoxicity or neuropathology in the available studies; the toxicological database is complete for FQPA assessment; the chronic dietary food exposure assessment utilizes tolerance level residue estimates and assumes 100% CT for all commodities, thus not likely to underestimate exposure/risk; the dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded; and the residential exposure assessment was conducted using standard assumptions which are based on carefully reviewed data.

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 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 EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/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 ground water 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*. A quantitative acute risk assessment was not performed. No adverse effect attributable to a single exposure(dose) of fluroxypyr was observed in the oral toxicity studies and no acute risk is expected.

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 <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants, and 1.4% of the cPAD for children (1-2 years old). In addition, there is potential for chronic dietary exposure to fluroxypyr 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 Table 3 of this unit. Based upon the use pattern, chronic (non-dietary) residential exposure to residues of fluroxypyr is not expected.

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

PopulationSubgroup	cPADmg/kg/day	%cPAD(Food)	Surface Water EEC(ppb)	Ground-Water EEC(ppb)	ChronicDWLOC (ppb)
U.S. Population	1	<1	3.3	0.042	35,000
All infants (<1 year old)	1	<1	3.3	0.042	10,000
Children (1-2 years old)	1	1.4	3.3	0.042	9,900

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 currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fluroxypyr.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 31,000 for the U.S. population and 4,500 for children (1-2 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition,

short-term DWLOCs were calculated and compared to the EECs for chronic exposure of fluroxypyr in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FLUROXYPYR

PopulationSubgroup	AggregateMOE(Food + Residential)	Aggregate Level of Concern(LOC)	Surface Water EEC(ppb)	Ground-Water EEC(ppb)	Short-Term DWLOC (ppb)
U.S. Population	31,000	100	3.3	0.042	35,000
Children(1-2 years old)	4,500	100	3.3	0.042	9,800

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

Fluroxypyr 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 fluroxypyr.

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 31,000 for the U.S. population and 4,500 for children (1-2 years old). These aggregate MOEs do not exceed the Agency's 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 fluroxypyr 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 Table 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO FLUROXYPYR

PopulationSubgroup	AggregateMOE(Food + Residential)	Aggregate Level of Concern(LOC)	Surface Water EEC(ppb)	Ground-Water EEC(ppb)	Inter-mediate-Term DWLOC (ppb)
U.S. Population	31,000	100	3.3	0.042	35,000
Children(1-2 years old)	4,500	100	3.3	0.042	9,800

5. *Aggregate cancer risk for U.S. population.* Fluroxypyr is classified as a not likely human carcinogen and is not expected to pose a cancer risk.

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.

IV. Other Considerations

A. Analytical Enforcement Methodology

The gas chromatography/mass selective detector (GC/MSD) enforcement method, submitted by Dow AgroSciences LLC, has been validated for the determination of residues of fluroxypyr and fluroxypyr 1-MHE as the acid equivalent in plant commodities. The method for livestock commodities has been validated for the determination of residues of fluroxypyr and fluroxypyr 1-MHE in cow milk and liver. The proposed plant and animal method is adequate for enforcement of tolerances in/on field corn, sweet corn, sorghum, range and pasture grass, and animal commodities as a result of this use.

Fluroxypyr has been tested through the FDAs Multiresidue Methodology, Protocols C, D, and E. The results have been published in the FDA Pesticide Analytical Manual, Volume I.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits, for residues of fluroxypyr in/on field corn, sweet corn, sorghum, range and pasture grass. Harmonization is not an issue for this petition.

C. Conditions

The following data are being required to confirm the results of the studies already reviewed by the Agency and/or to complete the database requirements prior to approval of an unconditional sweet corn registration:

i. Additional field trials - conduct and submit four (4) additional field trials in Regions III (1 trial), V(1 trial), XI(1 trial), and XII(1 trial). Residue analysis of sweet corn field trial samples should avoid using the DowElanco Method ACR 90.8, due to matrix interference cited in PP#2G04066.

ii. Storage stability data - submit to support the sweet corn field trial data.

iii. 28-Day Inhalation Toxicity Study

V. Conclusion

Therefore, the tolerances are established for combined residues of fluroxypyr 1-methylheptyl ester [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy) acetic acid, 1-methylheptyl] and its metabolite fluroxypyr [((4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy) acetic acid], free and conjugated, all expressed as fluroxypyr, in or on field corn, grain at 0.02 ppm; field corn, forage at 1.0 ppm; field corn, stover at 0.5 ppm; on or in sweet corn, kernels plus cob with husks removed at 0.02 ppm; sweet corn, forage at 1.0 ppm; sweet corn, stover at 2.0 ppm; on or in sorghum, grain at 0.02 ppm; sorghum, forage at 2.0 ppm; sorghum, stover (fodder) at 4.0 ppm; and on or in grass, forage at 120 ppm; grass, hay at 160 ppm. Tolerances are revised for combined residues of fluroxypyr on cattle, milk; goat, milk;

hog, milk; horse, milk; and sheep, milk at 0.3 ppm; and on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 1.5 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0377 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 March 1, 2004.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

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

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0377, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary

consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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 22, 2003.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.535 is amended by alphabetically adding new commodities and revising the commodities ''cattle, kidney,'' ''goat, kidney,'' ''hog, kidney,'' ''horse, kidney,'' ''milk,'' and ''sheep, kidney'' in the table in paragraph (a) to read as follows:

§ 180.535 Fluroxypyr; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Cattle, kidney	1.5
* * *	* *
Corn, field, forage	1.0
Corn, field, grain	0.02
Corn, field, stover	0.5
Corn, sweet, forage	1.0
Corn, sweet, kernel plus cob with husks removed	0.02
Corn, sweet, stover	2.0
* * *	* *
Goat, kidney	1.5
* * *	* *
Grass, forage	120
Grass, hay	160
* * *	* *
Hog, kidney	1.5
* * *	* *
Horse, kidney	1.5
* * *	* *
Milk	0.3
* * *	* *
Sheep, kidney	1.5
* * *	* *
Sorghum, grain, forage	2.0
Sorghum, grain, grain	0.02
Sorghum, grain, stover	4.0
* * *	* *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0394; FRL–7337–5]

Cyprodinil; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends the time-limited tolerances for residues of cyprodinil, 4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine in or on onion, dry bulb; onion, green; and strawberry. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance will expire on December 31, 2004.

DATES: This regulation is effective December 31, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0394, must be received on or before March 1, 2004.