

## List of Subjects in 40 CFR Parts 52 and 81

Environmental protection, Air pollution control, National parks, Wilderness areas, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: January 24, 2006.

**Wayne Nastri,**

*Regional Administrator, Region 9.*

[FR Doc. 06-1174 Filed 2-7-06; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2005-0508; FRL-7755-8]

#### Imazethapyr; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an increase in tolerances for the sum of the residues of imazethapyr and its metabolites, 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 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 rice grain at 0.3 ppm, rice straw at 0.4 ppm, and imazethapyr and its metabolite, CL 288511 in or on crayfish at 0.15 ppm. BASF Corporation requested the tolerances for rice grain and rice straw under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), because of a requested increase in the use rate of imazethapyr in rice. In addition, this regulation increases the tolerance on crayfish from 0.10 ppm to 0.15 ppm due to exposure of crayfish raised in rice fields to imazethapyr.

**DATES:** This regulation is effective February 8, 2006. Objections and requests for hearings must be received on or before April 10, 2006.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number EPA-HQ-OPP-2005-0508. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) web site. (EDOCKET, EPA's electronic public

docket and comment system was replaced on November 25, 2005, by an enhanced Federal-wide electronic docket management and comment system located at <http://www.regulations.gov/>. Follow the on-line instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

**FOR FURTHER INFORMATION CONTACT:**

James A. 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](mailto: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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to

certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

##### B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), 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 on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

## II. Background and Statutory Findings

In the **Federal Register** of June 29, 2005 (70 FR 37392) (FRL-7718-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F 6947) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, North Carolina 27709-3528. The petition requested that 40 CFR 180.447 be amended by establishing a tolerance for the sum of the residues of the herbicide Imazethapyr, and its metabolites CL 288511 and CL182704, in or on rice grain at 0.3 parts per million (ppm), and rice straw at 0.4 ppm. That notice included a summary of the petition prepared by BASF Corporation, the registrant. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

In addition, after completion of the dietary risk analysis for imazethapyr residues on rice, the Agency determined that the tolerance for combined residues for imazethapyr and the metabolite CL 288511 in crayfish needs to be increased from 0.10 ppm to 0.15 ppm. Crayfish are often raised in flooded rice fields, and thus are exposed to residues of pesticides that are applied to rice.

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

408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

### III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a tolerances for the sum of the residues of imazethapyr and its metabolites CL 288511 and CL 182704 on rice grain at 0.3 ppm, rice straw at 0.4 ppm, and for the sum of residues of imazethapyr and its metabolite 288511 in crayfish 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 Unit III.A. of the final rule that established imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (FR notice dated August 29, 2002, 67 FR 55323, FRL-7193-4).

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, 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.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at [www.epa.gov/pesticides](http://www.epa.gov/pesticides).

A summary of the toxicological endpoints for imazethapyr used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of (FR notice dated August 29, 2002, 67 FR 55323).

#### C. Exposure Assessment

The Registrant, BASF Corporation, has requested an amended registration to increase the use rate of, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid from 0.125 lbs acid equivalent (ae)/application/acre/crop season and a 45-day preharvest interval (PHI) to 0.188 lbs ae/application/acre per crop season and an 85-day PHI.

The dietary exposure for all populations continues to be <1% chronic population adjusted dose (cPAD) with the minor changes in tolerances for rice grain and straw, and crayfish established in this **Federal Register** Notice. The exposure assessment for imazethapyr is discussed in Unit III.C. of the final rule that established the original imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (FR notice dated August 29, 2002, 67 FR 55323). In this action, the tolerances for rice grain are increased from 0.2 ppm to 0.3 ppm, for rice straw are increased from 0.15 ppm to 0.4 ppm) and in crayfish are increased from 0.10 ppm to 0.15 ppm. These increases resulted in an increase in dietary exposure for the general population from 0.000393 milligram/kilogram/day (mg/kg/day) to 0.002367 mg/kg/day, which is still much less than 1% of the cPAD of 2.5 mg/kg/day. The highest dietary exposure as a result of the increased tolerances is 0.008824 mg/kg/day for

non-nursing infants, which is also less than 1% of the cPAD. (Since dietary exposure for non-nursing infants was not calculated separately in the previous dietary assessment, but was included as part of all infants, there is no meaningful comparison to previous dietary risk exposures.)

#### D. Safety Factor for Infants and Children

The safety factors for infants and children for imazethapyr are discussed in Unit III.D. of the final rule that established imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (FR notice dated August 29, 2002, 67 FR 55323).

#### E. Aggregate Risks and Determination of Safety

The aggregate risks and determination of safety for imazethapyr are discussed in Unit III.E. of the final rule that established imazethapyr tolerances in or on rice, crayfish, and meat byproducts of certain cattle (notice dated August 29, 2002, 67 FR 55323). 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

The enforcement method for use on rice grain and rice straw is Method M3120. This method measures the concentrations of imazethapyr and its metabolites CL 288511 and CL 182704. The method extracts residues with acidic aqueous methanol, and the extract is then eluted through C18, strong anion exchange, and strong cation exchange columns. Residues are quantified via capillary electrophoresis with a UV detector.

The enforcement method for use on crayfish is Method 3512. This method quantifies the residues for imazethapyr and its metabolite CL 299511. This method involves extraction of residues using acidic acetone, followed by elution through a C18 column, and residues are quantified using LC/MS analysis. The enforcement methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### B. International Residue Limits

There are no Codex maximum residue levels established or proposed for residues of imazethapyr on rice.

### C. Response to Comments

Public comments were received from B. Sachau. She objected that the several of the proposed tolerances levels, including the level for chicken, are too high. She questions who performed the tests showing these levels are necessary and whether EPA checked the tests. Ms. Sachau also objected to the use of animal testing, and the use of food intake survey data from 1994.

*Response:* EPA requires that petitioners submit data from studies on residue levels in treated crops and in animals that consume treated crops. Such studies are performed according to established protocols and EPA carefully examines the data from the studies after it is submitted. That was done with regard to the tolerance levels for imazethapyr. It is noted that imazethapyr tolerances in chicken are not being increased by this action. EPA has responded to B. Sachau's generalized comments, in including her generalized objections to animal testing, on numerous previous occasions (see January 7, 2005, 70 FR 1349, 1354, FRL-7691-4); (October 29, 2004, 69 FR 63083, 63096, FRL-7681-9). As to her claim that food consumption data from 1994 is out of date, EPA would note that the food consumption data relied upon was collected between 1994 and 1998 by the United States Department of Agriculture (USDA) in there (Continuing Survey of Food Intakes by Individuals (CSFII)). Generally, major surveys of consumption patterns have been conducted by the USDA every 5 to 10 years or so. EPA has found that changes between surveys are on the margin and EPA has no reason to believe that there have been significant shifts in food consumption patterns in the last several years. B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to imazethapyr, including all anticipated dietary exposures and all other exposures for which there is reliable information.

### V. Conclusion

Therefore, tolerances are established for the sum of the residues of imazethapyr, and its metabolites CL 288511 and CL 182704, in or on rice, grain at 0.3 ppm, and rice, straw at 0.4 ppm and for the sum of the residues of imazethapyr and its metabolite CL 288511 in or on crayfish at 0.15 ppm.

### VI. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify ID number EPA-HQ-OPP-2005-0508 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before April 10, 2006.

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 issue(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 (1900L), 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 Suite 350, 1099 14<sup>th</sup> St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m.

to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the EPA.* 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 **ADDRESSES**. Mail your copies, identified by docket ID number EPA-HQ-OPP-2005-0508, to: Public Information and Records Integrity Branch, Information Technology and Resource Management 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 **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: [opp-docket@epa.gov](mailto: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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

### VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply,*

*Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCFA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of

FFDCA. For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

**VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: January 25, 2006.

**Lois Rossi,**  
 Director, Registration Division, Office of Pesticide Programs.

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

**PART 180— [AMENDED]**

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

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

■ 2. Section 180.447 is amended by increasing the tolerance level for the following commodities in the tables in paragraphs (a)(2) and (a)(3) to read as follows:

**§ 180.447 Imazethapyr; tolerances for residues.**

- (a)(1) \* \* \*
- (2) \* \* \*

Commodity	Parts per million
* * *	* *
Rice, grain .....	0.3
Rice, straw .....	0.4

(3)\* \* \*

Commodity	Parts per million
* * *	* *
Crayfish .....	0.15
* * *	* *

\* \* \* \* \*

[FR Doc. 06–1036 Filed 2–7–06; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2005–0145; FRL–7757–9]

**Boscalid; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of boscalid, 3-pyridinecarboxamide, 2-chloro-N-(4'-chloro [1,1'-biphenyl]-2-yl) in or on banana (imported), celery, and spinach. In addition, existing tolerances are being increased on almond hulls. Finally, the existing lettuce exception listed for the indirect or inadvertent residues in vegetables, leafy, group 4, is being revised to include celery and spinach, as well as lettuce. BASF requested the tolerances on almonds and bananas, and Interregional Research Project #4 (IR-4) has proposed group tolerances on vegetable, leafy, except brassica, Group 4 (to include celery and spinach), under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).