also not subject to Executive Order 13211.

J. 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 the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

K. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 25, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action to reclassify the Atlanta area as a severe ozone nonattainment area and to adjust applicable deadlines may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: September 15, 2003.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

■ 40 CFR part 81 is amended as follows:

PART 81—[AMENDED]

■ 1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. In § 81.311 the table entitled ''Georgia—Ozone (1-hour standard)'' is amended by revising the entry for the Atlanta area to read as follows:

§ 81.311 Georgia.

* * * * *

GEORGIA—OZONE (1-HOUR STANDARD)

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Classification
Atlanta Area:				
Cherokee County	11/15/1990	Nonattainment	1/01/2004	Severe.
Clayton County	11/15/1990	Nonattainment	1/01/2004	Severe.
Cobb County	11/15/1990	Nonattainment	1/01/2004	Severe.
Coweta County	11/15/1990	Nonattainment	1/01/2004	Severe.
DeKalb County	11/15/1990	Nonattainment	1/01/2004	Severe.
Douglas County	11/15/1990	Nonattainment	1/01/2004	Severe.
Fayette County	11/15/1990	Nonattainment	1/01/2004	Severe.
Forsyth County	11/15/1990	Nonattainment	1/01/2004	Severe.
Fulton County	11/15/1990	Nonattainment	1/01/2004	Severe.
Gwinnett County	11/15/1990	Nonattainment	1/01/2004	Severe.
Henry County	11/15/1990	Nonattainment	1/01/2004	Severe.
Paulding County	11/15/1990	Nonattainment	1/01/2004	Severe.
Rockdale County	11/15/1990	Nonattainment	1/01/2004	Severe.
*	*	*	*	*

[1] This date is October 18, 2000, unless otherwise noted.

[FR Doc. 03–24404 Filed 9–25–03; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0264; FRL–7321–4]

Imazapyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of imazapyr [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid] in or on grass, forage; grass, hay; fish; shellfish; fats of cattle, sheep, goats, and horses; kidney of cattle, sheep, goats, and horses; meat byproducts (except kidney) of cattle, sheep, goats, and horses; meat of cattle, sheep, goats, and horses; and milk.. BASF 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0264, must be received on or before November 25, 2003.

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: Jim Tompkins, Registration Division, 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305-5697; e-mail address: *tompkins.jim@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)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in **FOR FURTHER INFORMATION CONTACT**. 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–2003–0264. 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 August 13, 2003 (68 FR 48362) (FRL–7321–7), 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 0F6166) by BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709–3528. That notice included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.500 be amended by establishing a tolerance for residues of the herbicide imazapyr, in or on grass, forage at 100 parts per million (ppm); grass, hay at 30 ppm; fish at 1.0 ppm; shellfish at 0.10 ppm; fats of cattle, sheep, goats, and horses 0.05 ppm; kidney of cattle, sheep, goats, and horses at 0.20 ppm; meat byproducts (except kidney) of cattle, sheep, goats, and horses at 0.05 ppm; meat of cattle, sheep, goats, and horses at 0.05 ppm; and milk at 0.01 ppm.

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

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of imazapyr on grass, forage at 100 ppm; grass, hay at 30 ppm; fish at 1.0 ppm; shellfish at 0.10 ppm; fats of cattle, sheep, goats, and horses 0.05 ppm; kidney of cattle, sheep, goats, and horses at 0.20 ppm; meat byproducts (except kidney) of cattle, sheep, goats, and horses at 0.05 ppm; meat of cattle, sheep, goats, and horses at 0.05 ppm; and milk at 0.01 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 imazapyr are discussed in Tables 1 and 2 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.—ACUTE TOXICITY OF IMAZAPYR TECHNICAL GRADE ACTIVE INGREDIENT (TGAI).

Guideline No/Study Type	Results	Toxicity Category
870.1100 Acute Oral	LD_{50} = >5,000 mg/kg	IV

TABLE 1.—ACUTE TOXICITY OF IMAZAPYR TECHNICAL GRADE ACTIVE INGREDIENT (TGAI).—Continued

Guideline No/Study Type	Results	Toxicity Category
870.1200 Acute Dermal	LD_{50} = >**2,000** mg/kg	III
870.1300 Acute Inhalation	LC_{50} = >1.3 mg/L (gravimetric) >5.1 mg/L (nominal)	III
870.2400 Primary Eye Irritation	Corneal Opacity; Conjunctive: redness, Chemosis & Discharge; Vascularization of Cornea; Corrosive: Irreversible Eye Damage	I
870.2500 Primary Skin Irritation	Non-irritating to slight erythema and edema	IV
870.2600 Dermal Sensitization	Negative	

