EPA APPROVED TENNESSEE REGULATIONS—Continued

State citation	Title/subject	Adoption date	EPA approval date	Federal Register notice
Section 1200–3–17–.03	Conflict of Interest in the Permitting of Municipal Solid Waste Incineration Units.	09/18/96	10/28/02	[Insert citation of publication]
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Chapter 1200–3–27	NITROGEN OXIDES			
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Section 1200–3–27–.02	General Provisions and Applicability	11/23/96	10/28/02	[Insert citation of publication]
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[FR Doc. 02–22089 Filed 8–28–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0189; FRL–7193–4]

Imazethapyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of imazethapyr, its metabolite CL 288511 and its metabolite CL 182704 in or on rice bran, rice grain, and rice straw. This regulation also establishes a tolerance for combined residues of imazethapyr and its metabolite CL 288511 in or on crayfish and meat byproducts of cattle, goat, hog, horse, and sheep. BASF requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 29, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0189, must be received on or before October 28, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0189 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0189. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of September 27, 2000 (65 FR 58074) (FRL–6744–6), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality

Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petition (PP 0F6168) by American Cyanamid, now BASF, 26 Davis Drive, Research Triangle Park, NC 27709. This notice included a summary of the petition prepared by American Cyanamid, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.447 be amended by establishing a tolerance for combined residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid as it free acid or ammonium salt and its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid both free and conjugated, in or on rice grain at 0.5 parts per million (ppm), rice straw at 0.3 ppm, and crayfish at 0.1 ppm.

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

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

After analysis of submitted residue chemistry data, EPA determined that appropriate tolerances for rice and crayfish differ from those proposed by the registrant. EPA determined that a tolerance of 1.2 ppm is needed for rice bran; no tolerance for rice bran was proposed by the registrant. EPA also determined that tolerances should be 0.20 ppm instead of 0.5 ppm for rice grain, and 0.15 ppm instead of 0.3 ppm for rice straw. Further, EPA determined that the tolerance expression for rice commodities should be for imazethapyr and the metabolites CL 288511 and CL 182704 (5-[1-(beta-D-glucopyranosyloxy)ethyl]-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid); the registrant's proposed tolerance expression for rice commodities was for imazethapyr as the free acid and ammonium salt and CL 288511 both free and conjugated. For crayfish, EPA determined that the tolerance expression should be for imazethapyr and CL 288511; the registrant's proposed tolerance expression for crayfish was for imazethapyr as the free acid and ammonium salt and CL 288511 both free and conjugated. Finally, EPA determined that tolerances of 0.10 ppm for imazethapyr and CL 288511 need to be established for meat byproducts of cattle, goat, hog, horse, and sheep; the registrant did not propose tolerances for these commodities. EPA determined that tolerances are not needed for eggs; milk; meat and fat of cattle, goat, hog, horse, and sheep; and poultry commodities because there is no reasonable expectation of finite residues based on the calculated maximum total dietary burdens and the results of the poultry metabolism study.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of imazethapyr and its metabolite CL 288511 on crayfish and meat byproducts of cattle, goat, hog, horse, and sheep at 0.10 ppm, and for tolerances for combined residues of imazethapyr, its metabolite CL 288511, and its metabolite CL 182704 on rice bran at 1.2 ppm, rice grain at 0.20 ppm, and rice straw at 0.15 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 imazethapyr are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

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

Guideline No.	Study Type	MRID No. (year)/Classification/Doses	Results
870.1100	Acute Oral	00159375 (1985) Acceptable/guideline 5,000 mg/kg	LD_{50} ≥5,000 mg/kg (male and female rats) Toxicity Category IV
870.1200	Acute Dermal	00159375 (1985) Acceptable/guideline 2,000 mg/kg	LD_{50} ≥2,000 mg/kg(male and female rabbits) Toxicity Category III
870.1300	Acute Inhalation	00159378 (1985) Acceptable/guideline 3.27 mg/L	LD_{50} ≥3.27 mg/L (male and female rats) Toxicity Category III
870.2400	Primary Eye Irritation	00159375 (1985) Acceptable/guideline 0.1 mL	Not an irritant Toxicity Category III

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

Guideline No.	Study Type	MRID No. (year)/Classification/Doses	Results
870.2500	Primary Skin Irritation	00159375 (1985) Acceptable/guideline 0.5 mL	Not an irritant Toxicity Category IV
870.2600	Dermal Sensitization	00159379 (1985) Acceptable/guideline 0.4 mL	Not a skin sensitizer (Toxicity Category Not Applicable)
870.3100	90–Day oral toxicity rodents-rat	00159381 (1986) Acceptable/guideline 0, 1,000, 5,000, or 10,000 ppm 0, 50, 250, or 500 mg/kg/day	NOAEL = 500 mg/kg/day (HDT). LOAEL = Not observed.
870.3150	90–Day oral toxicity nonrodents-dog	00159382 (1985) Acceptable/guideline 0, 1,000, 5,000 or 10,000 ppm 0, 25, 125 or 250 mg/kg/day	NOAEL = 250 mg/kg/day (HDT). LOAEL = Not observed.
870.3200	21–Day dermal toxicity-rabbit	00159383 (1985) Acceptable/guideline 0, 50, 200, or 1,000 mg/kg/day 0, 54.8, 219.3, or 1,096.5 mg/kg/day (adjusted for purity)	NOAEL = 1,096 mg/kg/day (HDT). LOAEL = Not observed.
870.3700	Prenatal developmental in rodents-rat	40429417 (1985) Acceptable/guideline 0, 125, 375, or 1,125 mg/kg/day	Maternal: NOAEL = 375 mg/kg/day LOAEL = 1,125 mg/kg/day based on increased incidences of clinical signs during the gestation Developmental: NOAEL = 1,125 mg/kg/day LOAEL =Not observed
870.3700	Prenatal developmental in non-rodents-rabbit	00159384 (1986) Acceptable/guideline 0, 100, 300, or 1,000 mg/kg/day	Maternal: NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on an increased incidence of clinical signs during gestation, ulcerations in the mucosal layer of the stomach and gall bladder, increased abortions, and maternal deaths. Developmental: NOAEL = 1,000 mg/kg/day (HDT) LOAEL = Not observed
870.3800	Reproduction and fertility effects-rat	40429418 (1987) Acceptable/guideline 0, 1,000, 5,000 or 10,000 ppm 0, 50, 250 or 500 mg/kg/day	Parental/Systemic NOAEL = 500 mg/kg/day (HDT). LOAEL = Not observed. Reproductive NOAEL = 500 mg/kg/day (HDT). LOAEL = Not observed. Offspring NOAEL = 500 mg/kg/day (HDT). LOAEL = Not observed.
870.4100	Chronic toxicity-dog	40429416 (1987) Acceptable/guideline 0, 1,000, 5,000 or 10,000 ppm 0, 25, 125, or 250 mg/kg/day	NOAEL = 250 mg/kg/day (HDT). LOAEL = Not observed.
870.4300	Chronic/ Carcinogenicity-rat.	40429414 (1987) Acceptable/guideline 0, 1,000, 5,000, or 10,000 ppm 0, 50, 250, or 500 mg/kg/day	NOAEL = 500 mg/kg/day (HDT). LOAEL = Not observed. No evidence of carcinogenicity.
870.4300	Carcinogenicity-mouse.	40429415 (1987) Acceptable/guideline 0, 1,000, 5,000, or 10,000 ppm 0, 150, 750, or 1,500 mg/kg/day	NOAEL = 750 mg/kg/day LOAEL = 1,500 mg/kg/day (HDT) based on the decrement in body weight gain No evidence of carcinogenicity at doses tested.
870.5100	Gene Mutation	00159719 (1986) Acceptable/guideline 0, 50, 158, 500, 1,000, 1581, 3162 or 5,000 µg/plate	Non-mutagenic when tested up to 5,000 µg/plate, in presence and absence of metabolic activation, in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA 1538 and *E.coli* strain WP2uvra.
870.5300	Gene Mutation	40429419 (1986) Acceptable/guideline up to 3333 µg/mL (limit of solubility) and 4000 µg/mL (beyond limit of solubility)	Negative for induction of forward mutation at the HPRT locus in Chinese hamster ovary cells, in the presence or absence of S9-activation at doses up to limit of solubility (3,333 µg/mL) and beyond (4,000 µg/mL).
870.5375	Chromosome aberration	40438201 (1986) Acceptable/guideline 0, 1.14, 1.71, 1.82, 2.05, and 2.28 mg/ml with and without S9 activation	Did not induce structural chromosome aberration in Chinese hamster lung (V79) cell cultures in the presence and absence of activation up to cytotoxic concentrations.
870.5450	Dominant Lethal Assay	00159720 (1985) Unacceptable/guideline 0, 200, 1,000 or 2,000 mg/kg	Negative for dominant lethal effects (chromosomal damage) at doses up to 2,000 mg/kg.

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

Guideline No.	Study Type	MRID No. (year)/Classification/Doses	Results
870.5550	Other Genotoxicity	00159721 (1985) Acceptable/guideline 0, 0.13, 0.4, 1.3, 4.0, 13, 40, 133, 400, 1,333, or 4,000 μg/mL	No evidence that unscheduled DNA synthesis was induced by imazethapyr, as determined by radioactive tracer procedures [nuclear silver grain counts].
870.7485	Metabolism and pharmacokinetics - rat	40429420 and 41467703 (1987) Acceptable/guideline 5.7 mg/kg single dose; 1,000 mg/kg single dose and 3 daily doses of 250 mg/kg followed by a single dose of 1000 mg/kg; 1,000 mg/kg/day single and repeated dose	In a rat metabolism study, almost 100% of the administered radiolabeled test material was recovered in the excreta within 96 hours (89–95% in the urine and 6–11% in the feces). Greater than 95% of the oral dose was excreted in the first 31 hours. The major residue in both urine and feces was the parent compound. Approximately 2% of the oral dose was metabolized and excreted as CL 288511 (1-hydroxy ethyl derivative of AC 263,499, parent). A high percentage of the administered material was excreted in the urine as the unmodified parent compound (> 97%) and a very small amount as the CL 288511. In the high dose group, the unmodified parent compound was the major fecal component in both sexes, particularly at 12 hours or less. The CL 288511 was the major metabolite. One unknown was also found in significant quantities. In the low dose group, six components were found in the feces: parent compound, the CL 288511, the unknown previously mentioned and several minor unknowns.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

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

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

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for imazethapyr used for human risk assessment is shown in the following Table 2:

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

Exposure Scenario	Dose Used in Risk Assessment, UF*	FQPA SF* and Level of Concern for Risk Assessment[1]	Study and Toxicological Effects
Acute Dietary for general population and females 13–50	None	N/A	No hazard has been identified. Quantitation of acute dietary risk is not required for both general population and female 13–50 years old population sub group.
Chronic Dietary all populations	NOAEL = 250 mg/kg/day UF = 100 cRfD = 2.5 mg/kg/day	FQPA SF= 1 cPAD = 2.5 mg/kg/day	Chronic Oral Toxicity [diet] - dog No toxicity was seen at the HDT of 250 mg/kg/day.

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

Exposure Scenario	Dose Used in Risk Assessment, UF*	FQPA SF* and Level of Concern for Risk Assessment[1]	Study and Toxicological Effects
Incidental Oral Short-Term (1–30 days) and Intermediate-Term (30 days–6 months)	Oral NOAEL= 300 mg/kg/day	FQPA SF= 1 LOC for MOE = 100 (residential)	Developmental Toxicity Study - rabbit Based on ulcerations in the mucosal layer of the stomach and the gall bladder seen at 1000 mg/kg/day (LOAEL).
Dermal Short-Term (1–30 days), Intermediate-Term (30 days–6 months), and Long-Term (6 months-life time)	None	N/A	No hazard has been identified. Quantitation of short-, intermediate- and long-term dermal exposure risk assessment is not required.
Inhalation, Short-Term (1–30 days) and Intermediate-Term (30 days–6 months)	Oral NOAEL= 300 mg/kg/day inhalation absorption factor 100%	LOC* for MOE = 100 (residential and occupational)	Developmental Toxicity Study - rabbit Based on ulcerations in the mucosal layer of the stomach and the gall bladder, increased incidence of clinical signs during gestation, increased abortions, and maternal deaths seen at 1,000 mg/kg/day (LOAEL).
Inhalation, Long-Term (6 months-life time)	Oral NOAEL= 250 mg/kg/day inhalation absorption factor 100%	LOC for MOE = 100 (residential and occupational)	Chronic Oral Toxicity [diet] - dog No toxicity was seen at the HDT of 250 mg/kg/day.

*UF = uncertainty factor, SF = Safety Factor, LOC = level of concern
[1] The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.447) for the combined residues of imazethapyr, its metabolite CL 288511, and its metabolite CL 182704 in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from imazethapyr 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. Since there were no developmental effects and the toxicological effects seen in the rabbit and rat developmental toxicity studies occurred after several days of dosing or at doses above the limit dose, acute (single dose) risk assessment for both the general population and the female 13–50 years old population subgroup was considered inappropriate. Therefore, an acute dietary risk assessment was not conducted.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary assessment assumed tolerance level residues for all registered and proposed commodities excluding corn grain (conservative corn grain residue estimate of 0.15 ppm was used). DEEM® default processing factors and 100% crop treated were assumed for all registered and proposed commodities.

iii. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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

EPA determined that the residue of concern in drinking water is only imazethapyr. EPA provided ground (SCI-GROW; 8.97 µg/l) and surface water (rice paddy model; peak and average - 93.18 µg/l) estimated environmental concentrations (EECs) for imazethapyr. The ground and surface water EECs were generated assuming a single application of imazethapyr at 0.094 lbs ae/acre (highest registered/proposed single application rate).

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use 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 imazethapyr they are further discussed in the aggregate risk sections in Unit IV.E. of this preamble.

Based on the rice paddy and SCI-GROW models the EECs of imazethapyr for chronic exposures are estimated to be 93.18 µg/L (parts per billion (ppb)) for surface water and 8.97 µg/L (ppb) for ground water. Because the Agency determined that an acute (single dose) risk assessment for both the general

population and the female 13–50 years old population subgroup was considered inappropriate (see unit III. C.1.i.), EECs of imazethapyr for acute exposures were not estimated.

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).

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

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

EPA has recently developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued for public comment on January 16, 2002 (67 FR 2210–2214) and is available from the OPP Website at: http://www.epa.gov/pesticides/trac/science/cumulative_guidance.pdf. Before undertaking a cumulative risk assessment, the Agencv will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the ''Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity'' (64 FR 5795–5796, February 5, 1999).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. EPA concluded that there is no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to imazethapyr in the rat and rabbit developmental toxicity studies. There is no quantitative and qualitative evidence of increased susceptibility following pre- or postnatal exposure to imazethapyr in the 2-generation reproduction study in rats.

3. *Conclusion*. There is a complete toxicity database for imazethapyr and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA SFC concluded that the safety factor could be removed (1x) for imazethapyr because the toxicological database is complete for FQPA assessment; there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children.

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 are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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*. Because no acute endpoint was identified for imazethapyr, no acute risk is expected from acute exposures.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to imazethapyr 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 (1–12 years old). There are no residential uses for imazethapyr that result in chronic residential exposure to imazethapyr. In addition, there is potential for chronic dietary exposure to imazethapyr in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	2.5	<1	93.18	8.97	8.7e+04
All Infants (<1 year old)	2.5	<1	93.18	8.97	2.5e+04
Children (1–6 years old)	2.5	<1	93.18	8.97	2.5e+04
Children (7–12 years old)	2.5	<1	93.18	8.97	2.5e+04
Females (13–50 years old)	2.5	<1	93.18	8.97	7.5e+04
Males (13–19 years old)	2.5	<1	93.18	8.97	8.7e+04
Males (20+ years old)	2.5	<1	93.18	8.97	8.7e+04
Seniors (55+ years old)	2.5	<1	93.18	8.97	8.7e+04

3. *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 imazethapyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Paul Golden, USEPA/OPP/BEAD/ACB, Environmental Science Center, 701 Mapes Road, Fort Meade, MD 20755–5350; telephone number: (410) 305–2960; e-mail address: golden.paul@epa.gov

B. International Residue Limits

Codex, Canada, and Mexico do not have maximum residue limits (MRLs) for residues of imazethapyr and CL 288511 in/on rice.

C. Conditions

The following will be imposed as conditions of registration of imazethapyr on rice: successful pesticide method validation (PMV) and radiovalidation of the rice, crayfish, and livestock enforcement methods, and submission of an acceptable crayfish residue and ruminant feeding studies.

V. Conclusion

Therefore, the tolerances are established for combined residues of imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, and its metabolite CL 182704, 5-[1-(beta-D-glucopyranosyloxy)ethyl]-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid, in or on rice grain at 0.5 parts per million (ppm), rice straw at 0.3 ppm. In addition, a tolerance is established for combined residues of imazethapyr and its metabolite CL 288511 in or on crayfish and meat byproducts of cattle, goat, hog, horse, and sheep at 0.10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0189 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 October 28, 2002.

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

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written 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.

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0189, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 21, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.447 is revised to read as follows:

§ 180.447 Imazethapyr; tolerances for residues.

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

Commodity	
Legume vegetables	0.1
Soybeans	0.1

(2)Tolerances are established for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid; its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid; and its metabolite CL 182704, 5-[1-(beta-D-glucopyranosyloxy)ethyl]-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid, applied as its acid or ammonium salt, in or on the following commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	3.0
Peanut	0.1
Rice, bran	1.2
Rice, grain	0.20
Rice, straw	0.15

(3) A tolerance is established for the sum of residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, and its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, applied as its acid or ammonium salt, in or on the following commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.10
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Crayfish	0.10
Goat, meat byproducts	0.10
Hog, meat byproducts	0.10
Horse, meat byproducts	0.10
Sheep, meat byproducts	0.10

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

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) of this chapter, are established for the sum of residues of the herbicide imazethapyr, 2- [4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl- 3-pyridine carboxylic acid, as its ammonium salt, and its metabolite, 2- [4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1- hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, applied as its acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	Parts per million
Endive (escorole)	0.1
Lettuce, head	0.1
Lettuce, leaf	0.1

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

[FR Doc. 02–22093 Filed 8–28–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0220; FRL–7195–8]

Diflufenzopyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of diflufenzopyr in or on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.05 part per million (ppm); corn, pop, grain and corn, pop, stover at 0.05 ppm; grass, forage at 22 ppm; and grass, hay at 7.0 ppm. This regulation also establishes time-limited tolerances for combined residues of diflufenzopyr in or on cattle, goat, hog, horse, and sheep meat at 0.60 ppm; cattle, goat, hog, horse, and sheep kidney at 4.0 ppm; cattle, goat, hog, horse, and sheep meat byproducts, except kidney at 0.50 ppm; cattle, goat, hog, horse, and sheep fat at 0.30 ppm; and milk at 3.0 ppm. The 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 (FQPA) of 1996.

DATES: This regulation is effective August 29, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0220, must be received on or before October 28, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0220 in the subject line on the first page of your response.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing