

Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before March 26, 2001 unless indicated otherwise, to discuss withdrawal of the application for amendment. This 180-day period will also permit interested members of the public to intercede with registrants prior to the Agency's approval of the deletion.

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2. — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Company No.	Company Name and Address
000862	Sun Company, Inc., P.O. Box 1135, Marcus Hook, PA 19061.
002724	Wellmark International, 1000 Tower Lane, Bensenville, IL 60106.
011556	Bayer Corporation, P.O. Box 390, Shawnee Mission, KS 66201.
068292	EDM Corporation, P.O. Box 8552, Porterville, CA 93258.

### III. What is the Agency Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

### IV. How and to Whom Do I Submit Withdrawal Requests?

1. *By mail:* Registrants who choose to withdraw a request for use deletion must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked March 26, 2001.

2. *In Person or by courier:* Deliver your withdrawal request to: Document Processing Desk (DPD), Information Services Branch, Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 266A, Crystal

Mall 2, 1921 Jefferson Davis Highway, Arlington, VA. The DPD is open from 8:00 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The DPD telephone number is (703) 305-5263.

3. *Electronically.* You may submit your withdrawal request electronically by e-mail to: hollins.james@gov. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format.

### V. Provisions for Disposition of Existing Stocks

The Agency has authorized the registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

#### List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Dated: September 18, 2000.

#### Richard D. Schmitt,

*Acting Associate Director, Information Resources Services Division, Office of Pesticide Programs.*

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**BILLING CODE 6560-50-S**

### ENVIRONMENTAL PROTECTION AGENCY

[PF-976; FRL-6744-6]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-976, must be received on or before October 27, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number

PF-976 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: James Tompkins, Registration Division (7505W), 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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-976. The official record consists of the

documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

#### *C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-976 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-976. Electronic comments

may also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set

forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### **List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 19, 2000.

**James Jones,**

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

### **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represent the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

### **American Cyanamid Company**

*OF6186*

EPA has received a pesticide petition (OF6186) from American Cyanamid Company, P.O. Box 400, Princeton, NJ. 08543-0400 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of 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 free acid or its ammonium salt (calculated as the acid), and its metabolite 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridinecarboxylic acid both free and conjugated in or on the raw agricultural commodities (RAC) rice grain at 0.5 parts per million (ppm) and rice straw at 0.3 ppm and in or on crayfish at 0.1 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

### A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues of imazethapyr in rice is adequately understood. Based on studies conducted on soybean, edible forage legumes, and corn, parent imazethapyr, and common metabolites CL 288511 and CL 182704 are the only residues of concern for tolerance setting purposes.

2. *Analytical method.* Practical analytical methods for detecting and measuring imazethapyr residues of concern in rice, its processed commodities, and crayfish are submitted to EPA with this petition. The analytical method for rice commodities, grain, and straw is based on capillary electrophoresis with limits of quantitation (LOQ) of 0.05 ppm. Measurement of imazethapyr residues in polished rice, hull, and bran are accomplished by liquid chromatography/atmospheric pressure ionization-electrospray (API/ES) mass spectrometry (LC/MS). The validated LOQ of the method is 0.025 ppm. A CZE-methodology is also submitted for the determination of imazethapyr in crayfish with limits of quantitation of 50 parts per billion (ppb). These independently validated methods are appropriate for the enforcement purposes of this petition.

3. *Magnitude of residues.* A total of nineteen field trials were conducted with imazethapyr and its metabolites on rice in 1997 and 1998 at several different use rates and timing intervals to represent the use patterns which would result in the highest residue. In these trials, residues of parent compound AC 263499 in grain and straw were less than the limit of quantitation (0.05 ppm). The hydroxy metabolite, CL 288511 was detected in grain samples at a maximum value of 0.085 ppm. All straw samples analyzed for CL 288511 residues were less than the limit of quantitation (0.05 ppm). The glucose conjugate, CL 182704 was detected at a maximum value of 0.11 ppm in grain. All straw samples analyzed for CL 182704 residues were less than the limit of quantitation (0.05 ppm). The RAC samples were also processed into polished rice, hull, and bran. Results from these studies support the proposed tolerances of 0.5 ppm for rice grain and 0.3 ppm for rice straw. Based on the chemical nature of imazethapyr, results from a fish bioaccumulation study and further studies conducted on a surrogate chemical, imazapyr (CL 243997), there is no reasonable expectation of finite residues of imazethapyr in crayfish.

However, the registrant is proposing a tolerance in or on crayfish at 0.1 ppm.

### B. Toxicological Profile

A complete, valid and reliable data base of mammalian and genetic toxicology studies support the proposed tolerances for imazethapyr. This data base was previously reviewed by the EPA in support of the tolerance petition and registration of imazethapyr on soybeans, legume vegetables, corn, alfalfa, and peanuts.

1. *Acute toxicity.* Imazethapyr technical is considered to be nontoxic (toxicity category IV) to the rat by the oral route of exposure. In an acute oral toxicity study in rats, the LD<sub>50</sub> value of imazethapyr technical was greater than 5,000 milligrams/kilograms (mg/kg) bwt for males and females. The results from an acute dermal toxicity study in rabbits indicate that imazethapyr is slightly toxic (toxicity category III) to rabbits by the dermal route of exposure. The dermal LD<sub>50</sub> value of imazethapyr technical was greater than 2,000 mg/kg bwt for both male and female rabbits. Imazethapyr technical is considered to be non-toxic (toxicity category IV) to the rat by the respiratory route of exposure. The 4-hour LC<sub>50</sub> value was greater than 3.27 mg/L (analytical) and greater than 4.21 mg/L (gravimetric) for both males and females. Imazethapyr technical was shown to be non-irritating to rabbit skin (toxicity category IV) and mildly irritating to the rabbit eye (toxicity category III). Based on the results of a dermal sensitization study (Buehler), imazethapyr technical is not considered a sensitizer in guinea pigs.

2. *Genotoxicity.* Imazethapyr technical was tested in a battery of four *in vitro* and one *in vivo* genotoxicity assays measuring several different endpoints of potential genotoxicity. Collective results from these studies indicate that imazethapyr does not pose a mutagenic or genotoxic risk.

3. *Reproductive and developmental toxicity.* The developmental toxicity study in Sprague Dawley rats conducted with imazethapyr technical showed no evidence of developmental toxicity or teratogenic effects in fetuses. Thus, imazethapyr is neither a developmental toxicant nor a teratogen in the rat. The no observed adverse effect level (NOAEL) for maternal toxicity was 375 mg/kg bwt/day, based on clinical signs of toxicity in the dams (e.g. excessive salivation) at 1,125 mg/kg bwt/day. Imazethapyr technical did not exhibit developmental toxicity or teratogenic effects at maternal dosages up to and including 1,125 mg/kg bwt/day, the highest dose tested (HDT). Results from a developmental toxicity study in New

Zealand white rabbits with imazethapyr technical also indicated no evidence of developmental toxicity or teratogenicity. Thus, imazethapyr technical is neither a developmental toxicant nor a teratogen in the rabbit. The NOAEL for maternal toxicity was 300 mg/kg bwt/day, based on decreased food consumption and bwt gain, abortion, gastric ulceration, and death at 1,000 mg/kg bwt/day, the next HDT. The NOAEL for developmental toxicity and teratogenic effects was determined to be >1,000 mg/kg bwt/day based on no developmental toxicity or fetal malformations associated with the administration of all doses. The results from the 2-generation reproduction toxicity study in rats with imazethapyr technical support a NOAEL for reproductive toxicity of 10,000 ppm (equivalent to 800 mg/kg bwt/day). The NOAEL for non-reproductive parameters (i.e. decreased weanling bwts) is 5,000 ppm.

4. *Subchronic toxicity.* A short-term (21-day) dermal toxicity study in rabbits was conducted with imazethapyr technical. No dermal irritation or abnormal clinical signs were observed at dose levels up to and including 1,000 mg/kg bwt/day (HDT), supporting a NOAEL for dermal irritation and systemic toxicity of 1,000 mg/kg bwt/day. In a subchronic (13-week) dietary toxicity study in rats with imazethapyr technical, no signs of systemic toxicity were noted, supporting a NOAEL of 10,000 ppm the highest concentration tested (HCT) (equivalent to 820 mg/kg bwt/day). In a subchronic (13-week) dietary toxicity study in dogs with imazethapyr technical, no signs of systemic toxicity were noted, supporting a NOAEL of 10,000 ppm (equivalent to 250 mg/kg bwt/day), the HCT.

5. *Chronic toxicity.* A 1-year dietary toxicity study was conducted with imazethapyr technical in Beagle dogs at dietary concentrations of 0, 1,000, 5,000, and 10,000 ppm. In this study, the NOAEL for systemic toxicity was 1,000 ppm (equivalent to 25 mg/kg bwt/day), based on slight anemia, i.e., decreased red cell parameters observed at 5,000 and 10,000 ppm concentrations. No treatment-related histopathological lesions were observed at any dietary concentration, including the HCT (10,000 ppm).

In a 2-year chronic dietary oncogenicity and toxicity study in rats conducted with imazethapyr technical, the NOAEL for oncogenicity, and chronic systemic toxicity was 10,000 ppm (equivalent to 500 mg/kg bwt/day), the HCT. An 1-month chronic dietary oncogenicity and toxicity study in mice with imazethapyr technical support, a

NOAEL for oncogenicity of 10,000 ppm, the HCT (equivalent to 1,500 mg/kg bwt/day), and a NOAEL for chronic systemic toxicity of 5,000 ppm (equivalent to 750 mg/kg bwt/day), based on decreased bwt gain in both sexes). The EPA has classified imazethapyr as a Group E carcinogen (evidence of non-carcinogenicity for humans) based on the absence of treatment-related tumors in acceptable carcinogenicity studies in both rats, and mice.

6. *Animal metabolism.* The rat, goat, and hen metabolism studies indicate that the qualitative nature of the residues of imazethapyr in animals is adequately understood. In 3 rat metabolism studies conducted with radio-labeled imazethapyr technical the major route of elimination of the herbicide was through rapid excretion in urine and to a much lesser extent in feces. In the first study, almost 100% of the administered material was recovered in excreta within 96 hours (89–95% in urine, 6–11% in feces). The major residue in urine and feces was parent compound. Approximately 2% of the dose was metabolized and excreted as the  $\alpha$ -hydroxyethyl derivative of imazethapyr. In the second study, the test material was rapidly and completely eliminated unchanged in the urine within 72 hours of dosing. After 24 hours, 92.1% of radio-activity was excreted in the urine with 4.67% in the feces. There was no significant bioaccumulation of radio-activity in the tissues from this rat metabolism study (< 0.01 ppm after 24 hours). In the third study, 4 groups treated with radio-labeled imazethapyr readily excreted >95% of the test material in the urine and feces within 48 hours. A high percentage (97–99%) of the test material was excreted in the urine as unchanged parent, the remainder as the  $\alpha$ -hydroxyethyl derivative of imazethapyr. For all 3 studies, the major route of elimination of the herbicide in rats was through rapid excretion of unchanged parent compound in urine. It is clear that imazethapyr and its related residues do not accumulate in tissues and organs.

In the goat metabolism study, parent  $^{14}\text{C}$ -imazethapyr was dosed to lactating goats at 0.25 ppm and 1.25 ppm. Results showed  $^{14}\text{C}$ -residues of <0.01 ppm in milk, and <0.05 ppm in leg muscle, loin muscle, blood, fat, liver, and kidney. Laying hens dosed at 0.5 ppm and 2.5 ppm with  $^{14}\text{C}$ -imazethapyr showed  $^{14}\text{C}$ -residues of <0.05 ppm in eggs and all tissues (blood, muscle, skin/fat, liver, and kidney).

Additional animal metabolism studies have been conducted with CL 288511

(main metabolite in treated crops fed to livestock) in both laying hens and lactating goats. These studies have been repeated to support subsequent use extensions on crops used as livestock feed items which would theoretically result in a higher dosing of imazethapyr-derived residues to livestock (i.e., corn, alfalfa). In these studies, lactating goats dosed at 42 ppm of  $^{14}\text{C}$ -CL 288511 showed  $^{14}\text{C}$ -residues of <0.01 ppm in milk, leg muscle, loin muscle, and omental fat.  $^{14}\text{C}$ -residues in blood were mostly <0.01 ppm but reached 0.01 ppm on 2 of the treatment days.  $^{14}\text{C}$ -residue levels in the liver, and kidney were 0.02 and 0.09 ppm, respectively. Laying hens dosed at 10.2 ppm of  $^{14}\text{C}$ -imazethapyr showed  $^{14}\text{C}$ -residues of <0.01 ppm in eggs and all tissues (blood, muscle, skin/fat, liver, and kidney).  $^{14}\text{C}$ -imazethapyr or  $^{14}\text{C}$ -CL 288511 ingested by either laying hens or lactating goats was excreted within 48 hours of dosing. These studies indicate that parent imazethapyr and CL 288511-related residues do not accumulate in milk or edible tissues of the ruminant.

7. *Metabolite toxicology.* Metabolism studies in soybean, peanut, corn, and alfalfa indicate that the only significant metabolites are the  $\alpha$ -hydroxyethyl derivative of imazethapyr, CL 288511 and its glucose conjugate CL 182704. The  $\alpha$ -hydroxyethyl metabolite has also been identified in minor quantities in the previously submitted rat metabolism studies and in goat and hen metabolism studies. No additional toxicologically significant metabolites were detected in any of the plant or animal metabolism studies.

8. *Endocrine disruption.* Collective organ weight data and histopathological findings from the 2-generation rat reproductive study, as well as from the subchronic and chronic toxicity studies in 3 different animal species demonstrate no apparent estrogenic effects or treatment-related effects of imazethapyr on the endocrine system.

### C. Aggregate Exposure

1. *Dietary exposure.* The potential dietary exposure to imazethapyr has been calculated from the proposed tolerance for use on rice and previously established tolerances for peanuts, legume vegetables, soybeans, alfalfa, endive, lettuce, and corn. This very conservative chronic dietary exposure estimate used the proposed tolerance of 0.5 ppm for rice, and tolerance values of 0.1 ppm for peanuts, 0.1 ppm for legume vegetables, 0.1 ppm for soybeans, 3.0 ppm for alfalfa, 0.1 ppm for endive (escarole), 0.1 ppm for lettuce, and 0.1 ppm for corn. In addition, these estimates assume that

100% of these crops contain imazethapyr residues.

i. *Food.* Potential exposure to residues of imazethapyr in food will be restricted to intake of rice, peanuts, legume vegetables, soybeans, alfalfa (sprouts), endive, lettuce, and corn. Using the assumptions discussed above, the theoretical maximum residue concentration (TMRC) values of imazethapyr were calculated for the U.S. general population and subgroups. Based on the tolerances given above, the TMRC values for each group are:

- 0.000419 mg/kg bwt/day for the general U.S. population.
- 0.001104 mg/kg bwt/day for all infants (<1-year).
- 0.001298 mg/kg bwt/day for non-nursing infants.
- 0.000870 mg/kg bwt/day for children 1 to 6 years of age.
- 0.000610 mg/kg bwt/day for children 7 to 12 years of age.

The TMRC values indicate that non-nursing infants are the most highly exposed population subgroup.

ii. *Drinking water.* As a screening-level assessment for aggregate exposure, the U.S. EPA evaluates a drinking water level of comparison (DWLOC), which is the maximum concentration of a chemical in drinking water that would be acceptable in light of total aggregate exposure to that chemical. In 1990, the EPA set the reference dose (RfD) for imazethapyr at 0.25 mg/kg bwt/day, based on the NOAEL from the 1-year dietary toxicity study in dogs of 25 mg/kg bwt/day and a 100-fold uncertainty factor. Based on the chronic RfD of 0.25 mg/kg bwt/day and the EPA's default factors for bwt and drinking water consumption, the DWLOCs have been calculated to assess the potential dietary exposure from residues of imazethapyr in water. For the adult population the chronic DWLOC was 8,735 ppb and for children the DWLOC was estimated to be 2,491 ppb.

Chronic drinking water exposure analyses were calculated for imazethapyr using EPA screening models screening concentration in ground water ((SCI-GROW) for ground water and (generic expected environmental concentration) (GENEEC) for surface water). The SCI-GROW value is 16.54 ppb and the calculated peak GENEEC value is 5.96 ppb by aerial application. For the U.S. adult population, the estimated exposures of imazethapyr residues in groundwater and surface water are approximately 0.19% and 0.07%, respectively, of the DWLOC. The estimated exposures of children to imazethapyr residues in ground water and surface water are approximately 0.66%, and 0.24%,

respectively, of the DWLOC. Therefore, the exposures to drinking water from imazethapyr use are negligible.

2. *Non-dietary exposure.* Imazethapyr products are not currently registered or requested to be registered for residential use; therefore the estimate of residential exposure is not relevant to this tolerance petition.

#### D. Cumulative Effects

Imazethapyr is a member of the imidazolinone class of herbicides. Other compounds of this class are registered for use in the United States. However, the herbicidal activity of the imidazolinones is due to the inhibition of acetohydroxyacid synthase (AHAS), an enzyme only found in plants. AHAS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack AHAS and this biosynthetic pathway. This lack of AHAS contributes to the low toxicity of the imidazolinone compounds in animals. We are aware of no information to indicate or suggest that imazethapyr has any toxic effects on mammals that would be cumulative with those of any other chemical. Therefore, for the purposes of this tolerance petition no assumption has been made with regard to cumulative exposure with other compounds having a common mode of action.

#### E. Safety Determination

1. *U.S. population.* The RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. In 1990, the EPA set the RfD for imazethapyr at 0.25 mg/kg bwt/day, based on the NOAEL from the 1-year dietary toxicity study in dogs of 25 mg/kg bwt/day and a 100-fold uncertainty factor. The chronic dietary exposure of 0.000419 mg/kg bwt/day for the general U.S. population will utilize only 0.2% of the RfD of 0.25 mg/kg bwt/day. EPA generally has no concern for exposures below 100% of the RfD. Due to the low toxicity of imazethapyr, an acute exposure dietary risk assessment is not warranted. The complete and reliable toxicity data base, the low toxicity of the active ingredient, and the results of the chronic dietary exposure risk assessment, support the conclusion that there is a "reasonable certainty of no harm" from the proposed use of imazethapyr on imidazolinone tolerant rice. Furthermore, these factors support the proposed tolerance on rice.

2. *Infants and children.* The conservative dietary exposure estimates of all registered uses including the proposed tolerance for rice show exposures of 0.001104, 0.000440,

0.000870, and 0.000610 mg/kg bwt/day which will utilize 0.4, 0.2, 0.3, and 0.2% of the RfD for all infants (<1 year), nursing infants, children 1-6 years, and children 7-12 years, respectively. The chronic dietary exposures for non-nursing infants, the most highly exposed subgroup, will utilize only 0.5% of the RfD. Results from the 2-generation reproduction study in rats and the developmental toxicity studies in rabbits and rats indicate no increased sensitivity to developing offspring when compared to parental toxicity. These results also indicate that imazethapyr is neither a developmental toxicant nor a teratogen in either the rat or rabbit. Therefore, an additional safety factor is not warranted, and the RfD of 0.25 mg/kg bwt/day, which utilizes a 100-fold safety factor is appropriate to ensure a reasonable certainty of no harm to infants and children.

#### F. International Tolerances

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

[FR Doc. 00-24680 Filed 9-26-00; 8:45 am]

**BILLING CODE 6560-50-S**

### ENVIRONMENTAL PROTECTION AGENCY

[PF-972; FRL-6742-4]

#### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-972, must be received on or before October 27, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-972 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@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	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-972. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record