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents (rat)	Dermal and Systemic NOAEL =1,695 mg/kg/day for males and =1,784 mg/kg/day for females highest dose tested (HDT). This was the HDT; therefore, there is no LOAEL.
870.3200	21/28-Day dermal toxicity (rabbit)	Dermal and Systemic NOAEL = 400 mg/kg/day. This was the HDT; therefore, there is no LOAEL.
870.3700	Prenatal developmental toxicity in rodents (rat)	Maternal NOAEL = 300 mg/kg bw/day. LOAEL =1,000 mg/kg bw/day, based on salivation. Developmental NOAEL =1,000 mg/kg/day. This was the HDT; therefore, there is no LOAEL.
870.3700	Prenatal developmental toxicity in nonrodents (rabbit)	Maternal NOAEL =400 mg/kg bw/day This was the HDT; therefore, there is no LOAEL. Developmental NOAEL =400 mg/kg bw/day. This was the HDT; therefore, there is no LOAEL.
870.3800	Reproduction and fertility effects (rat)	Parental systemic, reproductive and offspring NOAEL =10,000 ppm (738 mg/kg bw/day in males 933.3 mg/kg bw/day in females). This was the HDT; therefore, there is no LOAEL.
870.4100	Chronic toxicity (rodent)	NA; see 870.4300
870.4100	Chronic toxicity (dog)	NOAEL is =10,000 ppm (250 mg/kg/day). This was the HDT; therefore, there is no LOAEL.
870.4200	Carcinogenicity (rat)	NA; see 870.4300
870.4200	Carcinogenicity (mouse)	NOAEL =10,000 ppm (1,301 mg/kg/day in males and 1,639 mg/kg/day in females). This was the HDT; therefore, there is no LOAEL.
870.4300	Combined Chronic/carcinogenicity (rat)	Increase in brain astrocytomas in male rats for which there was a statistically significant positive trend, but which was not statistically significant in pairwise comparison to controls. The CPRC considered the astrocytomas in the male rats unrelated to treatment because there was no statistically significant pairwise increase. Dosing was considered to be adequate based on the HDT of 10,000 ppm which exceeds the limit dose of 7000 ppm for mice.
870.5100	Bacterial reverse mutation (Ames Assay)	Negative up to 5,000 μg/plate.
870.5300	*In vitro* mammalian cell gene mutation	Negative up to toxic doses (5,000 μg/ml) with and without activation.
870.5375	*In vitro* mammalian chromosome aberration (CHO)	Negative up to toxic doses (5,000 μg/ml) with and without activation.

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5450	Rodent Dominant Lethal	Reported as negative (though unacceptable).
870.5550	Unscheduled DNA synthesis (RPH)	Reported as negative (though unacceptable).
870.7485	Metabolism and pharmacokinetics (rat)	No sex-related differences in absorption were apparent. Within 48 hours of treatment, >90% of the administered dose was recovered in the excreta suggesting that elimination of the labeled test material was rapid. No specific sequestering tissues or organs were identified. Seven days after treatment, essentially all the test material had been eliminated. Rats that received the test material by intravenous injection excreted 87-95% of the administered dose in the urine and approximately 6% into the feces. This suggests that 15-28% if the administered dose recovered in the feces represents unabsorbed material. Metabolite characterization studies show that essentially all of the test material was excreted unchanged. Two minor metabolites CL 252,974 and CL 60,032 were detected in the urine or feces of treated rats; however, their contribution combined was <0.5% of the administered dose. Up to 12 additional unidentified metabolites were isolated, but they constituted >3% of the administered dose. Based on the results, the study author suggests that what limited metabolism of CL 243,997 occurs, proceeds through hydrolysis to form the 2-carbonyl derivatives: CL 252,974 and CL 60,032.
870.7600	Dermal penetration	NA

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 margin of exposure (MOE). A UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

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

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

A summary of the toxicological endpoints for imazapyr used for human risk assessment is shown in Table 3 of this unit:

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMAZAPYR FOR USE IN HUMAN RISK ASSESSMENT.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age and General population including infants and children)	none	none	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributable to a single dose.
Chronic Dietary (All populations)	Oral Study NOAEL= 250 mg/kg/day UF = 100 Chronic RfD= 2.5 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 2.5 mg/kg/day	1-Year Dog [feeding] Study No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT); HIARC recommended this dose for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic
Short- and Intermediate- Term Incidental Oral (1-30 days and 1-6 months)	Oral Study NOAEL= 250 mg/kg/day	LOC for MOE= NA (Occupational) LOC for MOE =100 (Residential, includes the FQPA SF - At present time no residential uses)	1-Year Dog [feeding] Study No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT); HIARC recommended this dose for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IMAZAPYR FOR USE IN HUMAN RISK ASSESSMENT.—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short- and Intermediate- and Long-Term Dermal (1 to 30 days, 1 to 6 months, ≤6 months)	Oral study NOAEL= 250 mg/kg/day (dermal absorption rate = 100 %)	LOC for MOE =100 (Occupational) LOC for MOE =100 (Residential, includes the FQPA SF - At present time no residential uses)	1-Year Dog [feeding] Study No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT); HIARC recommended this dose for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic.
Short- and Intermediate- and Long-Term Inhalation (1 to 30 days, 1 to 6 months, >6 months)	Oral study NOAEL= 250 mg/kg/day (inhalation absorption rate = 100%	LOC for MOE =100 (Occupational) LOC for MOE =100 (Residential, includes the FQPA SF - At present time no residential uses)	1-Year Dog [feeding] Study No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT); HIARC recommended this dose for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic
Cancer Risk	A quantitative cancer risk assessment is not required for imazapyr	N/A	2-Year Chronic [feeding] Toxicity/Carcinogenicity Study in Rats: Group E - ''no evidence of carcinogenicity in at least 2 adequate animal tests in different species.''

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.500) for the residues of imazapyr, in or on corn, field, forage; corn, field, grain; and corn field, stover at 0.05 ppm. Risk assessments were conducted by EPA to assess dietary exposures from imazapyr in food as follows:

i. *Acute exposure.* Quantitative 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 appropriate endpoint attributable to a single exposure was identified for imazapyr.

ii. *Chronic exposure.*In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The dietary exposure analysis assumed 100% crop treated tolerances and residues. Based on total food exposure for imazapyr, all population subgroups are below 1% cPAD (Chronic Population Adjusted Dose).

iii. *Cancer.* Imazapyr showed no evidence of carcinogenicity in at least 2 adequate animal tests in different species, and therefore, a quantitative cancer risk assessment was not performed.

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

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, 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 imazapyr they are further discussed in the aggregate risk section E.

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of imazapyr for acute exposures are estimated to be 137 parts per billion (ppb) for surface water and 1,700 ppb for ground water. The EECs for chronic exposures are estimated to be 81 ppb for surface water and 1,700 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). Imazapyr is currently registered for use on the following residential sites that could

result in non-occupational, non-dietary exposure: Driveways, parking areas, brick and gravel pathways, patios, and along sidewalks and bare ground. In addition to residential sites on which imazapyr is registered, there is the possibility of recreational exposure for post application exposure from the registered use on golf courses and fairgrounds and exposure from incidental ingestion and dermal exposure from swimming in treated water from the proposed aquatic weed control use. The risk assessment was conducted using the following exposure assumptions:

i. *Residential handler*. Short-term (1 to 30 days) dermal and inhalation exposure from mixing, loading and application via sprinkler can could occur. For the Outdoor Residential Exposure Task Force study reviewed, the Health Effects Division (HED) used a hose-end sprayer as surrogate data for the sprinkler can scenario. The registered label states that the product offers long-term weed control and prevents re-growth for up to one year with a single application; therefore only short-term handler exposures are anticipated.

ii. *Residential post-application*. Adults and children are anticipated to have short-term dermal exposures; however, given that the product is not intended for lawn use, dermal exposures by adults and children are considered to be negligible as compared to recreational post-application exposures. (See fairground post-application). However, toddlers could potentially ingest soil from treated bare ground in the residential use scenario. The assumptions used to assess the soil ingestion scenario were: Day of treatment residues are assumed to be available for short-term exposure, toddler body weight is estimated at 15 kg, 100 % of application rate is available in the top 1 cm of soil for soil ingestion exposures, and a toddler can possibly ingest 100 mg soil/day.

iii. *Golfer post-application*. Golfer exposure assumptions are: One round of golf (18 holes) takes 4 hours and an average golfer plays 18 times per year, so short-term dermal exposures are anticipated. Inhalation exposures are considered to be negligible since the vapor pressure of imazapyr was reported by the registrant to be $<2x\ 10^{-7}$ mm Hg (vs. HED ExpoSAC vapor pressure threshold of 1×10^{-5} mm Hg). 5% of the maximum application rate is available as turf transferrable residues (TTR) available on Day 0 (assumes no dissipation). The transfer coefficient (TC) for dermal exposure is assumed to be 500 cm2/hr based on golfers wearing short pants and short-sleeved shirts. The exposure estimate for child golfers is 1.7 times the adult exposure estimate to account for differences in body weight and surface area. Maximum labeled application rate is 0.0041 lb ae/A broadcast liquid formulation applications.

iv. *Fairground post-application*.—a. The following assumptions were used to assess dermal exposures to adults and toddlers after contact with treated lawns: Adult and toddler body weights are 70 kg and 15 kg respectively, 5% of the maximum application rate represents fraction of imazapyr available as dislodgeable foliar reside (DFR) on the day of treatment. Dermal TC for adults is 14,500 cm2/hr, and for toddlers, 5,200 cm2/hr with an exposure duration of 2 hours.

b. To assess hand-to-mouth exposures for toddlers after contact with treated turf, the following assumptions were used: residues are assumed to be available for the short-term and intermediate-term exposure durations. Toddler body weight is 15 kg, hand surface area is 20 cm2, and a toddler performs 20 hand-to-mouth events per hour for short-term exposures. 5% of application rate represents fraction of imazapyr available for transfer to hands on the day of treatment with a 50% saliva extraction factor. 100% of the application rate is available in the top 1 cm of soil for soil ingestion exposures, and a toddler can ingest 100 mg of soil a day. The exposure duration is 2 hours per day.

c. To assess object-to-mouth exposures for toddlers after contact with treated turf, the following assumptions were used: Residues are assumed to be available for the short-term and intermediate-term exposure durations, the toddlers' body weight is 15 kg, 20% of the application rate is available as dislodgeable residues on the day of treatment, the object area is 25 cm2, 100% of the application rate is available in the top 1 cm of soil for soil ingestion exposures,a toddler can ingest 100 mg of soil a day, and the exposure duration is 2 hours per day.

v. *Swimmer post-application*. For incidental ingestion and dermal exposure, the following assumptions are made: The worst-case estimate of imazapyr in the top one-foot of the water column in a treated waterbody is 550 ppb. 100% of this concentration is assumed available for ingestion at a rate of 0.05 L/hr. The exposure duration is 2 hours a day for non-competitive adult and child swimmers. Body weights of 70 kg for adults, 29 kg for children, and 15 kg for toddlers are assumed. For dermal exposure, the body surface area of an adult is 20,670 cm2 and 14,580 cm2 for toddlers and children. The permeability coefficient is assumed at 5.85×10^{-5} cm/hr.

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

EPA does not have, at this time, available data to determine whether imazapyr 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, imazapyr 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 imazapyr has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. No prenatal or postnatal sensitivity was found.

3. *Conclusion*. There is a complete toxicity data base for imazapyr and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency has determined that the Special FQPA SF of 10x can be reduced to 1x because:

i. Lack of concern for pre- and post-natal toxicity.

ii. No qualitative/quantitative evidence of increased susceptibility of rat or rabbit fetuses to in utero exposure was reported in the developmental studies at doses up to 1,000 mg/kg/day (limit dose) in the rat and 400 mg/kg/day (HDT) in the rabbit.

iii. There is no concern for developmental neurotoxicity resulting from exposure to imazapyr. While there were no neurotoxicity studies available from the published literature, there was no evidence of neurotoxicity/neuropathology in adult animals in the available studies.

iv. The toxicology database is complete based on the developmental studies in the rat and rabbit and the 2-generation reproduction study in the rat

v. No developmental neurotoxicity (DNT) study was required.

vi. No residual uncertainties were identified in the exposure database.

vii. The chronic dietary food exposure assessment utilizes tolerance level residues and 100% CT information for all commodities. By using these screening level assumptions, actual exposures/risks will not be underestimated.

viii. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations which will not likely be exceeded.

ix. Residential exposure and risk were assessed using standard assumptions from Science Advisory Council on Exposure (Expo SAC) Standard Operating Procedure (SOP). These assumptions are not expected to underestimate risk.

E. Aggregate Risks and Determination of Safety

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

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 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 groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (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*. No acute risk from exposure to imazapyr is expected because there were no toxic effects of concern attributable to a single dose identified in available data.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to imazapyr from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for all infants (<1 year old) and <1% of the cPAD for children ages 1–2 years old. Based the use pattern, chronic residential exposure to residues of imazapyr is not expected. In addition, there is potential for chronic dietary exposure to imazapyr 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 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IMAZAPYR.

Population Subgroup	cPAD (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Maximum Chronic Water Exposure[1] (mg/kg/day)	Ground Water EEC[2] ppb	Surface Water EEC[2] ppb	Chronic DWLOC[3] ppb
U.S. Population	2.5	0.00034	2.499	1,700	81	87,000
All infants (< 1 year old)	2.5	0.000273	2.499	1,700	81	25,000
Children (1-2 years old)	2.5	0.000828	2.499	1,700	81	25,000
Children (3-5 years old)	2.5	0.00073	2.499	1,700	81	25,000
Children (6-12 years old)	2.5	0.000499	2.499	1700	81	75,000
Youth (13-19 years old)	2.5	0.000309	2.499	1,700	81	75,000
Adults (20-49 years old)	2.5	0.000267	2.499	1,700	81	87,000
Females (13-49 years old)	2.5	0.000257	2.499	1,700	81	87,000

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IMAZAPYR.—Continued

Population Subgroup	cPAD (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Maximum Chronic Water Exposure[1] (mg/kg/day)	Ground Water EEC[2] ppb	Surface Water EEC[2] ppb	Chronic DWLOC[3] ppb
Adults (50+ years old)	2.5	0.000287	2.499	1,700	81	87,000

[1]maximum water exposure (mg/kg/day) = cPAD (mg/kg/day) - food exposure (mg/kg/day)
[2]The crop producing the highest level was used.
[3]DWLOC calculated as follows: DWLOC = (maximum water exposure (mg/kg/day)) * (body weight (kg)) * (1,000 µg/mg)/water consumption (liter/day)

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).

Imazapyr 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 imazapyr. Short-term aggregate risk assessments are required for adults as there is potential for both dermal and inhalation handler exposure, and dermal post-application exposure from the residential and recreational uses of imazapyr on turf and swimmer exposure. In addition, short-term aggregate risk assessments are required for children and toddlers because there is a potential for oral and dermal post-application exposure resulting from the residential uses of imazapyr on turf and from swimming. The short-term residential handler scenario results in the highest exposure for adults. Therefore, for adults, the homeowner handler scenario was aggregated with the chronic dietaryfood exposure for the U.S. General population. The swimmer scenario resulted in the highest exposure for toddlers and children. Therefore, the swimmer scenario exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for children 1-2 years old.

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 75,000 for the United States population, and 55,000 for children 1-2 years old. These aggregate MOEs do not exceed the Agency's level of concern, an MOE of 100, for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of imazapyr 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 5 of this unit:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO IMAZAPYR

Population Subgroup	Aggregate MOE (Food + Residential)[1]	Aggregate Level of Concern (LOC)[2]	Surface Water EEC[3] (µg/L)	Ground Water EEC[3] (µg/L)	Short-Term DWLOC[4] (ppb)
U.S. Population	75,000	100	81	1,700	87,000
Children 1-2 years old	55,000	100	81	1,700	25,000

[1]Aggregate MOE = [NOAEL / (Avg Food Exposure + Residential Exposure)]
[2]The level of concern (target MOE) includes 10X for interspecies extrapolation and 10X for intraspecies variation (MOE<100)
[3]The crop producing the highest level was used
[4]DWLOC calculated as follows: DWLOC = (maximum water exposure (mg/kg/day)) * (body weight (kg)) * (1,000 µg/mg)/water consumption (liter/day)

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). Though residential exposure could occur with the use of imazapyr, the short-term and intermediate-term endpoints are the same and thus the short-term assessment is conservative for the intermediate-term. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Imazapyr is not expected to pose a cancer risk because no evidence of carcinogenicity was found in at least 2 adequate animal tests in different species.

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 imazapyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Two methods are currently listed in the Pesticide Analytical Manual (PAM) Vol. II for enforcing tolerances of imazapyr in or on corn commodities; Method M 2468 is a gas chromatography/mass spectrometry (GC/MS) methods with a limit of quantitation (LOQ) of -0.01 ppm for imazapyr in or on corn grain, forage and fodder, and Method M 2657 is a capillary electrophoresis (CE) method with ultraviolet (UV) detection that has a LOQ of 0.05 ppm for imazapyr in or on corn grain, forage and fodder.

CE/UV methods were proposed for determining imazapyr in or on grass forage and hay (M 3023), in livestock tissues (M 3184), in milk and milk fat (M 3075 and M 3223), and in fish and shellfish tissues (M 3066). These methods are similar to the current enforcement method M 2657, and based on the concurrent method recovery data

submitted, are adequate for collecting data on residues of imazapyr in grass forage and hay, cattle tissues and milk, and fish and shellfish.

The CE/UV Methods M 3023, M 3184, M 3075, and M 3066 have been forwarded to the Analytical Chemistry (ACB) for petition method validation (PMV) trials. Conclusions regarding the suitability of the proposed enforcement methods will be deferred until completion of the PMV trials.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for residues of imazapyr in or on any of the crops involved in the proposed new uses.

C. Conditions

Prior to granting unconditional registration, the registrant will be required to address the following issues:

1. Fish metabolism study

2. Corn or grass storage stability information or study

3. Additional spray additive information supporting the grass field trials.

V. Conclusion

Therefore, the tolerance is established for residues of imazapyr in or on grass, forage at 100 ppm; grass, hay at 30 ppm; fish at 1.0 ppm; shellfish at 0.10 ppm; fats of cattle, sheep, goats, and horses 0.05 ppm; kidney of cattle, sheep, goats, and horses at 0.20 ppm; meat byproducts (except kidney) of cattle, sheep, goats, and horses at 0.05 ppm; meat of cattle, sheep, goats, and horses at 0.05 ppm; and milk at 0.01 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0264 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 25, 2003.

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–2003–0264, 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 the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. 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 record keeping requirements.

Dated: September 16, 2003.

Debra Edwards,

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 180.500 is revised to read as follows:

§ 180.500 Imazapyr; tolerances for residues.

(a) *General.* Tolerances are being established for residues of the herbicide imazapyr, [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid], applied as the acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.20
Cattle, meat	0.05
Cattle, meat by-products (except kidney)	0.05
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Fish	1.0
Goats, fat	0.05
Goats, kidney	0.20
Goats, meat	0.05
Goats, meat by-products (except kidney)	0.05
Grass, forage	100
Grass, hay	30
Horses, fat	0.05
Horses, kidney	0.20
Horses, meat	0.05
Horses, meat by-products (except kidney)	0.05
Milk	0.01
Sheep, fat	0.05
Sheep, kidney	0.20
Sheep, meat	0.05
Sheep, meat by-products (except kidney)	0.05
Shellfish	0.10

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

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

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

[FR Doc. 03–24123 Filed 9–25–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0289; FRL–7324–8]

Etoxazole; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on cotton, pome fruits, strawberries, and imported tangerines. Valent U.S.A. Corporation 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 September 26, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0289, must be received on or before November 25, 2003.

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: Daniel C. Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address: *kenny.dan@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)
- Animal Production (NAICS 112)
- Food Manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

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–2003–0289. 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 August 13, 2003 (68 FR 48377) (FRL–7322–6), 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 2F6420) by Valent U.S.A. Corporation, 1333 North California Blvd., Suite 600, Walnut Creek, CA 94596. That notice included a summary of the petition prepared by Valent U.S.A. Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide etoxazole, 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole, in or on cottonseed at 0.05 parts per million (ppm); cotton, gin byproducts (gin trash) at 1.0 ppm, pome fruit (Crop Group 11) at 0.2 ppm, apple, wet pomace at 1.0 ppm, strawberry at 0.5 ppm, and oranges at 0.10 ppm (to support the importation of mandarin oranges into the U.S.). As residues in processed commodities fed to animals may be transferred to milk and edible tissue of ruminants, tolerances were also proposed for animal fat at 0.03 ppm and milk fat at 0.04 ppm.

Based on EPA's review, the petition was revised by the petitioner to propose tolerances for residues of etoxazole on cotton, undelinted seed at 0.05 ppm; cotton, gin byproducts at 1.0 ppm; fruit, pome, group 11 at 0.20 ppm; apple, wet pomace at 0.50 ppm; strawberry at 0.50 ppm; tangerine at 0.10 ppm; liver of cattle, goat, horse, and sheep at 0.01 ppm; fat of cattle, goat, horse, and sheep at 0.02 ppm; and milk, fat at 0.01 ppm. Although EPA requested a number of changes to the initial petition, the nature of the changes (i.e., clarification and correction of commodity terms and adjustments in tolerance levels) are not considered significant. Therefore, EPA is issuing this as a final action.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes