2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

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

II. Background

This document announces EPA's intent to hold a public meeting or Technical Briefing to present to interested stakeholders the Agency's risk assessments for the soil fumigant pesticides dazomet, metam sodium, methyl bromide, and 1,3-D or Telone. EPA is assessing risks and will develop risk management decisions for five soil fumigants, including dazomet, metam sodium, and methyl bromide, plus chloropicrin and a new active ingredient, iodomethane. 1,3-D risks will be discussed for comparative purposes; however, the Agency's risk management decision for 1,3-D was completed in September 1998. Risk assessments for chloropicrin and iodomethane will follow about a month later due to recently submitted data which are currently under review. The Technical Briefing is part of EPA's process to involve the public in developing pesticide registration and reregistration eligibility decisions. Through these programs, the Agency is ensuring that all pesticides meet current health and safety standards.

At the Technical Briefing, EPA will describe the risk assessments and the data, information and methodologies used in developing them. Stakeholders will have an opportunity to ask clarifying questions. On the day of the Technical Briefing, the soil fumigant risk assessments and related documents will be available in their respective pesticide Dockets and EDOCKET on the Agency's web site. These docket ID numbers will be as follows: Methyl bromide (OPP–2005–0123), 1,3-D (OPP–2005–0124), metam sodium (OPP–2005–0125), and dazomet (OPP–2005–0128). EPA will solicit public comment on the risk assessments and related documents through **Federal Register** notices of availability, which are scheduled to be published on the day of the Technical Briefing.

After considering public comments received, EPA will revise the risk assessments for dazomet, metam sodium, methyl bromide, and 1,3-D (and later for chloropicrin and iodomethane) and develop any needed risk mitigation. Stakeholders and the public will have opportunities, including stakeholder meetings during public comment periods, to review the revised risk assessments and provide ideas and recommendations on risk mitigation options.

EPA is evaluating the soil fumigants to ensure that its risk assessment approaches are consistent, and to ensure that risk tradeoffs and economic outcomes can be adequately predicted in reaching risk management decisions. Using this approach, the Agency expects to address risks of concern while maintaining key use benefits.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 23, 2005.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 05–12917 Filed 6–28–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0161; FRL–7718–5]

Imazethapyr; 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 identification (ID) number OPP–2005–0161, must be received on or before July 29, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–-0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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

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

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2005–0161. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet

under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

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

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0161. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2005–0161. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2005–0161.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0161. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 ID 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 theelements set forth in FFDCA 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: June 10. 2005.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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.

BASF Corporation

PP 5F 6947

EPA has received a pesticide petition (5F 6947) from BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, North Carolina 27709–3528 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of 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 commodity rice grain at 0.3 parts per million (ppm) and rice straw at 0.4 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 supports 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 and 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*. 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 available for the determination of imazethapyr in crayfish with limits of quantitation of 50 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 raw agricultural commodity (RAC) samples were also processed into polished rice, hull and bran. Results from these studies support the proposed tolerances of 0.3 ppm for rice grain and 0.4 ppm for rice straw.

B. Toxicological Profile

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_{50} value of imazethapyr technical was greater than 5,000 mg/kg body weight 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_{50} value of imazethapyr technical was greater than 2,000 mg/kg bw 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_{50} 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-Observable-Effect-Level (NOEL) for maternal toxicity was 375 mg/kg bw/day, based on clinical signs of toxicity in the dams (e.g. excessive salivation) at 1,125 mg/kg bw/day. Imazethapyr technical did not exhibit developmental toxicity or teratogenic effects at maternal dosages up to and including 1,125 mg/kg bw/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 NOEL for maternal toxicity was 300 mg/kg bw/day, based on decreased food consumption and body weight gain, abortion, gastric ulceration and death at 1,000 mg/kg bw/day, the next HDT. The NOEL for developmental toxicity and teratogenic effects was determined to be <1,000 mg/kg bw/day based on no developmental toxicity or fetal malformations associated with the administration of all doses.

The results from the two-generation reproduction toxicity study in rats with imazethapyr technical support a NOEL for reproductive toxicity of 10,000 ppm (equivalent to 800 mg/kg bw/day). The NOEL for non-reproductive parameters (i.e. decreased weanling body weights) 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 bw/day (HDT), supporting a NOEL for dermal irritation and systemic toxicity of 1,000 mg/kg bw/day.

In a subchronic (13–week) dietary toxicity study in rats with imazethapyr technical, no signs of systemic toxicity were noted, supporting a NOEL of 10,000 ppm the highest concentration tested (equivalent to 820 mg/kg bw/day).

In a subchronic (13–week) dietary toxicity study in dogs with imazethapyr technical, no signs of systemic toxicity were noted, supporting a NOEL of 10,000 ppm (equivalent to 250 mg/kg b.w./day), the highest concentration tested.

5.*Chronic toxicity*. A one-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 NOEL for systemic toxicity was 1,000 ppm (equivalent to 25 mg/kg bw/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 highest concentration tested (10,000 ppm).

In a two-year chronic dietary oncogenicity and toxicity study in rats conducted with imazethapyr technical, the NOEL for oncogenicity and chronic systemic toxicity was 10,000 ppm (equivalent to 500 mg/kg bw/day), the highest concentration tested. An 18–month chronic dietary oncogenicity and toxicity study in mice with imazethapyr technical supports a NOEL for oncogenicity of 10,000 ppm, the highest concentration tested (equivalent to 1,500 mg/kg bw/day), and a NOEL for chronic systemic toxicity of 5,000 ppm (equivalent to 750 mg/kg bw/day), based on decreased body weight gain in both sexes).

The EPA has classified imazethapyr as negative for carcinogenicity (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 three rat metabolism studies conducted with radiolabeled 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 α-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 radioactivity was excreted in the urine with 4.67% in the feces. There was no significant bioaccumulation of radioactivity in the tissues from this rat metabolism study (<0.01 ppm after 24 hours). In the third study, four groups treated with radiolabeled 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 α-hydroxyethyl derivative of imazethapyr. For all three 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 imazathapyr and its related residues do not accumulate in tissues and organs.

In the goat metabolism study, parent ^{14}C-imazethapyr was dosed to lactating goats at 0.25 ppm and 1.25 ppm. Results showed ^{14}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}C-imazethapyr showed ^{14}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}C-CL 288511 showed ^{14}C-residues of <0.01 ppm in milk, leg muscle, loin muscle and omental fat. ^{14}C-Residues in blood were mostly <0.01 ppm but reached 0.01 ppm on two of the treatment days. ^{14}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}C-imazethapyr showed ^{14}C-residues of <0.01 ppm in eggs and all tissues (blood, muscle, skin/fat, liver and kidney). ^{14}C-imazethapyr or ^{14}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 α-hydroxyethyl derivative of imazethapyr, CL 288511 and its glucose conjugate CL 182704. The α-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 two-generation rat reproductive study, as well as from the subchronic and chronic toxicity studies in three different animal species demonstrate no apparent estrogenic effects or treatment-related effects of imazethapyr on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. BASF has determined that there are no toxic effects attributable to a single dose of imazethapyr. Therefore, a quantitative acute dietary exposure and risk assessment was not required.

Assessments were conducted to evaluate the potential risk due to chronic dietary exposure of the U.S. population to residues of imazethapyr. This herbicide and its metabolites (CL 288511, CL 182704) were expressed as the parent compound (imazethapyr). A dietary exposure analysis was conducted for all current crops, including the increased tolerance for rice grain and straw, and secondary residues in meat, meat byproducts, and fat. The commodities include canola, field corn, crop group 6, soybeans, alfalfa, nongrass animal feed group, peanuts, endive, crayfish, head lettuce, and leaf lettuce.

The tier 1 chronic dietary exposure estimates were based on the tolerance values, 100 percent crop treated values, default concentration/processing factors and consumption data from the USDA Continuing Survey of Food Intake by Individuals (CSFII 1994 – 1996, 1998) and the EPA Food Commodity Ingredient Database (FCID) using Exponent's Dietary Exposure Evaluation Module (DEEM-FCID) software. Resulting exposure estimates were compared against the imazethapyr chronic Population Adjusted Dose (cPAD) of 2.5 mg/kg bw/day.

Exposure estimates for the imazethapyr chronic dietary assessments were well below U.S. EPA's level of concern (See Table 1). The estimated chronic dietary exposure was <0.1% of the cPAD for all subpopulations. Additional refinements such as the use of anticipated residues and predicted percent crop treated would further reduce the estimated chronic dietary exposure.

TABLE 1.—SUMMARY OF CHRONIC DIETARY EXPOSURE AND RISK FOR IMAZETHAPYR CONSIDERING ALL CURRENT CROPS AND SECONDARY ANIMAL RESIDUES

Population Subgroups	Exposure Estimate (mg/kg bw/day)	%cPAD (cPAD = 2.5 mg/kg bw/day)
U.S. Population	0.000476	0.019
All Infants (<1 year old)	0.000693	0.028
Children (1-2 years old)	0.000945	0.038
Children (3-5 years old)	0.000959	0.038
Children (6-12 years old)	0.000701	0.028
Youth (13-19 years old)	0.000514	0.021
Females (13-49 years old)	0.000379	0.015
Adults (20-49 years old)	0.000424	0.017
Adults (50+ years old)	0.000304	0.012

ii. *Drinking water*. Because the Agency does not have 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. Surface water (rice paddy model; peak and average 126 µg/l) estimated drinking water concentrations (EDWCs) for imazethapyr were calculated. The surface water EDWCs were generated assuming two applications of imazethapyr at 0.188 lbs ae/acre (highest registered/proposed multiple application rate). Based on several prospective ground water studies the upper bound ground water exposure would not be expected to exceed 1 µg/L. The estimated drinking water concentrations (EDWC) for both surface water and ground water are well below the allowable level. Drinking water level of comparison (DWLOC) calculations and comparisons to surface water estimations are given as follows in Table 2.

TABLE 2. — ESTIMATED CHRONIC DRINKING WATER VALUES FOR IMAZETHAPYR

$DWLOC_{chronic}$	U.S. Population[1]	All Infants <1 year)	Children (1-6 years)	Females (13-49 years)	Adults (20-49 years)
DWLOC chronic (µg/L)	87483	24993	24991	74989	87485
		EDWC's			
PRZM/EXAMS (BASF) Surface water (µg/L)*	126	126	126	126	126

*acute value for surface water

iii. *Aggregate exposure (diet + water).* The estimated chronic aggregate exposure of imazethapyr from potential residues in food and water are summarized in Table 3 as follows. Imazethapyr is not registered for residential use and therefore residential exposure was not considered.

TABLE 3. — ESTIMATED CHRONIC AGGREGATE EXPOSURE FROM THE USE OF IMAZETHAPYR

Population Subgroup	Chronic Food Exposure (mg/kg/day)	Chronic Drinking Water Exposure[1] (mg/kg/day)	Aggregate Exposure[2] (mg/kg/day)	Aggregate %cPAD
U.S. Population	0.000476	0.003600	0.004076	0.16
Infants (< 1 year old)	0.000693	0.012600	0.013293	0.53
Children (1-6 years old)	0.000937	0.012600	0.013537	0.54
Females (13-49 years old)	0.000379	0.004000	0.004379	0.18
Adults (20-49 years old)	0.000424	0.003600	0.004024	0.16

[1] Aggregate Exposure = Food Exposure + Drinking Water Exposure
[2] Drinking Water Exposure (mg/kg/day) = [Drinking Water Concentration (µg/L) * Water Consumed (L/day)/ Body weight (kg)]/1,000

The assessment results indicate the aggregate exposure of imazethapyr from potential residues in food and drinking water will not exceed the U.S. EPA's level of concern (100% of PAD). The percent chronic PAD was <1% for all subpopulations. Additional refinements such as the use of anticipated residues and predicted percent crop treated would further reduce the estimated chronic dietary exposure and %cPAD. Overall, considering a ''worst-case'' scenario, we can conclude with reasonable certainty that no harm will occur from chronic aggregate exposure of imazethapyr residues from the current crops, including the higher proposed tolerance values.

2. *Non-dietary exposure* . Imazethapyr products are not currently registered for 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.* Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated the aggregate exposure to imazethapyr will utilize less than 1% of the cPAD for the U.S. population and all subpopulations, respectively.

2. *Infants and children.* All subpopulations based on age were considered. Infants and children remained below 1% of the aggregate cPAD for food and water. BASF, considering a worst-case situation, concludes with reasonable certainty that no harm will result to infants or children from aggregate exposure to imazethapyr residues.

No additional FQPA safety factor(s) are considered to be appropriate for imazethapyr. There is a complete toxicity database for imazethapyr and the exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the toxicology data and conclusions, a FQPA safety factor of 1X appears to be appropriate for imazethapyr.

F. International Tolerances

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

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0033; FRL–7718–8]

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

AGENCY: Environmental Potection 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 identification (ID) number OPP–2005–0033, must be received on or before July 29, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:(703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or