Nominations are requested within 60 days of this notice, and may be submitted online at *www.epa.gov/iris/whatsnew/2004nominations* or by mail or electronic mail. Submissions by mail may be made to the IRIS Submission Desk, c/o ASRC, 6301 Ivy Lane, Suite 300, Greenbelt, MD 20770. Please send two copies, with one copy unbound. Alternatively, nominations may be sent electronically to *IRIS.desk@epa.gov.* Electronic information must be submitted in WordPerfect format or as an ASCII file. Information also will be accepted on 3.5″ floppy disks or CD. The IRIS Submission Desk will acknowledge receipt of your information.

Dated: August 8, 2003.

Peter W. Preuss,

Director, National Center for Environmental Assessment.

[FR Doc. 03–20528 Filed 8–12–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0266; FRL–7321–7]

Imazapyr; 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 ID number OPP–2003–0266, must be received on or before September 12, 2003.

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 pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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

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

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

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0266. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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–2003–0266. 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–2003–0266. 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–2003–0266.

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, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0266. 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 the elements 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: August 7, 2003.

Debra Edwards,

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 0F6166

EPA has received a pesticide petition (PP 0F6166) from BASF, 26 Davis Drive, Research Triangle Park, NC 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 imazapyr [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-l*H*-imidazol-2-yl]-3-pyridinecarboxylic acid], applied as the isopropylamine salt, in or on the raw agricultural commodity on grass forage at 125 parts per million (ppm) and hay at 35 ppm, fish at 1 ppm, shellfish at 0.1 ppm, milk at 0.01 ppm, and kidney at 0.5 ppm, meat by-products other than kidney at 0.05 ppm, meat at 0.05 ppm, and fat at 0.05 ppm of cattle, sheep, goats, and horses. 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*—i. *Bermudagrass*. Radiolabeled imazapyr was applied at 1.5 lb acid equivalents/acre (ae)/A to field-grown bermudagrass. Parent imazapyr accounted for the majority of the total radioactive residue (TRR) in all harvested samples. No metabolites were identified which require regulation.

ii. *Ruminant*. Goats were dosed with radiolabeled imazapyr at 17.7 ppm, 42.5 ppm, or 47 ppm dietary equivalents for 7 days. As assessed for goats receiving the 17.7 or 42.5 ppm doses, TRR in fat, liver and leg and loin muscle were non-detectable < 0.05 ppm. TRR in milk were a maximum of 0.01, 0.02, and 0.02 ppm for the three goats, respectively, while TRR in kidney were 0.08, 0.11, and 0.08 ppm, respectively. Of these residues, parent imazapyr accounted for 50–66% of the TRR in milk and 82–95% of the TRR in kidney. No metabolites were identified which require regulation.

iii. *Confined crop rotation*. Radiolabeled imazapyr was applied to soil at a rate of 0.79 lb ae/A. Root (carrot), lettuce (leafy vegetables), and wheat (cereal grains), were planted at 330 through 540 days; shorter intervals were not required as rangeland and pastures are not normally rotated to other crops. The TRR in all harvested samples were <0.02 ppm and the major extractable component of these residues was parent imazapyr. Therefore, there is no reasonable expectation of inadvertent residues in rotational crops planted 12 months after application.

2. *Analytical method*. M 3023 is a reliable capillary electrophoresis method with ultraviolet (CE/UV) detection for the determination of imazapyr residues in grass forage and grass hay. M 3184 is a reliable CE/UV method for the determination of imazapyr residues in meat, kidney, other meat byproducts, and fat of cattle, sheep, goats, and horses. M 3075 is a reliable CE/UV method for the determination of imazapyr residues in milk. M 3066 is a reliable CE/UV method for the determination of imazapyr residues in fish and shellfish.

3. *Magnitude of residues*—i. *Grass*. Imazapyr was applied at a nominal rate of 0.75 lb ae/A to bluegrass, bermudagrass, tall fescue, and bromegrass for a total of 14 field trials. Residues of imazapyr were reached a maximum of 98 ppm in grass forage immediately after treatment and 27 ppm upon drying to grass hay cut 7 days after treatment. Therefore, tolerances of 125 ppm in/on grass forage and 35 ppm in/on grass hay are proposed.

ii. *Ruminants*. Lactating dairy cows were dosed orally each day for 28 or 29 consecutive days at feed equivalents of 0, 58, 157, 607, and 1,680 milligrams (mg) imazapyr per kilogram (kg) dry matter consumed. The 58 mg/kg dose is equivalent to 1.4 times the anticipated dietary burden for the worst-case cattle diet where 10% of the grass received an imazapyr spot treatment, the proposed label use for range and pasture grasses. At 58 mg/kg, imazapyr residues in milk were < 0.01 ppm; residues in muscle, fat, and liver were <0.05 ppm; and residues in kidney averaged 0.25 ppm. Furthermore, imazapyr residues in milk were shown not to be concentrated into milk fat. Therefore, the following tolerances for imazapyr residues in cattle, sheep, goats, and horses are proposed: Milk at 0.01 ppm; meat byproducts (except kidney) at 0.05 ppm; meat at 0.05 ppm; fat at 0.05 ppm; and kidney at 0.5 ppm.

iii. *Fish and shellfish*. Imazapyr was applied at 1.6 lb ae/A to two ponds containing fish and aquatic invertebrates. Imazapyr residues were observed from the organisms collected from the treated ponds at only one site and only in the 3-hour-after-treatment samples. Average residues from these samples were: Bluegill, 0.636 ppm; tilapia, 0.233 ppm; catfish, 0.068 ppm; crayfish, 0.059 ppm. In a separate study, freshwater clams were exposed to a dose of imazapyr equivalent to 1.5 lb ae/A as applied to a 2.2-foot deep pond; residues of imazapyr in these clams remained <0.05 ppm at all intervals evaluated (up to 28 days post-treatment). Given these results, tolerances for imazapyr are proposed at 1 ppm for fish and 0.1 ppm for shellfish.

B. Toxicological Profile

1. *Acute toxicity*. Based on a battery of acute toxicity studies, imazapyr has been placed in toxicity category I for eye irritation, category IV for oral LD_{50} and primary dermal irritation, and category III for dermal LD_{50} and inhalation LC_{50}. Imazapyr was a non-sensitizer when tested for dermal sensitization (Buehler Method).

2. *Genotoxicity*. Studies on gene mutation and other genotoxic effects, Ames Salmonella Assay, CHO/HGPRT Point Mutation Assay, *in vitro* CHO cell chromosome aberration assay, dominant lethal assay, and unscheduled DNA synthesis (UDS) in primary rat hepatocytes yielded negative results.

3. *Reproductive and developmental toxicity*—i. For a rat developmental toxicity study at doses of 0, 100, 300, or 1,000 mg/kg body weight/day (b.w./day), the only clinical sign of toxicity was salivation in gravid dams at 1,000 mg/kg b.w./day. The No-Observed-Adverse-Effect Level (NOAEL) for maternal toxicity is 300 mg/kg b.w./day. There were no developmental findings in this study up to the limit dose of 1,000 mg/kg b.w./day, the highest dose tested (HDT).

ii. For a rabbit development toxicity study at doses of 0, 25, 100, and 400 mg/kg b.w./day, the maternal and developmental NOAEL is 400 mg/kg b.w./day HDT. Doses were based on pilot range-finder study, which tested at 0, 250, 500, 1,000, and 2,000 mg/kg b.w./day. The only toxic effect observed was increased salivation at 1,000 and 2,000 mg/kg b.w./day.

iii. A 2–generation rat reproduction study at doses of 0, 1,000, 5,000, or 10,000 ppm yielded a NOAEL of 10,000 ppm highest concentration tested (HCT) (800 mg/kg b.w./day for males, 980 mg/kg b.w./day for females, as based on food consumption data).

4. *Subchronic toxicity*—i. A 90–day dietary study in rats at doses of 0, 15,000, or 20,000 ppm resulted in a

NOAEL of 20,000 ppm HCT (approximately 1,695 mg/kg b.w./day for males, 1,785 mg/kg b.w./day for females, as based on food consumption data).

ii. A 21–day rabbit dermal toxicity study at doses of 0, 100, 200, or 400 mg/kg b.w./day resulted with the NOAEL of 400 mg/kg b.w./day HDT.

5. *Chronic toxicity*—i. A 1–year chronic toxicity study in dogs at doses of 0, 1,000, 5,000, or 10,000 ppm yielded a NOAEL of 10,000 ppm HCT (equivalent to 250 mg/kg b.w./day).

ii. A 2–year chronic toxicity/carcinogenicity study in rats at doses of 0, 1,000, 5,000, or 10,000 ppm provided NOAELs for both systemic toxicity and oncogenicity of 10,000 ppm HCT (approximately 500 mg/kg b.w./day for males, 640 mg/kg b.w./day for females, as based on food consumption data).

iii. An 18–month oncogenicity study in mice at doses of 0, 1,000, 5,000, or 10,000 ppm provided NOAELs for both systemic toxicity and oncogenicity of 10,000 ppm HCT (equivalent to 1,500 mg/kg b.w./day).

6. *Animal metabolism*. Results from a rat metabolism study indicated that imazapyr was rapidly absorbed and excreted by 7 days post-dosing, with the majority of the administered 14C-label (90%) eliminated in the urine within 48 hours. Metabolite characterization studies showed that essentially all the test material was excreted unchanged. Two minor metabolites were detected in the urine or feces of treated rats; however, their contribution combined was less than or equal to 0.5% of the administered dose. An additional 12 unidentified metabolites were isolated, but they contributed less than 3% of the total dose.

7. *Metabolite toxicology*. There were no metabolites identified in plant or animal commodities which require regulation.

8. *Endocrine disruption*. There is sufficient data from the 2–generation rat reproduction study as well as from the subchronic (90–day) rat feeding study and chronic feeding studies in the dog (1–year), rat (24–month), and mouse (18–month), to determine whether imazapyr has potential estrogenic properties or causes other endocrine effects. The collective data from these studies, indicate that imazapyr is not associated with any treatment-related estrogenic or endocrine effects.

The 2–generation rat reproduction study, conducted at dietary concentrations up to 10,000 ppm, showed no treatment-related effects on reproductive performance (including estrous cycle data, mating indices, pregnancy rates, fertility indices, gestational length, and gestation indices) or on pup growth and development from parturition to adulthood for both litter intervals. Histopathological examinations of the testes, epididymides, prostate gland, and seminal vesicles, were conducted for high-dose and control P_1 and F_1 adult males. Histopathological examinations of the mammary gland, ovaries, uterus (corpus and cervix), and vagina, were conducted for high-dose and control P_1 and F_1 adult females. In addition, for F_{2b} pups, histopathological examinations of the adrenal glands, pancreatic islets, pituitary gland, thyroid gland, parathyroid glands, testes, epididymides, prostate gland, seminal vesicles, mammary gland, ovaries, uterus (corpus and cervix), and vagina, were conducted. For all of these tissue examinations, no treatment-related microscopic findings were observed in either males or females. Further, no treatment-related macroscopic findings were observed for either parental or pup generations.

Organ weight data and histopathological examinations from the subchronic (90–day) rat feeding study and chronic feeding studies in the dog (1–year), rat (24–month), and mouse (18–month), may also be utilized to determine whether imazapyr has potential estrogenic properties or causes other endocrine effects. Absolute and relative weights of the adrenal glands (not measured in the dog study), pituitary gland, thyroid/parathyroid gland, ovaries, and testes (with/without epididymides) were recorded for animals at the interim (if applicable) and terminal sacrifice periods in these studies. In addition, detailed macroscopic and microscopic examinations of the following organs were performed: Pituitary gland, thyroid gland, parathyroid glands, pancreatic islets, adrenal glands, testes, epididymides, prostate gland, seminal vesicles (not performed in the dog study), mammary gland, ovaries, uterus (corpus and cervix), and vagina. No information was found from the organ weight data or macroscopic and microscopic examinations, from the subchronic (90–day) rat feeding study and chronic feeding studies in the dog (1–year), rat (24–month), and mouse (18–month), that suggests that imazapyr is associated with any treatment-related estrogenic effects or effects on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*—a. *Acute dietary exposure*. An acute dietary risk assessment is not required because no acute toxicological endpoints were identified by the EPA for imazapyr.

b. *Chronic dietary exposure*. Novigen Sciences, Inc. conducted a Tier 1 assessment of potential chronic dietary exposure from the proposed uses of imazapyr for weed control in pasture/range grasses and for aquatic weed control. These uses may result in dietary residues in shellfish, freshwater finfish, milk, and tissues of cattle, sheep, goats, and horses. This assessment also included the current tolerances on field corn commodities. For this Tier 1 analysis, tolerance values were used for fish at 1.0 ppm; shellfish at 0.1 ppm; kidney of cattle, sheep, goats, and horses at 0.5 ppm; other meat byproducts of cattle, sheep, goats, and horses at 0.05 ppm; meat of cattle, sheep, goats, and horses 0.05 ppm; fat of cattle, sheep, goats, and horses at 0.05 ppm; and milk at 0.01 ppm. Tolerance level residues were assumed, including those for field corn grain (0.05 ppm). Chronic dietary exposure analyses for the overall U.S. population and 25 population subgroups, including infants and children, were compared to the chronic Reference Dose (RfD) of 2.5 mg/kg b.w./day. Results of the chronic dietary analyses for all population subgroups examined were less than 0.1% of the chronic RfD. Exposure estimates for children 1 to 6 years of age, the most highly exposed population group, were only 0.000575 mg/kg b.w./day or less than 0.1% of the RfD. Therefore, the results of the chronic dietary assessment demonstrate a reasonable expectation of no harm from the proposed and existing uses of imazapyr.

ii. *Drinking water*. According to label restrictions, ARSENAL herbicide will not be applied directly to water within ½ mile upstream of an active potable water intake in flowing water (i.e., river, stream, etc.) or within ½ mile of an active potable water intake in a standing body of water such as lake, pond or reservoir. However, for purposes of demonstrating the large margin of exposure to imazapyr residues in drinking water, no label restrictions will be presumed. Rather, a level of 0.200 ppm in the water will be used, as based upon data from Missouri and Florida sites at 1–hour after treatment (maximum levels of imazapyr were approximately 0.197 ppm and 0.092 ppm, respectively). If 0.200 ppm is chosen as the maximum potential residues in the aquatic dissipation studies, then the standard (chronic) exposure analyses would be:

Adult male (200 µg/L x 10^{-3} mg/µg X 2 L/day) / 70 kg = 0.0057 mg/kg/day

Adult female (200 µg/L x 10^{-3} mg/µg X 2 L/day) / 60 kg = 0.0067 mg/kg/day

Children (200 µg/L x 10^{-3} mg/µg X 1 L/day) / 10 kg = 0.02 mg/kg/day

The degree of risk can be characterized by the magnitude of the margin of exposure (MOE), which is the ratio of the NOAEL from the animal toxicity study used to set the RfD to an estimated human exposure value (MOE = NOAEL/Human Exposure). Based on the NOAEL of 250 mg/kg b.w./day from the chronic dog study and children's exposure value (worst case) of 0.02 mg/kg b.w./day, a very high, favorable MOE of 12,500 times is derived. Thus, there is a reasonable expectation of no harm from the proposed and existing uses of imazapyr.

2. *Non-dietary exposure*. There is no available information quantifying non-dietary exposure to imazapyr. However, based on physical and chemical characteristics of the compound, the use patterns, and available information concerning its environmental fate, non-dietary exposure is expected to be negligible.

Previous registrations for imazapyr included non-crop sites. Labeled use sites for one group of imazapyr products include railroad, utility, pipeline, and highway rights-of-way, utility plant sites, petroleum tank farms, pumping installations, fence rows, storage areas, non-irrigation ditchbanks, under asphalt, under pond liners, wildlife management areas, forestry site preparation, and other non-crop areas. Imazapyr products for the above uses are clearly not intended for use in residential or recreational areas that have a high potential of exposure for the general population. The labels state that these imazapyr products are not for use on lawns, walks, driveways, tennis courts or similar areas.

Other imazapyr products are labeled as plant growth regulators for applications to limited care-low maintenance areas, such as roadsides, airports, fairgrounds, and golf course roughs, and to limited wear areas such as industrial, institutional, and cemetery grounds. These low rate uses entail minimal exposure potential for the general population. The product labeling does not allow use on turf that is being grown for sale or other commercial use, such as sod. There are imazapyr products marketed for residential use. These total vegetation control products are used for spot treatments or bare ground applications. These products are to be applied only where no plant growth is desired and are not to be used on lawns. Therefore, even for the limited residential uses, the potential for exposure is minimal.

For the aquatic use, a recreational swimmer risk assessment is not required because no acute toxicological endpoints for oral, dermal, and inhalation routes of exposure were identified by EPA for imazapyr. Moreover, the dermal NOAEL for the 21–day rabbit toxicity study is the HDT (400 mg/kg b.w./day), indicating that imazapyr is non-toxic following repeated dermal exposure.

3. *Operator exposure*. Specifically, for potential short- and intermediate-term occupational exposure, professional contractors (representing worst-case for the proposed uses) would be mixing/loading/applying the end-use product for less than 90 days per year (and less than 30 consecutive days per year). Importantly, in its risk characterization of imazapyr for use in/on corn (1997), EPA found no toxicological endpoints indicating potential for adverse effects that were identified for short-term (1–7 days) and intermediate-term (7 days to several months) occupational exposure. In the 21–day dermal toxicity study, the NOAEL was determined to be 400 mg/kg b.w./day HDT. This was further supported by oral NOAELs of 250 mg/kg b.w./day HDT in the chronic dog study and 500 mg/kg b.w./day HDT (males) or 640 mg/kg b.w./day HDT (females) in the chronic rat study. Therefore, short- and intermediate-term risk assessments are not required.

D. Cumulative Effects

Imazapyr belongs to the imidazolinone class of compounds. Other compounds in this class are registered herbicides. 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 imazapyr has any toxic effects on mammals that would be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population*. Based on the chronic RfD of 2.50 mg/kg b.w./day, the proposed application will utilize less than 0.1% of this value. Exposure estimates for the general U.S. population were only 0.000227 mg/kg b.w./day. Exposure estimates for children 1 to 6 years of age, the most highly exposed population group, were only 0.000575 mg/kg b.w./day or less than 0.1% of the RfD. EPA generally has no concern for exposure below 100% of the RfD which represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The complete and reliable toxicity data, indicating low potential mammalian toxicity, and the conservative chronic exposure assumptions support the conclusion that there is a ''reasonable certainty of no harm'' from aggregate exposure to imazapyr residues.

2. *Infants and children*. No developmental, reproductive or fetotoxic effects were noted at the highest doses of imazapyr tested. The only maternal effect in the rat teratology study was increased salivation in the highest dose group. The NOAEL used to calculate the RfD for the general U.S. population is 250 mg/kg b.w./day derived from the 1–year chronic toxicity study in dogs. That NOAEL is lower than the developmental NOAELs for the teratology studies in rabbits and rats (1.6 and 4 times, respectively), as well as lower than the NOAEL for the 2–generation reproduction study in male and female rats (3.2 - 3.9 times).

EPA has found the data base relative to prenatal and postnatal effects for children to be complete, valid and reliable. There were no effects observed in the offspring in the developmental studies in rats and rabbits. In the reproduction study, the lack of any pup effects observed at 10,000 ppm (the highest dose tested) in their growth and development from parturition through adulthood, suggests that there is no additional sensitivity for infants and children. Therefore, an additional safety (uncertainty) factor is not warranted and the RfD of 2.50 mg/kg b.w./day, which utilizes a 100-fold safety factor, is appropriate to assure a reasonable certainty of no harm to infants and children.

Therefore, the registrant believes that the results of the toxicology and metabolism studies support both the safety of imazapyr to humans based on the intended use as a herbicide for aquatic and grass uses and the granting of the requested tolerances.

F. International Tolerances

There are no Codex tolerances established for imazapyr.

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