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Reregistration Eligibility Decision for Imazapyr

Reregistration Eligibility Decision (RED) Document for Imazapyr

List C

Case Number 3078

Approved by: _____ Date: _____

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formulation
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of water, air, or feed, e.g., mg/l, mg/kg, or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligram Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification Number. EPA 's system for recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides, and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity

RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Abstract

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of imazapyr. The Agency has determined that imazapyr-containing products are eligible for reregistration, provided that the risk mitigation measures identified in this document are adopted and label amendments are made to reflect these measures. Imazapyr is a systemic, non-selective herbicide used for the pre- and post-emergence control of a broad range of terrestrial and aquatic weeds. There are currently twenty-four tolerances established in 40 CFR §180.500 for residues of the herbicide imazapyr, applied as the acid or ammonium salt which were reassessed in 2003 when new food uses were established. The Agency has conducted human health and environmental fate and ecological effect risk assessments for imazapyr and reassessed all the existing tolerances. The risk conclusions of these assessments are summarized below.

In the human health risk assessment, dietary risks (food and drinking water) are below the Agency's level of concern. Residential handler dermal and inhalation risks for all scenarios are below the Agency's level of concern, as are residential post-application exposures (including incidental oral exposure to toddlers and oral and dermal exposure from swimming activities in treated lake water). Aggregate risks (food, drinking water, and residential exposure) are also below the Agency's level of concern.

There is a potential for exposure to workers through handling and applying imazapyr as well as exposure to post-application residues. For workers, short- and intermediate-term risks from mixing, loading, and applying imazapyr do not exceed the Agency's level of concern at either baseline clothing, or with the addition of gloves. There are no dermal post-application risks to workers, and inhalation post-application risks are considered negligible; however, the Agency has determined that imazapyr is a Toxicity Category I primary eye irritant. The restricted entry interval (REI) on current imazapyr labels is 12 hours. Under the Worker Protection Standard (WPS; 40 CFR Part 170), a 48-hour REI is required for Category I eye irritants. The WPS also requires that coveralls, shoes and socks, chemical resistant gloves, and protective eyewear be used for early entry.

There are no risks of concern to terrestrial birds, mammals, and bees, or to aquatic invertebrates and fish. However, there are ecological risks of concern associated with the use of imazapyr for non-target terrestrial plants and aquatic vascular plants, and potential risks to federally listed threatened and endangered species ("listed species") which include aquatic vascular plants, terrestrial and semi-aquatic monocots and dicots that cannot be precluded at this time. Imazapyr use at the labeled rates on non-crop areas when applied as a spray or as a granular to forestry areas present risks to non-target plants located adjacent to treated areas. Imazapyr use at the labeled rates on Clearfield™ corn, which is resistant to imidazolinone herbicides, also present risks of concern to non-target plants located adjacent to treated areas.

Because imazapyr is an herbicide and may therefore harm non-target plants exposed via drift, the Agency is requiring strict use restrictions to be placed on the labels for all imazapyr products to help minimize spray drift. The Agency has determined that the specific drift language amendments specified in this RED will substantially reduce, though may not completely eliminate, the risks of imazapyr use to non-target plants.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Food Quality Protection Act of 1996 (FQPA) and the Pesticide Registration Improvement Act of 2003 (PRIA) to set time frames for the issuance of Reregistration Eligibility Decisions. FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the U.S. Environmental Protection Agency. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires the Agency to review all tolerances in effect on August 2, 1996, by August 3, 2006. When the Agency reassessed the imazapyr tolerances in 2003, the Agency considered, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. The Agency decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires the Agency to consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Unlike other pesticides for which the Agency has followed a cumulative risk approach based on a common mechanism of toxicity, the Agency has not made a common mechanism of toxicity finding for imazapyr with any other substances. Therefore, for the purposes of tolerance reassessment, which was completed in 2003, the Agency did not assume that imazapyr shared a common mechanism of toxicity with any other compound. In the future, if additional information suggests imazapyr shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary. For information regarding the Agency's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the Agency's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://EPA.gov/pesticides/cumulative/.

This document presents a summary of the Agency's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for imazapyr. The document consists of six sections. Section I contains the regulatory framework for reregistration and tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and ecological risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents and contains the appendices that list related information and supporting documents. The preliminary and revised risk assessments for imazapyr are available in the Public Docket, under docket number OPP-2005-0495 and on EPA's web page, http://www.regulations.gov.

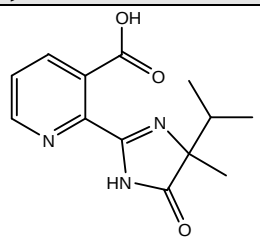
II. Chemical Overview

Imazapyr is part of the imidazolinone chemical class. Imazapyr is a systemic, non-selective, pre- and post-emergent herbicide used for the control of a broad range of terrestrial and aquatic weeds, and controls plant growth by preventing the synthesis of branched-chain amino acids. Imazapyr is applied either as an acid or as the isopropylamine salt.

A. Chemical Background

Imazapyr technical was first registered in 1985; however, a non-crop end use product had been previously registered in July 1984. The first food use on corn was registered in April 1997. In 2003, the aquatic and grassland uses were registered which resulted in the establishment of additional tolerances. Currently there are 24 tolerances listed in 40 CFR § 180.500 for residues of the herbicide imazapyr, applied as the acid or isopropylamine salt, which were reassessed in 2003.

B. Imazapyr Acid and Salt Nomenclature:

Imazapyr, acid	
Structure	
Molecular Formula	$C_{13}H_{15}N_3O_3$
IUPAC Name	[2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-nicotinic acid]
CAS Number	81334-34-1
PC Code	128821

Imazapyr, salt	
Molecular Formula	$C_{13}H_{15}N_3O_3C_3H_9N$
IUPAC Name	2-Propanamine, 2-(4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-3-pyridinecarboxylate
CAS Number	81334-34-1
PC Code	128821

C. Use Sites:

- Imazapyr is used for pre- and post-emergence control of a broad range of weeds, including terrestrial annual and perennial grasses, broad-leaved herbs, woody species, and riparian and emergent aquatic species.

- Agricultural uses of imazapyr include field corn and grass. Tolerances are established for imazapyr residues in field corn and its forage and stover, and in grass forage and hay. Tolerances are also established for secondary residues of imazapyr in milk, meat, fish, and shellfish.

- Imazapyr is also registered for use on a variety of commercial and residential use sites, including forestry sites, rights-of-way, fence rows, hedge rows, drainage systems, outdoor industrial areas, outdoor buildings and structures, domestic dwellings, paved areas, driveways, patios, parking areas, walkways, various water bodies (including ponds, lakes, streams, swamps, wetlands, stagnant water, and urban areas).

- Imazapyr may also be used as a spot treatment in recreation areas, athletic fields, and golf course roughs.

D. Formulations:

- Imazapyr is formulated as a liquid, a wettable powder (in water soluble bags only), and a granular.

E. Methods of Application:

- Aquatic applications of imazapyr can be made as a liquid. Application methods include aerial and application to water via boat. Aqueous imazapyr formulations may be mixed with surfactants or oils for application. Applications to smaller areas may be made with handheld equipment, including backpack sprayers, sprinkling cans, and handgun sprayers.

- Terrestrial applications of imazapyr consist of ground and aerial spray, as well as granular broadcast applications. Granular formulations may also be mixed with fertilizers, surfactants or oils for application. Applications to smaller areas may be made with handheld equipment, including low-pressure handwand sprayers, high-pressure/volume handwand sprayers, push-type granular spreaders, backpack granular spreaders, sprinkling cans, and handgun sprayers. Aqueous imazapyr formulations may be mixed with surfactants or oils for application as well as mixed with other herbicides and fertilizers.

F. Use rates:

- Application rates of imazapyr range from 0.014 pounds acid equivalent per acre (lbs a.e./acre) on corn to 1.5 lbs a.e./acre on non-crop areas and aquatic sites.

G. Annual usage:

- For terrestrial agricultural uses of imazapyr, the use on corn is approximately 20,000 lbs/year, and the use on pastures and rangeland is approximately 2,000 lbs/year. The average percent crop treated is less than one percent for both uses.

H. Technical Registrant:

- BASF Corporation.

III. Summary of Risk Assessment

The following is a summary of the Agency's revised human health effects and ecological risk assessment for imazapyr, as presented fully in the documents, *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document,* dated December 8, *2005*, and *Screening Level Ecological Risk Assessment for the Reregistration Eligibility Decision Document for Imazapyr,* dated December 9, 2005. The purpose of this summary is to assist the reader by identifying key features and findings of these risks assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the regulatory decisions for imazapyr. While the risk assessments and related addenda are not included in this document, they are available in the Public Docket, under docket number OPP-2005-0495 and on the internet at http://www.regulations.gov. Hard copies of these documents may be found in the OPP public docket under this same docket number.

A. Human Health Risk Assessment

The Agency has conducted a human health assessment for imazapyr for the purposes of making a reregistration decision. The Agency evaluated toxicological and chemistry studies submitted for imazapyr and determined that the data are adequate to support a reregistration decision. In addition, the Agency has conducted dietary, drinking water, residential, aggregate, and worker assessments to determine the potential risks associated with the use of imazapyr. More in-depth details of the health effects of imazapyr are provided in the human health risk assessment.

For a complete discussion, see Section 6.0 of *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document*, dated December 8, 2005.

1. Hazard Profile

The toxicological database for imazapyr is complete. Imazapyr has low acute toxicity via the oral (Toxicity Category IV) and dermal (Toxicity Category III) routes of exposure. Imazapyr has been placed in acute Toxicity Category II for the inhalation route of exposure. It is not irritating to the skin, and is negative for dermal sensitization; however, imazapyr results in irreversible eye damage (Toxicity Category I) as seen in Table 1. Normally, an acute hazard value is chosen from acute (non-lethal), subchronic, or developmental toxicity studies from which there is reasonable evidence that a single exposure can lead to a potential effect. The available data suggest that a single exposure to imazapyr does not result in an effect of concern for risk assessment purposes.

Table 1. Acute Toxicity Data for Imazapyr

Guideline Number Study Type	MRID Numbers	Toxicity Category
870.1100 Acute Oral Toxicity	41551002 93048016	IV
870.1200 Acute Dermal Toxicity	41551003 93048017	III
870.1300 Acute Inhalation Toxicity	00132032 93048018	II
870.2400 Acute Eye Irritation	41551001 93048019	I Tested with 99.3% technical fine powder
870.2500 Acute Dermal Irritation	41551004 93048020	IV
870.2600 Skin Sensitization	00131607 93048021	Negative

Most of the toxicity studies with imazapyr showed no effects to minimal effects, even at the HDT (highest dose tested). There is no evidence of acute or chronic neurotoxicity resulting from exposure to imazapyr. No developmental toxicity was observed in rabbits or rats up to the HDT; however, maternal toxicity, based on salivation, was observed in rats at the mid-dose (300 mg/kg/day). Neither the rat nor the rabbit study showed an increased susceptibility of the fetus to imazapyr administered pre-natally or post-natally. In addition, a 2-generation reproduction rat study did not show increased susceptibility to offspring at doses up to the HDT. There were no compound-related effects in a one-year dietary toxicity study in beagle dogs up to the HDT. Imazapyr was classified by the Agency in October 1995 as a "Group E" chemical, with no evidence of carcinogenicity in at least 2 adequate studies in the rat and mouse. This decision was reaffirmed on May 22, 2003 by a subcommittee of the Cancer Assessment Review Committee (CARC). Imazapyr is negative for mutagenic potential and a quantitative cancer risk assessment is not required.

The Agency selected NOAELs and endpoints for risk assessment purposes in February 2003. A 1-year dog feeding study with a NOAEL of 250 mg/kg/day was selected for calculating the chronic RfD because it was the lowest NOAEL in the imazapyr database. Actually, the 250 mg/kg/day dose in the dog study was both the NOAEL and the highest dose tested for that study. Because there were no adverse effects seen in the dog study or in any of the imazapyr toxicity studies, EPA relied on a structural analog, the pesticide imazapic (Cadre®), to choose an endpoint. Imazapic causes skeletal muscle effects in dogs at 5000 ppm (137 mg/kg/day in males and 180 mg/kg/day in females). Despite imazapyr's structural similarity to imazapic, as well as its similarity to the pesticides, imazethapyr and imazamethabenz-methyl (Assert®), the available data do not support the conclusion that these pesticides share a common mechanism of toxicity such that combined exposure to them would result in cumulative effects. First, as noted, the toxicity data for imazapyr show no adverse effects, including no skeletal muscle effects. Second, the toxic endpoints for the three structurally similar pesticides are quite varied: imazapic (skeletal muscle effects); imazethapyr (an increased incidence of clinical signs during gestation, ulcerations in the mucosal layer of the stomach and gall bladder, increased abortions, maternal deaths, decrements in body weight gain) and

imazamethabenz-methyl (transient decreased body weight, mild liver effects, slight increase in a common kidney lesion). Accordingly, for the purposes of this RED, EPA has not assumed that imazapyr has a common mechanism of toxicity.

Non-cancer risk estimates are expressed as a margin of exposure (MOE) that is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern that reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100X and includes a 10X for interspecies extrapolation (to account for differences between laboratory animals and humans) and a 10X for intraspecies variation (to account for differences between humans). Additional uncertainty or safety factors may also be applied. In the case of imazapyr, the Agency's level of concern is an MOE of 100 which includes a factor of 10X for interspecies extrapolation and 10X for intraspecies variation. The Special FQPA Safety Factor has been reduced to 1X because there are no residual exposure uncertainties, no increased sensitivity to infants and children, and the toxicity database is essentially complete. Table 2 shows the endpoints selected to assess risks for imazapyr.

Table 2. Summary of Toxicological Doses and Endpoints for Imazapyr Used in the Human Health Risk Assessment

Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF and Level of Concern (LOC) for Risk Assessment**	**Study and Toxicological Effects and MRID No.**
Acute Dietary (Females 13-50 years of age and General population including infants and children)	An acute dietary endpoint was not selected based on the absence of an appropriate endpoint attributable to a single dose.		
Chronic Dietary (All populations)	NOAEL= **250** mg/kg/day UF = **100** **Chronic RfD** = **2.5** mg/kg/day	FQPA SF = **1x** **cPAD** = chronic RfD / FQPA SF = **2.5** mg/kg/day	**1-Year Dog** [feeding] **Study** No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT; MRID 41039502). [HIARC assumed this dose as an endpoint for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic.]
Short and Intermediate Term Incidental Oral (1-30 days and 1-6 months)	NOAEL= **250** mg/kg/day	**Residential** LOC for MOE =100)	**1-Year Dog** [feeding] **Study** No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT; MRID 41039502). [HIARC assumed this dose as an endpoint for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic.]

Short and Intermediate and Long-Term Dermal (1 to 30 days, 1 to 6 months, >6 months)	Oral study NOAEL= **250** mg/kg/day (dermal absorption rate = **100 %**)	**Occupational** LOC for MOE = **100** (**Residential** LOC for MOE = **100**)	**1-Year Dog** [feeding] **Study** No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT; MRID 41039502). [HIARC assumed this dose as an endpoint for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic.]
Short- and Intermediate and Long-Term Inhalation (1 to 30 days, 1 to 6 months, >6 months)	Oral study NOAEL= **250** mg/kg/day (inhalation absorption rate **= 100%)**	**Occupational** LOC for MOE = **100** (**Residential** LOC for MOE = **100**)	**1-Year Dog** [feeding] **Study** No LOAEL was demonstrated with imazapyr at doses up to 250 mg/kg/day (HDT; MRID 41039502). [HIARC assumed this dose as an endpoint for RA for imazapyr, based on skeletal muscle effects seen in dogs with structural analog imazapic.]
Cancer	Classified as Group E. No evidence of carcinogenicity; risk assessment not required.		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic),RfD = reference dose, MOE = margin of exposure, LOC = level of concern.

2. Dietary Risk (Food)

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. Dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose predicted to result in no unreasonable adverse health effects to any human population subgroup, including sensitive members of such population subgroups. This level of concern is referred to as the population-adjusted dose (PAD), which reflects the reference dose (RfD), acute or chronic, adjusted to account for the FQPA safety factor.

Estimated risks that are less than 100% of the PAD are below EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on any given day with no adverse health effects expected. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no adverse health effects expected. For imazapyr, a chronic RfD of 0.25 mg/kg/day is used in estimating the dietary risk. The RfD includes a 10x for interspecies extrapolation and a 10x for intraspecies variation. Because the Special FQPA Safety Factor has been reduced to 1X, the PAD is equivalent to the RfD. The imazapyr dietary risk assessment uses was performed using the Dietary Exposure Evaluation Model (DEEM^{TM}).

For a complete discussion, see Section 6.0 of *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document*, dated December 8, 2005.

a. Acute Dietary Risk (Food))

As noted above, an acute dietary exposure assessment was not necessary because no toxic effects resulting from acute exposures were seen in the imazapyr acute toxicity database. The Agency does not expect acute risks resulting from dietary exposure.

b. Chronic Dietary Risk (Food)

For the chronic dietary exposure assessment, an estimate of the residue level in each food or food-form on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food-form. The resulting residue consumption estimate is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and risk is expressed as a percent of the chronic PAD (cPAD).

Food items may be exposed to residues of imazapyr in three ways: via direct application, via irrigation water previously treated with imazapyr, or via livestock ingestion of treated commodities resulting in secondary residues. To assess risks resulting from residues on food, a screening level assessment was performed using the Dietary Exposure Evaluation Model (DEEM^{TM}).

The results of the DEEM^{TM} analysis show that all population subgroups' dietary exposure to imazapyr residues in food comprises less than 0.1% of the cPAD. These results are based on tolerance level residues, 100% crop treated, and default processing factors, all of which are considered to be conservative estimates of potential chronic dietary risk. Table 3 shows exposure levels for the general population and children one to two years old, the most highly exposed population subgroup.

For a complete discussion of the health effects to imazapyr, please see *Imazapyr: Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision*, dated March 26, 2003.

Table 3. Summary of Food Chronic Dietary Exposure and Risk from Imazapyr

Population Subgroup	Dietary Exposure mg/kg/day	% cPAD
General U.S. Population	0.000340	<0.1
Children 1-2 years old	0.000828	<0.1

3. Cancer Dietary Risk (Food)

A cancer dietary exposure assessment is not required because imazapyr is classified as a Group E chemical, "not likely to be carcinogenic."

4. Drinking Water Dietary Exposure

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. The Agency considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. For imazapyr, non-cancer chronic concentration in drinking water was estimated. A cancer concentration in drinking water was not estimated because imazapyr is considered "not likely to be carcinogenic in humans."

To estimate drinking water concentrations resulting from the use of imazapyr, screening level models were used. Non-crop uses with high and low application rates, and corn uses were modeled to represent the labeled imazapyr uses (1.5, 0.9, and 0.014 lbs. a.i./acre, respectively). The highest labeled rate for imazapyr is 1.5 lbs. a.i./acre.

The Agency has determined that the residue of concern for imazapyr in drinking water is parent only. Environmental fate data suggest that imazapyr is mobile and persistent. Except for photolysis in water, imazapyr was stable under the conditions and duration of the submitted fate studies. In the photolysis study, imazapyr degraded with half-lives of approximately 3 to 5 days.

To predict concentrations of imazapyr that may be present in surface water as a result of the terrestrial uses, Tier I FQPA Index Reservoir Screening Tool (FIRST) exposure modeling was performed. The modeled estimates of drinking water concentrations (EDWCs) of imazapyr in surface water for chronic durations range from 0.34 to 79µg/L. These values were established by modeling imazapyr use on corn and non-crop uses with high and low application rates.

To predict concentrations of imazapyr in ground water as a result of terrestrial uses, Tier I Screening Concentration in Ground Water (SCI-GROW) exposure modeling was performed. The modeled concentrations of imazapyr in ground water are not expected to exceed 36µg/L. This value was established by modeling imazapyr non-crop uses at the highest maximum application (1.5 lbs a.i./A).

Exposure to imazapyr from drinking water resulting from aquatic applications is also possible. The EDWC's for both surface and ground water from direct application to surface water are both 61 µg/L. This does not take into account the current imazapyr label requirement of a one-half mile setback from drinking water intakes because the Agency does not currently have an approved methodology for calculating EDWCs in water bodies where pesticides are applied with a setback distance from drinking water intakes. As a result, the EDWC is more conservative than had setback distances been considered. Direct applications to water were modeled assuming uniform application over an entire reservoir at the maximum labeled rate.

For a complete discussion, see Section 6.2 of the *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document*, dated December 8, 2005.

5. Chronic Risk from Food and Drinking Water

To assess chronic risk from food plus drinking water, exposure estimates from chronic dietary (food) and chronic drinking water assessments were combined in the DEEM^{TM} modeling program. The modeled EDWC of imazapyr in surface water of 79µg/L was used in the chronic dietary (food plus water) assessment. This value was established by modeling imazapyr non-crop uses at the highest maximum application. The combined chronic exposure for the general U.S. population and all population subgroups is <0.1% of the cPAD. The most highly exposed population subgroup is infants <1 year old (Table 4). These values are below the Agency's level of concern.

Table 4. Summary of Food and Water Dietary Exposure and Risk

Population Subgroup	Dietary Exposure mg/kg/day	% cPAD (Food + Water)
General U.S. Population	0.002005	0.1
All Infants <1 year old	0.005732	0.1

6. Residential Risk

Residential exposure to a pesticide can occur while mixing, loading, or applying (handling) a pesticide, or after entering areas where the pesticide had previously been applied. Residential non-cancer risk estimates are expressed as a margin of exposure (MOE), which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern that reflects the dose selected for risk assessment and UFs applied to that dose. The standard UF is 100X and includes a 10X for interspecies extrapolation (to account for differences between laboratory animals and humans) and a 10X for intraspecies variation (to account for differences between humans). Additional uncertainty or safety factors may also be applied. In the case of imazapyr, the Agency's level of concern for inhalation, dermal, and incidental oral is an MOE of 100 that includes a factor of 10X for interspecies extrapolation and 10X for intraspecies variation. The Special FQPA Safety Factor has been reduced to 1X because there are no residual exposure uncertainties, no increased sensitivity to infants and children, and the toxicity database is essentially complete.

Short-term exposures were assessed for residential handlers and residential post-application exposures based on use and exposure patterns of registered imazapyr products. Based on the current use pattern for imazapyr and the fact that endpoints are the same across all durations of exposure, the Agency does not expect that intermediate or long-term residential exposures will be higher than those for short-term exposures. Inhalation, dermal, and incidental ingestion were considered to be the routes of exposure for persons exposed to imazapyr. The maximum labeled rates were used for the non-cancer residential handler and non-cancer residential post-application risk assessments.

For a complete discussion, see Section 6.3 of the *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document*, dated December 8, 2005.

a. Residential Handler Summary

Residential handler assessments are based on the assumptions that individuals complete all tasks associated with the use of imazapyr (mixing, loading, and application), up to 1,000 square feet are treated, and individuals are wearing shorts, short-sleeved shirts, socks, and shoes. The residential handler exposure scenarios consider dermal and inhalation exposure to adult pesticide handlers. The two residential handler scenarios were assessed: 1) mixing/loading/applying emulsifiable concentrates with low-pressure handwand, and 2) mixing/loading/applying emulsifiable concentrates with hose-end sprayer. The risks for these scenarios are below the Agency's level of concern with MOEs well above the target MOE of 100, at 25,000 and 85,000, respectively.

b. Residential Post-application Summary

Residential post-application exposure scenarios are also considered to be short-term and consider exposures to individuals that occur as a result of an area previously treated with imazapyr. The residential post-application assessment considers dermal exposure to children and adults, as well as incidental oral ingestion exposures to toddlers. A series of assumptions and exposure factors served as the basis for completing the residential postapplication risk assessments. The assumptions and factors used in the risk calculations are consistent with current Agency policy for completing residential exposure assessments (i.e., Standard Operating Procedures for Residential Exposure Assessment). The scenarios included in the residential post-application exposure assessment were: (1) adult dermal exposure/residential turf (high contact activities); (2) toddler dermal exposure/residential turf (high contact activities); (3) toddler oral exposure/hand-to-mouth activity on turf; (4) toddler oral exposure/object-to-mouth activity on turf; (5) toddler oral exposure/incidental soil ingestion; and (6) toddler oral exposure/incidental ingestion of granules. Post-application residential risks to adults and toddlers are below the Agency's level of concern for all scenarios assessed with MOEs of 720 and 430, respectively, on the day of application.

c. Combined Post-application Residential Summary

Additionally, combined residential risks resulting from the combining of separate post-application exposure scenarios, when it is likely they can occur simultaneously, do not exceed the Agency's level of concern with MOEs greater than 100 on the day of application. These combined post-application exposure scenarios for toddlers are: dermal, hand-to-mouth, object-to-mouth, and incidental soil ingestion. The combined non-dietary MOE for toddlers using the turf spray scenario is 410.

d. Recreational Uses

Imazapyr may be applied by broadcast application to aquatic freshwater sites to control floating or emergent aquatic vegetation. Adults and children may be exposed when swimming in treated water bodies following application of imazapyr. The potential for postapplication incidental ingestion and dermal exposure to adults, children, and toddlers as a result of swimming in treated waters immediately following application has also been assessed. Post-application risks to adults, children, and toddlers swimming in treated waters following application of imazapyr are below the Agency's level of concern with MOEs ranging from 68,000 to 1,000,000.

7. Aggregate Risk

Aggregate risk combines exposure from food, drinking water, and, if applicable, residential exposure. For imazapyr, the following aggregate risk assessments were conducted: short-term aggregate (food + drinking water + short-term residential) and long-term aggregate risk assessment (food + drinking water only). Based on the current use patterns of imazapyr, the Agency does not expect exposure durations that would result in intermediate- or long-term residential exposures; therefore long-term aggregate risk assessment consists of exposure from food and drinking water only. A cancer aggregate risk assessment is not required because imazapyr is classified as a Group E chemical, "not likely to be carcinogenic".

For adult short-term aggregate exposure, the Agency aggregated chronic food and drinking water exposures with residential handler and post-application exposures. The adult residential exposure scenarios resulting from application and post-application activities on turf were used. For short-term aggregate exposure to children, the Agency aggregated chronic food and drinking water exposures for toddlers (1-2 years of age) and combined these with post-application dermal and incidental oral exposures (combined hand-to-mouth, object-to-mouth, and soil ingestion) from activity on turf. The estimated MOEs are above 100, with values of 410 for children and 720 for adults. Therefore, short-term aggregate risks are below the Agency's level of concern.

Because the Agency does not expect chronic residential exposure, long-term aggregate risks are equal to chronic dietary risks (food plus water). As described above in Section 5, these risks are below the Agency's level of concern.

For a complete discussion, see Section 7.0 of the *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document*, dated December 8, 2005.

8. Occupational Risk

Workers can be exposed to a pesticide while mixing, loading, or applying a pesticide, and when entering a treated site. Non-cancer worker risk estimates are expressed as a margin of exposure (MOE) that is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern that reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is

100X and includes a 10X for interspecies extrapolation (to account for differences between laboratory animals and humans) and a 10X for intraspecies variation (to account for differences between humans). Additional uncertainty or safety factors may also be applied. In the case of imazapyr, the NOAEL is 250 mg/kg/day taken from the 1-year dog feeding study and an MOE of 100 is considered protective for worker risks.

The Agency initially calculates the handler risks using the least protective measures. This is called the baseline assessment, and assumes normal work clothing and no personal protective equipment (PPE). If there is a risk concern at this level, the Agency considers the use of protective measures (e.g., personal protective equipment and engineering controls) to lower the risk. PPE can include an additional layer of clothing, chemical-resistant gloves, and a respirator. Common examples of engineering controls include: enclosed tractor cabs, closed loading systems, and water-soluble packaging.

For a complete discussion, see the *Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Imazapyr*, dated August 31, 2005.

a. Occupational Handler Summary

The Agency has determined that workers may be exposed to imazapyr while mixing, loading, and applying, as well as flagging for aerial applications. In the absence of chemical-specific monitoring data for imazapyr, exposure analyses were performed using surrogate data from the Pesticide Handlers Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (ORETF). For information on the scenarios that use ORETF data, please see the *Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Imazapyr*, dated August 31, 2005. The MOEs for occupational exposures were calculated for short-term and intermediate-term exposures because these durations of exposures are likely based on current labels. Long-term handler exposures are not expected to occur for imazapyr.

For all scenarios, short- and intermediate-term risks do not exceed the Agency's level of concern (i.e., the MOEs are greater than 100) at either baseline PPE (long-sleeved shirt, long pants, no gloves, and no respirator), or with the addition of gloves. MOEs ranged from 10 to 1,100,000. Scenarios that require the addition of chemical resistant gloves include mixing and loading liquid formulations for aerial applications to aquatic sites, terrestrial non-crop sites, forestry sites, and areas grazed or cut for hay. The addition of chemical resistant gloves are also required for workers that are mixing, loading, and applying liquid and granular formulations via handwands, backpack spreaders and sprayers, and handgun sprayers for non-crop and aquatic uses. MOEs for these scenarios with the addition of chemical resistant gloves ranged from 460 to 22,000.

b. Post-application Occupational Summary

The Agency has determined that individuals may be exposed to imazapyr by working in areas that have previously been treated. Both short-term and intermediate-term occupational postapplication dermal exposure may occur. Inhalation exposures are

expected to be negligible in outdoor postapplication scenarios because imazapyr has a low vapor pressure and due to the dilution with ambient air expected after outdoor application. As such, inhalation postapplication exposures are not considered in this assessment.

All risks calculated for short-term and intermediate-term dermal postapplication exposure to workers resulting from scouting, hand weeding, irrigation, detasseling, and hand-harvesting are below the Agency's level of concern (MOEs range from 4,100 to 700,000) on day zero approximately 12 hours following application. Although the MOEs are greater than 100 for post-application workers, the restricted-entry level (REI) must be set at 48-hour REI because imazapyr has high acute toxicity (Category I for eye irritation).

9. Incident Reports

Approximately 20 incidents involving human exposure to imazapyr have been reported. However, none were listed under the "definite," "probable," or "possible" certainty categories. In general, medical care was less frequently used in all cases compared to other pesticide-related incidents, and not a single case required hospitalization or treatment in a critical care unit. The most common symptom reported was eye irritation, which was four times more prevalent than any other symptom. Additional health effects included: dermal irritation, throat irritation, nausea, and coughing or choking.

For a complete discussion, see the *Review of Imazapyr Incident Reports*, dated February 23, 2006.

B. Ecological Risk Assessment

The Agency has conducted an environmental assessment for imazapyr for the purposes of making a reregistration decision. The Agency evaluated environmental fate and ecological studies submitted for imazapyr and determined that the data are adequate to support a reregistration decision. More in-depth details of the environmental fate and persistence of imazapyr are provided in the environmental risk assessment.

For a complete discussion, see the *Screening Level Ecological Risk Assessment for the Reregistration Eligibility Decision Document for Imazapyr*, dated December 9, 2005.

1. Environmental Fate and Transport

The herbicide imazapyr is an anionic, organic acid that is non-volatile and is both persistent and mobile in soil. Commercial formulations contain either imazapyr acid or the imazapyr isopropylamine salt, both of which are dissolved in a water solution. Imazapyr is mainly in anionic form at typical environmental pH levels, and the behavior of the acid and salt forms are expected to be similar. Laboratory studies show imazapyr is essentially stable to hydrolysis, aerobic and anaerobic soil degradation, as well as aerobic and anaerobic aquatic metabolism. Field dissipation study observations are consistent with imazapyr's intrinsic ability to persist in soils and move via runoff to surface water and to leach to groundwater.

Upon direct application, or indirect release into surface water, photolysis is the only identified mechanism for imazapyr degradation in the environment. The half-life of imazapyr is approximately 3 to 5 days in surface water. The major identified metabolites were pyridine hydroxy-dicarboxylic acid, pyridine dicarboxylic acid, and nicotinic acid. Under laboratory aerobic aquatic conditions, the aerobic aquatic metabolism half-lives for hydroxy-dicarboxylic acid and pyridine dicarboxylic acid were in the range of 3 to 8 days in two different sediment/water systems. Metabolites hydroxy-dicarboxylic acid and pyridine dicarboxylic acid are expected to be more polar, thus more rapidly excreted than imazapyr, and no more toxic than the parent compound. Additionally, pyridine hydroxy-dicarboxylic acid is considered to be less stable than the parent compound. Nicotinic acid is a possible neurotoxin at high dose levels, but there is no concern for low exposures. Nicotinic acid (also called Niacin and referred to as Vitamin B3) is considered an essential nutrient. Imazapyr is not expected to bioaccumulate in aquatic organisms because it exists as an anion at typical environmental pHs.

2. Ecological Risk Assessment

To estimate potential ecological risk, the Agency integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are a screening level measure for potential risk and are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs).

Table 5 lists the LOCs used in the risk assessment. Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

Table 5. Levels of Concern for Ecological Risk

If RQ > LOC value given below…			Then EPA presumes…
Terrestrial Organisms	**Aquatic Organisms**	**Plants**	**Risk Presumption**
0.5	0.5	1	**Acute Risk**- there is potential for acute risk; regulatory action may be warranted
0.1	0.05	1	**Acute Endangered Species**- regulatory action may be warranted; further analysis is needed
1	1	N/A	**Chronic Risk**-there is potential for chronic risk; regulatory action may be warranted

The Agency has determined that there are no risks of concern to terrestrial birds, mammals, and bees, or to aquatic invertebrates and fish. For terrestrial organisms, available acute and chronic toxicity data indicate that imazapyr acid and salt are practically non-toxic to birds, mammals, and honeybees. Acute risks to both mammals and birds were not calculated because LC_{50}/LD_{50} (Median Lethal Concentration/Median Lethal Dose) values were greater than highest concentration tested. Chronic LOC's were also not exceeded for these organisms. In addition, imazapyr shows low toxicity to bees. Therefore, there is minimal risk to birds, mammals, and honeybees.

For aquatic organisms, available acute and chronic toxicity data indicate that imazapyr acid and salt are practically non-toxic to fish, invertebrates, and non-vascular aquatic plants. Acute risks to fish and aquatic invertebrates were not calculated because LC_{50} values were greater than the highest concentration tested. Chronic LOC's were also not exceeded for these organisms. In addition, no LOC's were exceeded for aquatic non-vascular plants. Therefore, there is minimal risk to fish, aquatic invertebrates, and aquatic non-vascular plants. However, there is an uncertainty for estuarine/marine fish and invertebrates, since no toxicity data were available to observe the prolonged effects of imazapyr to estuarine/marine fish and invertebrates. These organisms were assumed to have similar sensitivity as freshwater fish and invertebrates.

The Agency has determined that there are ecological risks of concern associated with the use of imazapyr for non-target terrestrial plants and aquatic vascular plants, and potential risks to endangered species (aquatic vascular plants, terrestrial and semi-aquatic monocots and dicots). Because the ecological risks of concern for imazapyr are only to non-target plants, the remainder of this Ecological Risk Assessment section of the RED document will address risks to non-target plants.

a. Plant Toxicity

Terrestrial plant toxicity studies with monocots and dicots indicate that seedling emergence and vegetative vigor are severely impacted by exposure to imazapyr acid and to the isopropylamine salt of imazapyr. Seedling emergence, based on "fresh weight", was adversely impacted in monocots (wheat) at an EC_{25} (Effect Concentration) of 0.0046 lb a.e./acre and in dicots (sugar beet) with an EC_{25} of 0.0024 lb a.e./acre (Table 6). Vegetative vigor in monocots, based on "fresh weight", was adversely impacted by both imazapyr acid and the isopropylamine salt of imazapyr at an EC_{25} of 0.012 lb a.e./acre in wheat. In vegetative vigor studies with dicots (cucumber), imazapyr acid was more toxic than the isopropylamine salt of imazapyr with an EC_{25} of 0.0009 lbs a.e./acre. Non-lethal effects included stunting, chlorosis, and necrosis.

Table 6.Summary of Selected Endpoints for Imazapyr Terrestrial Toxicity Studies

Plant Species	Effect	Endpoint (lbs a.e./acre)		
		EC 25	EC 05/NOAEC	MRID
Terrestrial Monocots				
Wheat	Emergence	0.0046	0.00099	40811801
	Vegetative Vigor	0.012	0.0039	43889101
Terrestrial Dicots				
Sugar Beet	Emergence	0.0024	0.00017	40811801
Cucumber	Vegetative Vigor	0.0009	0.000064	40811801

For aquatic plants, available toxicity studies indicate that imazapyr acid and the isopropylamine salt are highly toxic and expected to exert detrimental effects to aquatic vascular plants. The EC_{50} for the aquatic vascular plant (duckweed) is 0.018 mg a.e./L (NOAEC 0.011 mg a.e./L), based on inhibition of plant growth and reduction of frond count (Table 7).

Table 7. Summary of Selected Endpoints for Imazapyr Aquatic Toxicity Studies

Plant Species	Effect	Endpoint (mg a.e./L)		
		EC 50	NOAEC	MRID
Aquatic Vascular	Inhibition of plant growth	0.018	0.011	43889102
Aquatic Nonvascular	Inhibition of plant growth	11.5	7.6	43889102

b. Terrestrial Plant Risk

Table 8 presents the RQs for terrestrial plants for three imazapyr uses and both ground and aerial spray applications. For the terrestrial non-crop use of imazapyr and the application rates of 0.9 and 1.5 lbs a.e./acre, RQ LOCs exceeded for all non-endangered and endangered monocots and dicots located adjacent to treated areas, in semi-aquatic areas, and as a result of runoff and spray drift with the exception of non-endangered monocots receiving spray drift alone from ground applications at 0.9 lb a.e./acre. RQs were higher for aerial applications when compared to ground applications, as expected given the assumption that 5% of aerial sprays and 1% of ground sprays drift to non-target areas.

For Clearfield™ corn and the label application rate of 0.014 lbs a.e./acre, LOCs were exceeded for non-endangered monocots and dicots located in semi-aquatic areas (based on "channelized runoff" ratio) when exposed to imazapyr via ground or aerial spray application. LOCs were not exceeded for non-endangered monocots and dicots inhabiting dry areas (based on "sheet runoff" ratio) via ground or aerial application, or from spray drift alone. With the exception of monocots receiving drift alone, the endangered species LOCs were exceeded for terrestrial plants located adjacent to treated areas, in semi-aquatic areas and as a result of spray drift alone from aerial application on cornfields. For ground application, the endangered species LOCs were exceeded for both monocots and dicots located in semi-aquatic areas. However, the endangered species LOCs were not exceeded for monocots inhabiting dry areas or exposed to spray drift alone. Exposure to dicots from spray drift alone exceeds the endangered species LOC but is not expected to exceed the non-endangered species LOC.

Table 8.Terrestrial Plant Risk Quotient Summary for Terrestrial Spray Uses

Scenario	Non-endangered RQs			Endangered RQs		
	Adjacent to treated sites	Semi-aquatic areas	Drift	Adjacent to treated sites	Semi-aquatic areas	Drift
Terrestrial non-crop high application rate (1.5 lbs a.e./acre						
Ground spray application						
Monocot	20**	166**	1.3**	91*	773*	3.9*
Dicot	38**	319**	17**	529*	4500*	234*
Aerial spray application						
Monocot	26**	114**	6.3**	121*	530*	19*
Dicot	50**	219**	83**	706*	3090*	1170*
Terrestrial non-crop low application rate (0.9 lbs a.e./acre)						
Ground spray application						
Monocot	12**	100**	0.75	55*	464*	2.3*
Dicot	23**	191**	10**	318*	2700*	141*
Aerial spray application						
Monocot	16**	68**	3.8**	73*	318*	124*
Dicot	30**	131**	50**	424*	1850*	703*
Clearfield™ Corn (0.014 lbs a.e./acre)						
Ground spray application						
Monocot	0.18	1.6**	0.01	0.85	7.2*	0.04
Dicot	0.35	3.0**	0.16	4.9*	42*	2.2*
Aerial spray application						
Monocot	0.24	1.1**	0.06	1.1*	5.0*	0.18
Dicot	0.47	2.0**	0.78	6.6*	29*	11*

* indicates an exceedance of the Endangered Species LOC (LOC=1).
** indicates an exceedance of the Acute Risk LOC (LOC=1).

For the aquatic non-crop use of imazapyr at the maximum application rate of 1.5 lbs a.e./acre, LOCs were exceeded for non-endangered and endangered monocots and dicots located adjacent to or on the edge of lakes and ponds as a result of flooding semi-aquatic areas and spray drift from a direct application to surface water (Table 9). RQs were higher for plants adjacent to or on the edge of lakes and ponds versus those exposed via drift.

Table 9. Terrestrial Plant Risk Quotient Summary for Aquatic Spray Uses

Scenario	Non-endangered RQs		Endangered RQs	
	Water overflows to flood a terrestrial site	**Incoming tide pushes water to flood a terrestrial site**	**Water overflows to flood a terrestrial site**	**Incoming tide pushes water to flood a terrestrial site**
Aquatic non-crop high application rate (1.5 lbs a.e./acre)				
Ground spray application				
Monocot	163**	24*	758**	111*
Dicot	313**	46*	4412**	647*

* indicates an exceedance of the Endangered Species LOC (LOC=1).
** indicates an exceedance of the plant LOC (LOC=1).

For the granular uses of imazapyr at the maximum application rates of 1.5 lbs a.e./acre and 0.5 lbs a.e./acre, LOCs were exceeded for both non-endangered and endangered monocots and dicots located adjacent to treated areas, in semi-aquatic areas and as a result of runoff from application on non-crop areas (Table 10). Currently, EFED does not perform chronic risk assessments for terrestrial plants.

Table 10. Terrestrial Plant Risk Quotient Summary for Granular Uses

Scenario	Non-endangered RQs		Endangered RQs	
	Adjacent to treated sites	Semi-aquatic areas	Adjacent to treated sites	Semi-aquatic areas
Terrestrial non-crop high application rate (1.5 lbs a.e./acre)				
Monocot	16**	163**	76*	758*
Dicot	31**	313**	441*	4410*
Terrestrial non-crop low application rate (0.5 lbs a.e./acre)				
Monocot	5.4**	54**	25*	253*
Dicot	10**	104**	147*	1471*

* indicates an exceedance of the Endangered Species LOC (LOC=1).
** indicates an exceedance of the Acute Risk LOC (LOC=1).

For a complete discussion, see the *Screening Level Ecological Risk Assessment for the Reregistration Eligibility Decision Document for Imazapyr*, dated December 9, 2005.

c. Aquatic Plant Risk

For imazapyr, there are exceedances of the endangered and non-endangered LOCs for vascular plants for runoff/drift from ground and aerial spray and granular applications at high and low rates for terrestrial use sites (Table 11). However, there were no exceedances of non-vascular aquatic plant LOCs for these scenarios. There were no exceedances of aquatic plants LOCs for the Clearfield™ corn application scenario.

Table 11. Aquatic Plant Risk Quotient Summary for Terrestrial Uses

Scenario	Non-endangered RQs		Endangered RQs
	Non-Vascular	Vascular	Vascular
Non-Crop (high application rate, 1.5 lbs a.e./acre)			
Ground Application	<0.01	4.5**	7.4*
Aerial Application	<0.01	4.7**	7.6*
Non-Crop (low application rate, 0.9 lbs a.e./acre)			
Ground Application	<0.01	2.5**	4.1*
Aerial Application	<0.01	2.8**	4.6*
Forestry Granular (high application rate, 1.5 lbs a.e./acre			
Broadcast	<0.01	4.3**	7.0*
Forestry Granular (low application rate, 0.5 lbs a.e./acre			
Broadcast	<0.01	1.4**	2.3*
Clearfield™ Corn (0.014 lbs a.e./acre)			
Ground Application	<0.01	0.04	0.07
Aerial Application	<0.01	0.04	0.07

* indicates an exceedance of Endangered Species LOC (LOC=1).
** indicates an exceedance of plant LOC (LOC=1).

The imazapyr direct application to water scenario for aquatic uses indicated exceedance of the non-endangered LOCs for vascular plants inhabiting various water depths (Table 12). Likewise, endangered vascular plant LOCs were exceeded for the direct application to waters at all three depths considered. There were no LOC exceedances for non-vascular aquatic plants.

Table 12. Aquatic Plant Risk Quotient Summary for Aquatic Use

Scenario	Water Depth	Non-endangered		Endangered
		Non-Vascular	Vascular	Vascular
Direct Application to Water (1.5 lbs a.e./acre)	1 foot	0.048	31**	50*
	3 feet	0.016	10**	17*
	2 meters	<0.01	4.7**	7.6*

* indicates an exceedance of Endangered Species LOC (LOC=1).
** indicates an exceedance of Acute Risk LOC (LOC=1).

For a complete discussion, see the *Screening Level Ecological Risk Assessment for the Reregistration Eligibility Decision Document for Imazapyr*, dated December 9, 2005.

3. Incident Reports

The Environmental Incident Information System (EIIS) database has records of 12 incidents related to the use of imazapyr (April 2005). Incidents reported include impacts to terrestrial and aquatic plants and possibly birds and fish. There are several reports of spray drift affecting plants on adjacent property and one report of agricultural runoff to a pond resulting in a possible fish kill from imazapyr. In this report, it could not be definitively determined that the fish kill was due to exposure to imazapyr. Another report concerning mortality in birds and fish was based on an incident using a mixture of herbicides, one of which was imazapyr. Because a mixture was used, it could not be definitively determined that the mortalities were due to exposure to imazapyr. One incident was a mixed herbicidal spray, including imazapyr, that resulted in a bird, terrestrial and aquatic plant, and fish kill. Another incident involved a goldfish kill from suspected runoff following aerial application of imazapyr. However, the cause of the kill could not be determined. Nine other incidents involving plants have also been reported.

4. Endangered Species Risk.

As discussed previously, imazapyr acid and the imazapyr isopropylamine salt are used in both aquatic and terrestrial environments. The screening level risk assessment for endangered species indicates that imazapyr RQs exceed the endangered species LOCs for the specified use scenario in the following taxonomic groups:

- non-target aquatic vascular plants for non-crop uses (both high and low application rates) and for direct application to water (RQs are listed in Tables 11 and 12).

- non-target terrestrial plants - monocots and dicots adjacent to treated areas, semi-aquatic areas, and subject to drift for non-crop uses at both high and low application rates by ground and aerial spray and granular applications; monocots and dicots adjacent to semi-aquatic areas for Clearfield™ corn use by ground spray application; dicots adjacent to treated sites for Clearfield™ corn use by ground spray application; and monocots and dicots adjacent to treated areas and semi-aquatic areas for Clearfield™ corn use by aerial spray application; and for dicots, drift from Clearfield™ corn use by ground and aerial spray application (RQs are listed in Tables 8, 9, and 10).

Registered uses of imazapyr acid and the imazapyr isopropylamine salt will have no direct effect on endangered or threatened fish, aquatic invertebrates, non-vascular aquatic plants (algae), birds or mammals. However, there is a potential concern for indirect effects to listed species with either broad or narrow dependencies on impacted plant species/populations/communities for habitat, feeding or cover requirements.

Risks to endangered species identified in the Environmental Fate and Ecological Risk Assessment for Imazapyr are based solely on the Agency's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Rather, this assessment serves as a screen to determine the need for any species-

specific assessments that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments result in the need to modify use of the pesticide in specific geographic areas, those changes to the pesticide's registration will take effect through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

For a complete discussion, see the *Screening Level Ecological Risk Assessment for the Reregistration Eligibility Decision Document for Imazapyr*, dated December 9, 2005.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether pesticides containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing imazapyr.

The Agency has completed its assessment of the dietary, residential, occupational, and ecological risks associated with the use of pesticides containing the active ingredient imazapyr. Based on a review of these data and public comments on the Agency's assessments for the active ingredient imazapyr, the Agency has sufficient information on the human health and ecological effects of imazapyr to make decisions as part of the reregistration process under FIFRA, as amended by the Food Quality Protection Act (FQPA). Note that the Agency reassessed the imazapyr tolerances in 2003. The Agency has determined that currently registered uses of imazapyr will not pose unreasonable risks or adverse effects to humans or the environment if the risk mitigation measures and label changes outlined in the RED are implemented; therefore, products containing imazapyr are eligible for reregistration. These products containing imazapyr are eligible for reregistration provided that: (i) required product-specific data are submitted; (ii) the risk mitigation measures outlined in the document are adopted; and, (iii) label amendments are made to reflect these measures. Products that contain active ingredients in addition to imazapyr will be reregistered when all of their other active ingredients also are reregistered. Label changes are described in Section V of this document. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of imazapyr and lists the submitted studies that the Agency found acceptable.

The Agency has determined that specific drift language amendments proposed in this RED will substantially reduce, though may not eliminate, the risks to non-target plants.

Based on its evaluation of imazapyr, the Agency has determined that imazapyr products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of imazapyr. If all changes outlined in this document are incorporated into the product labels, then all current risks for imazapyr will be adequately mitigated for the purposes of this determination under FIFRA. Once a comprehensive endangered species assessment is completed, further changes to these registrations may be necessary.

B. Public Comments and Responses

Through the Agency's public participation process, the Agency worked with stakeholders and the public to reach the regulatory decisions for imazapyr. During the public comment period on the risk assessments, which closed on February 21, 2006, the Agency received comments from the BASF Corporation, the Nebraska Department of Agriculture, and the California Indian Basketweavers Association (CIBA). For responses to public comments from the BASF Corporation and the Nebraska Department of Agriculture please refer to the *EFED Responses to Imazapyr Phase 3 Comments*, dated March 29, 2006 and is located in the public docket, http://www.regulations.gov, OPP-2005-0495. Response to comments from CIBA is as follows:

As stated above, the CIBA submitted a public comment dated 2/21/06 to Docket ID Number EPA-OPP-2005-0495 in response to the *Imazapyr: HED Chapter of the Reregistration Eligibility Decision Document*, dated December 8, 2005. This group is concerned about long-term use of pesticides such as imazapyr in forests and on rangeland and their possible effects on wildlife, native plants, life cycles and contamination of basket-making materials, water, and traditional foods. CIBA stated, "Currently, no pesticide residue tolerance has been established for traditional foods eaten and gathered by Native Americans, and the health and risk assessment is not protective for Native American uses of plants growing on public lands where high volumes of imazapyr and other herbicide uses occur. CIBA cited a study conducted by C. Ando, et al. at the California Department of Pesticide Regulation (CDPR) claiming that, following forest treatments, the researchers found that residues of "herbicides" in certain forest plants used by Indians greatly exceed tolerances currently established for the same chemicals in certain fruits, berries, herbs, and grains."

Many of CIBA's statements seem to be addressing general concerns associated with various pesticide uses on rangeland and in forests. The published study supporting the group's claims only addressed the use of glyphosate, hexazinone, and triclopyr in California forests and residues of these three pesticides in four native species used by local Indians. Maximum residues of these three herbicides in the four sampled native plants were found at 19-241 ppm on the day of treatment; half-lives varied from 1 week to 19 weeks. However, none of the tested pesticides are chemically similar to imazapyr. There are several details about imazapyr that, taken together, should minimize CIBA's concerns for imazapyr risks, specifically: Imazapyr tolerances at 40 CFR 180.500 have been established at 100 ppm in grass forage and 30 ppm in grass hay. These tolerances

reflect spot treatment of weed species in pasture and rangeland at 0.75 lb a.i./A, but ≤10% of any given acre may be treated. Therefore, the likelihood of imazapyr use on plants traditionally used by Native Americans, unless targeted as a weed, is unlikely. If spot-treated as a weed, the plant is likely to be exhibiting symptoms of phytotoxicity. Applications in forests are also typically directed, spot treatments although broadcast treatments may be applied at <1.5 lb a.i./A. The preharvest interval is 7 days. The Agency has usage information indicating that <2.5% of all U.S. pasture and rangeland is treated with imazapyr.

As described in the 12/8/05 HED Chapter of the RED, there are no acute risks associated with imazapyr because a single dose of the chemical does not induce adverse effects. Aggregate chronic/long-term risk is <0.1% of the chronic Population Adjusted Dose (cPAD), i.e., a negligible risk. Short-term aggregate risks (MOEs of 410 in children and 720 in adults) are well below the Agency's level of concern (i.e., the MOEs estimated for pesticide exposures are greater than 100).

In other words, additional human exposures to imazapyr in excess of those expected from consumption of default, high volume foods could still occur in subpopulations before the Agency's levels of concern (100% of the cPAD and an MOE of 100 for short-term) would be approached. Note that greater emphasis is being placed by the Agency on determining consumption and exposure patterns of U.S. subpopulations, such as Native Americans, that have thus far not been sufficiently represented in USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994-1996 and 1998 to permit more refined dietary exposure assessments to be conducted for these groups.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

Imazapyr tolerances were reassessed in 2003 when new food uses were established. However, part of reregistration under FIFRA, the Agency assessed the risks associated with imazapyr. The Agency has concluded that aggregate exposure to imazapyr through food, drinking water, and residential sources is within its own "risk cup" and that human health risks from these combined exposures are within acceptable levels. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, the Agency has concluded that the tolerances for imazapyr meet FQPA safety standards. In reaching this determination, the Agency has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, drinking water, and residential uses. The FQPA safety factor has not been retained for imazapyr because acceptable developmental and reproduction studies have been submitted and reviewed and there is low concern and no residual uncertainties for pre- and post-natal toxicity. In addition, the dietary and residential assessments are not expected to underestimate exposure.

b. Endocrine Disruptor Effects

The Agency is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), the Agency determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. The Agency also adopted EDSTAC's recommendation to include evaluations of potential effects in wildlife. For pesticides, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on imazapyr, there was no evidence of endocrine disruption. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, imazapyr may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

c. Cumulative Risks

Risks summarized in this document are those that result only from the use of imazapyr. Unlike other pesticides for which the Agency has followed a cumulative risk approach based on a common mechanism of toxicity, the Agency has not made a common mechanism of toxicity finding for imazapyr and any other substances. Therefore, for the purposes of reregistration, the Agency has not assumed that imazapyr shares a common mechanism of toxicity with other compounds.

2. Tolerance Summary

Imazapyr tolerances were reassessed in 2003 when new food uses were established. This document does not result in any additional tolerances being reassessed. The following information is provided for informational purposes only. A tolerance summary is presented below in Table 13. The Agency has determined that the residue of concern for tolerance expression in plants, livestock, fish, and water is imazapyr *per se*.

Existing tolerances are established in 40 CFR §180.500 for residues of the herbicide imazapyr, [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid], applied as the acid or ammonium salt, in/on corn, grass, milk, meat, poultry, eggs, fish, and shellfish. Adequate data are available to reassess the existing tolerance levels for imazapyr.

The submitted magnitude of the residue data for corn, grass, milk, meat, poultry, and eggs are fulfilled and are adequate for the purposes of reregistration; however, acceptable supporting storage stability data on corn forage and fodder and clarification of

the identity and quantity of spray additives utilized in the grass field trials remain outstanding. The submitted processing data on corn are acceptable, and the results of these studies show that imazapyr does not appreciably concentrate in the processed commodities of field corn. The submitted confined rotational crop data are adequate for the purposes of reregistration, and limited field rotational crop data and rotational crop tolerances are not required at this time.

Imazapyr is registered for use on aquatic areas and the treated water from these sites may be diverted to irrigate food or feed crops. No data depicting imazapyr residue levels in irrigated crops have been submitted and at present, no label restriction prohibits use of imazapyr treated waters for irrigated crops. Data on irrigated crops or label restrictions that prohibit the irrigation of crops with imazapyr treated water for 120 days following application and/or demonstrates non-detectable residue levels of imazapyr in irrigation water by laboratory analysis prior to use are required for reregistration.

Two methods are currently listed in the Pesticide Analytical Manual (PAM) Vol. II for enforcing tolerances of imazapyr in/on corn commodities. Method M 2468 is a gas chromatograph/ mass spectrometry (GC/MS) method with a limit of quantitation (LOQ) of $\tilde{}$ 0.01 ppm for imazapyr in/on corn grain, forage and fodder, and Method M 2657 is a capillary electrophoresis (CE) method with UV detection that has a LOQ of 0.05 ppm for imazapyr in/on corn grain, forage and fodder.

A series of CE/UV Methods are currently listed as enforcement methods for determining imazapyr in/on grass forage and hay (Method M 3023), in livestock tissues (Method M 3184), in milk and milk fat (Methods M 3075 and M 3223), and in fish and shellfish tissues (Method M 3066). These methods are similar to the enforcement method M 2657, and each of these methods also includes directions for a confirmatory analysis using LC/MS.

Each of the above methods has undergone a successful independent laboratory validation (ILV) trial. Adequate radiovalidation data were also submitted for CE/UV methods M 3066, M 3075, and M 3184, demonstrating the efficiency of these methods in extracting residues from aged samples.

The Food and Drug Administration (FDA) multiresidue methods do not exhibit sufficient sensitivity to other imidazolinone herbicides, and thus there is no reasonable expectation that these methods would prove to be useful for determining residues of imazapyr.

Currently there are no Codex, Canadian or Mexican tolerances for residues of imazapyr in/on corn, grass, fish, shellfish, or livestock commodities. Thus, international harmonization of tolerances is not an issue at this time.

a. Tolerances Currently Listed and Tolerance Reassessment

Table 13. Tolerance Table

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments (Correct commodity definition)
Corn, field, forage	0.05	0.05	The available residue data support the reassessed tolerances.
Corn, field, grain	0.05	0.05	
Corn, field, stover	0.05	0.05	
Grass, forage	100	100.0	The available residue data support the reassessed tolerances.
Grass, hay	30	30.0	
Fish	1.0	1.0	The available residue data support the reassessed tolerances.
Shellfish	0.1	0.10	The available residue data support the reassessed tolerances.
Fat of cattle	0.05	0.05	The available residue data support the reassessed tolerances.
Kidney of cattle	0.20	0.20	
Meat byproducts, excluding kidney, of cattle	0.05	0.05	
Meat of cattle	0.05	0.05	
Fat of sheep	0.05	0.05	
Kidney of sheep	0.20	0.20	
Meat byproducts, excluding kidney of sheep	0.05	0.05	
Meat of sheep	0.05	0.05	
Fat of goats	0.05	0.05	
Kidney of goats	0.20	0.20	
Meat byproducts, excluding kidney, of goats	0.05	0.05	
Meat of goats	0.05	0.05	
Fat of horses	0.05	0.05	
Kidney of horses	0.20	0.20	
Meat byproducts, excluding kidney, of horses	0.05	0.05	
Meat, of horses	0.05	0.05	
Milk	0.01	0.01	

D. Regulatory Rationale

The Agency has determined that imazapyr is eligible for reregistration provided the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. This decision considers the risk assessments conducted by the Agency and the significance of the use of imazapyr.

The following is a summary of the rationale for managing risks associated with the use of imazapyr. Where labeling revisions are warranted, specific language is set forth in the summary tables in Section V of this document.

1. Human Health Risk Management

In the human health risk assessment, dietary risks (food and drinking water), residential handler dermal and inhalation risks, residential oral and dermal post-application risks, and aggregate risks do not exceed the Agency's level of concern. Therefore, no risk mitigation measures are required to address these exposure scenarios.

a. Occupational Risk Mitigation

As discussed in Section III.A.7.a, short- and intermediate-term dermal and inhalation risks to occupational handlers who may be exposed to imazapyr during mixer/loader/applicator activities are below the Agency's level of concern at either the baseline level of personal protective equipment or with the addition of gloves. To protect workers mixing and loading liquid formulations for aerial applications to aquatic sites, terrestrial non-crop sites, forestry sites, and areas grazed or cut for hay, these handlers are required to wear chemical resistant gloves. To protect workers mixing, loading, and applying liquid and granular formulations via handwands, backpack spreaders and sprayers, and handgun sprayers for non-crop and aquatic uses, those handlers are required to wear chemical-resistant gloves. As a condition of reregistration, imazapyr formulation into wettable powder end use products is not allowed unless they are packaged in water soluble bags. Label language will include the following measures:

- Liquids: Chemical-resistant gloves are required for all mixers and loaders of liquid formulations and for applicators using hand-held equipment.

- Granulars: Chemical-resistant gloves are required for all mixers and loaders of granular formulations and applicators using hand-held equipment.

- Dry Flowables and Wettable Powders (water soluble bags): Chemical-resistant gloves are required for all mixers and loaders of dry flowable and water soluble bag formulations and applicators using hand-held equipment.

For all agricultural postapplication exposure scenarios, postapplication occupational risks are below HED's level of concern (i.e., the MOEs are greater than 100) on day 0 – approximately 12 hours following application. However, the Agency has determined that imazapyr is a Toxicity Category I primary eye irritant and under the Worker Protection Standard (WPS; 40 CFR Part 170), a 48-hour REI is required. Also under the WPS, early entry requires that coveralls, shoes and socks, chemical resistant gloves, and protective eyewear be used.

2. Environmental Risk Management

To address risks to non-target aquatic and terrestrial plants, additional directions for use and use restrictions will be added to product labels to reduce potential risks. Specific language and restrictions are discussed below.

a. Non-target Terrestrial Plant Risk Mitigation

As mentioned earlier, screening-level risk quotients (RQs) for non-target terrestrial plants resulting from the terrestrial and aquatic spray uses range from 0.01 to 319 for non-target terrestrial plants and from 0.04 to 4,500 for endangered terrestrial plants. Likewise, RQs for non-endangered terrestrial plants from the granular use range from 5.4 to 313 for non-target terrestrial plants and from 25 to 4,410 for endangered non-target terrestrial plants. For aquatic uses of imazapyr, the RQs for non-endangered terrestrial plants ranged from 24 to 313 and 111 to 4,412 for endangered terrestrial plants. Direct exposure scenarios were not calculated, but RQs for plants and endangered plants would be significantly higher than those estimated from exposure via spray drift and/or runoff.

Because imazapyr is an herbicide and may therefore harm non-target plants exposed via drift, to be eligible for reregistration labels must require that imazapyr be applied in a manner that minimizes spray drift. Strict use restrictions to minimize spray drift will be placed on the labels for all imazapyr products. This language will include:

- For aerial applications, applicators are required to use a Coarse or coarser droplet size (ASABE S572) or, if specifically using a spinning atomizer nozzle, applicators are required to use a volume mean diameter (VMD) of 385 microns or greater for release heights below 10 feet; Applicators are required to use a Very Coarse or coarser droplet size or, if specifically using a spinning atomizer nozzle, applicators are required to use a VMD of 475 microns or greater for release heights above 10 feet; applicators must consider the effects of nozzle orientation and flight speed when determining droplet size;

- For aerial applications, applicators are required to use upwind swath displacement;

- For aerial applications, the boom length must not exceed 60% of the wingspan or 90% of the rotor blade diameter, to reduce spray drift;

- For aerial applications, applications with wind speeds less than 3 mph and with wind speeds greater than 10 mph are prohibited;

- For groundboom applications, applicators are required to use a nozzle height below 4 feet above the ground or plant canopy and Coarse or coarser droplet size (ASABE S572) or, if specifically using a spinning atomizer nozzle, applicators are required to use a volume mean diameter (VMD) of 385 microns or greater;

- For groundboom applications, applications with wind speeds greater than 10 mph are prohibited;

- Applications into temperature inversions are prohibited.

The Agency has determined that specific drift language amendments proposed in this RED will substantially reduce, though may not completely eliminate, the risks to non-target plants.

b. Non-target Aquatic Plant Risk Mitigation

Screening-level risk quotients (RQs) for both the aquatic and terrestrial uses of imazapyr were calculated. The RQs for non-endangered aquatic plants from the aquatic use range from <0.01 for non-vascular aquatic plants to 31 for vascular aquatic plants and from 7.6 to 50 for endangered vascular aquatic plants. The non-target endangered and non-endangered aquatic plant RQs resulting from the terrestrial uses range from <0.01 for non-vascular plants to 4.7 for vascular aquatic plants and from 0.07 to 7.6 for endangered vascular aquatic plants. The Agency has determined that the specific drift requirements listed above will substantially reduce the risks to non-target aquatic plants from terrestrial uses of imazapyr.

For non-target plant risks resulting from the aquatic use of imazapyr, there is currently the statement, "Do not apply to bodies of water or portions of bodies of water where emergent and/or floating weeds do not exist" on labels that allow application to water bodies. The Agency believes that this statement also substantially reduces the risks to non-target aquatic plants (including endangered plants) from this use. However, the Agency feels that this language should be placed in a more prominent location on the label. Therefore, the Agency is requiring the statement be placed in the General Use Precautions and Restrictions section of the label. Putting this use requirement in this section will make it clearer that this is a use restriction when applying to bodies of water. Currently, this statement is in the General Information section of the label.

3. Significance of Imazapyr Use

The application of imazapyr for aquatic and semi-aquatic weed control is predominantly conducted to control nuisance and nonnative weed species; most often species such as Purple Loosestrife (*Lythrum salicaria* L.). When these species begin to invade shoreline areas of lakes, streams, or canals, their establishment is rapid and often results in their out-competing indigenous species, which then leads to a monoculture. Since imazapyr has no effect on submerged aquatic vegetation (SAV), it can be used in these margin, or shoreline, areas to control weeds without the risk of damaging desirable SAV.

4. Other Labeling Requirements

In order to be eligible for reregistration, imazapyr use and safety information will be included in the labeling of all end-use products containing imazapyr. Imazapyr is classified as a Toxicity Category I primary eye irritant; therefore, the WPS requires a REI of 48 hours. Also under the WPS, early entry requires that coveralls, shoes and socks, chemical resistant gloves, and protective eyewear be used.

For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

5. Threatened and Endangered Species Considerations

a. The Endangered Species Program

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, the Agency uses basic toxicity and exposure data developed for the REDs and then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will also consider the risk mitigation measures that are being implemented as a result of this RED.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of imazapyr "may effect" listed species or their designated critical habitat, the Agency will employ the provisions in the Services regulations (50 CFR Part 402). Until the species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to imazapyr at levels of concern. The Agency is not requiring

specific imazapyr label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Program.

b. General Risk Mitigation

Imazapyr end-use products (EUPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing imazapyr specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) must be adopted.

V. What Registrants Need to Do

The Agency has determined that imazapyr is eligible for reregistration provided that the risk mitigation measures identified in this document are adopted and label amendments are made to reflect these measures; however, additional data are required to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amend labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data that the Agency intends to require for imazapyr to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of imazapyr has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and are included in the generic DCI for this RED.

Table 14. Confirmatory Data Requirements for Reregistration

New Guideline Number	Old Guideline Number	Study/Requirements
123-1(a)	850.4225	Seedling Emergence- Tier II using Imazapyr isopropylamine salt PLUS the adjuvant/surfactant/wetting agent as required on the label
123-1(b)	850.4250	Vegetative Vigor- Tier II using Imazapyr isopropylamine salt PLUS the adjuvant/surfactant/wetting agent as required on the label
171-4e	860.1380	Storage stability data for corn or grass
171-4f, g, h, 165-5	860.1400	Magnitude of residues in fish
171-4k	860.1500	Identity and quantity of spray additives used in all of the grass field trials

Imazapyr is registered for use on aquatic areas and the treated water from these sites may be diverted to irrigate food or feed crops. No data depicting imazapyr residue levels in irrigated crops have been submitted and presently no label restriction prohibits use of imazapyr treated waters for irrigated crops. Data on irrigated crops or label restrictions that prohibit the irrigation of crops with imazapyr treated water for 120 days following application and/or demonstrates non-detectable residue levels of imazapyr in irrigation water by laboratory analysis prior to use are required to confirm this for reregistration decision.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use products (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The technical and MP labeling should also bear the labeling statements contained in Table 15, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g) (2) (B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticides after a determination of eligibility has been made. The registrant must review previous data submissions to ensure they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrations Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements will be issued in the near future.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in the Label Changes Summary Table below.

a. Label Changes Summary Table

In order to be eligible for reregistration, registrants must amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 15: Summary of Labeling Changes for Imazapyr

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into an ***herbicide*** for the following uses: liquid, wettable powder (in water soluble bags only), and granular." "Not for formulation into wettable powder end use products unless they are packaged in water soluble bags."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards	"This product is toxic to plants. Drift and run-off may be hazardous to plants in water adjacent to treated areas. Do not apply to water except as specified on the label. Treatment of aquatic weeds may result in oxygen depletion or loss due to decomposition of dead plants. Do not treat more than one half the surface area of the water in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outward in bands to allow aquatic organisms to move into untreated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements."	Precautionary Statements

End Use Products for Occupational Use (WPS and non-WPS)		
PPE Requirements Established by the RED[1] For All Formulations	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G, or H*] "on an EPA chemical-resistance category selection chart. "Mixers, loaders, applicators, and other handlers must wear: > Long-sleeve shirt and long pants, > Shoes plus socks, > Chemical resistant gloves for all mixers and loaders, plus applicators using handheld equipment."	Precautionary Restrictions
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Immediately following the PPE requirements
Engineering controls for Products Applied Aerially as Sprays	"Pilots must use an enclosed cockpit that meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Immediately following the User Safety Requirements

User Safety Recommendations	"User Safety Recommendations Users should wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"This product is toxic to plants. Drift and run-off may be hazardous to plants in water adjacent to treated areas. Do not apply to water except as specified on the label. Treatment of aquatic weeds may result in oxygen depletion or loss due to decomposition of dead plants. Do not treat more than one half the surface area of the water in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outward in bands to allow aquatic organisms to move into untreated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Directions for Use, In Agricultural Use Requirements Box

Entry Restrictions for Products with Directions for Use not Within the Scope of WPS	For products applied as Sprays: "Do not enter or allow others to enter treated areas until sprays have dried" For products applied as Dry: "Do not enter or allow others to enter treated areas until dusts have settled."	
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls * shoes plus socks * chemical-resistant gloves made of any waterproof material * protective eyewear"	Direction for Use, In Agricultural Use Requirements box, immediately following the REI
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Spray Drift	<u>Spray drift requirements</u> <u>Aerial Applications:</u> (1) Applicators are required to use a Coarse or coarser droplet size (ASABE S572) or, if specifically using a spinning atomizer nozzle, applicators are required to use a volume mean diameter (VMD) of 385 microns or greater for release heights below 10 feet; Applicators are required to use a Very Coarse or coarser droplet size or, if specifically using a spinning atomizer nozzle, applicators are required to use a VMD of 475 microns or greater for release heights above 10 feet; Applicators must consider the effects of nozzle orientation and flight speed when determining droplet size.	Directions for Use

	(2) Applicators are required to use upwind swath displacement. (3) The boom length must not exceed 60% of the wingspan or 90% of the rotor blade diameter to reduce spray drift. (4) Applications with wind speeds less than 3 mph and with wind speeds greater than 10 mph are prohibited. (5) Applications into temperature inversions are prohibited. <u>Ground Boom Applications:</u> (1) Applicators are required to use a nozzle height below 4 feet above the ground or plant canopy and Coarse or coarser droplet size (ASABE S572) or, if specifically using a spinning atomizer nozzle, applicators are required to use a volume mean diameter (VMD) of 385 microns or greater. (2) Applications with wind speeds greater than 10 mph are prohibited. (3) Applications into temperature inversions are prohibited.	
	The use of treated waters on irrigated crops within 120 days of treatment is prohibited.	

End Use Products Primarily Intended for Residential Use		
Environmental Hazard Statements	"This product is toxic to plants. Drift and run-off may be hazardous to plants in water adjacent to treated areas. Do not apply to water except as specified on the label. Treatment of aquatic weeds may result in oxygen depletion or loss due to decomposition of dead plants. Do not treat more than one half the surface area of the water in a single operation and wait at least 10 to 14 days between treatments. Begin treatment along the shore and proceed outward in bands to allow aquatic organisms to move into untreated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements."	Precautionary Statements immediately following the User Safety Recommendations
Entry Restrictions for products applied as a spray	For products applied as Sprays: "Do not enter or allow others to enter treated areas until sprays have dried" For products applied as Dry: "Do not enter or allow others to enter treated areas until dusts have settled."	Directions for use under General Precautions and Restrictions
General Application Restrictions	"Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions

[1] PPE that is established on the basis of Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

VI. Appendices

Appendix A. IMAZAPYR USE PATTERNS ELIGIBLE FOR REREGISTRATION

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ae/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	0.5% granular [228-307]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not appy where runoff or irrigation water may flow onto agricultural land. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	0.5% granular [228-308]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not appy where runoff or irrigation water may flow onto agricultural land. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	0.5% granular [241-295]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not appy where runoff or irrigation water may flow onto agricultural land. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	5.0% granular [241-308]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not appy where runoff or irrigation water may flow onto agricultural land. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	0.5% granular [241-344]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not appy where runoff or irrigation water may flow onto agricultural land. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Noncropland Areas Pre-emergence Aerial, groundboom, low-pressure handwand, right-of-way sprayer, backpack	7.78% dispersable granules [241-372]	1.5 initial application 0.5 reapplication	1.5 lb ae/A in a 12 month period	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.

Site Application Type Application Timing Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ae/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations
Clearfield Corn Hybrids Post-emergence Backpack, low-pressure, handgun, airblast, aerial	17.5% dispersable granules [241-377]	0.014	1	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not use in California. New York - Not for sale or use on Long Island
Clearfield Corn Hybrids Post-emergence Backpack, low-pressure, handgun, airblast, aerial	4.0% dispersable granules [241-384]	0.014	1	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not use in California. New York - Not for sale or use on Long Island
Trees Post-emergence Aerial, groundboom, handgun, rights-of-way sprayer	75% soluble granules [241-387]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Clearfield Corn Hybrids Post-emergence Aerial, groundboom, low-pressure handwand, right-of-way sprayer, backpack	5.05% liquid [241-400]	0.014	1	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not mix or load within 50 feet of any wells, sink holes, perennial or intermittent streams and rivers, and natural or impounded reservoirs. Not for use in California or New York.
Trees Post-emergence Aerial, groundboom, handgun, rights-of-way sprayer	75.0% soluble granules [241-402]	1.25	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not use on Christmas trees. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses.
Noncropland Areas Pre-emergence Aerial, groundboom, low-pressure handwand, right-of-way sprayer, backpack	0.15% liquid [2217-802]	0.014	1	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply through any irrigation system.
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	0.5% granules [13283-19]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses.

Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	0.5% granules [34913-22]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not use on food or feed crops. Do not treat irrigation ditches, or water used for crop irrigation or for domestic uses. Do not use on lawns, walks, driveways tennis cours, or similar areas. Do not use in California.
Noncropland Areas Pre-emergence aerial, tractor-drawn spreader	5% granules [34913-24]	1.5	1 (herbaceous) 1-2 per 10 years (brush)	N/S	Do not use on food or feed crops. Do not apply on ditches used to transport irrigation water. Do not apply where runoff or irrigation water may flow onto agricultural land. Do not use on lawns, walks, driveways, tennis courts, or similar areas.
Grass Pasture and Rangeland Post-emergence Spot treatment ground equipment	2 lb ae/gal EC [241-346]	0.75	1 per 5 years	7-day PHI[2]	Applications may not exceed more than 1/10 of a given acre, therefore the maximum rate per acre is 0.075 lb ae/A. Do not cut forage for hay for 7 days after application. Rotational crops: 12 months after application, a successful field bioassay must be completed. If no crop injury is evident in the bioassay, then the intended rotational crop may be planted the following year. Post-emergence applications require the addition of a spray adjuvant (nonionic surfactant or methylated seed oils or vegetable oil concentrates).
Aquatic Areas or Draw Down Area Post-emergence Aerial, boat	2 lb ae/gal EC [241-346]	1.5	N/S	N/S	Do not apply to marine or estuarine areas. Do not apply within ½ mile (standing water) or within ½ mile upstreat (flowing water) of an active irrigation or potable water intake. For application within ½ mile of a water intake, the water intake must be turned off for a minimum of 48 hours after the application. Allow 1 hour after treatment before refilling draw down area. Apply in a minimum of value of 5 gal/A.

1. N/S—not specified
2. PHI—post-harvest interval

Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within Case #3078 (Imazapyr) covered by this RED. It contains generic data requirements that apply to Imazapyr in all products, including data requirements for which a "typical formulation" is the test substance.
The data table is organized in the following formats:
1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

A. Terrestrial food
B. Terrestrial feed
C. Terrestrial non-food
D. Aquatic food
E. Aquatic non-food outdoor
F. Aquatic non-food industrial
G. Aquatic non-food residential
H. Greenhouse food
I. Greenhouse non-food
J. Forestry
K. Residential
L. Indoor food
M. Indoor non-food
N. Indoor medical
O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

New Guideline Number	Old Guideline Number	Requirement	Use Pattern	Bibliographic Citation(s)
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	A,B,C,E, F, G,J,K	43423700, 43423701
830.1600	61-2(a)	Start. Mat. & Mfg. Process	A,B,C,E, F, G,J,K	43423700
830.1620	61-2(b)	Description of Production Process	A,B,C,E, F, G,J,K	43423700
830.1650	158.165	Description of Formulation Process	A,B,C,E, F, G,J,K	43423700
830.1670	61-2(b)	Discussion of Formation of Impurities	A,B,C,E, F, G,J,K	43423701-03
830.1700	62-1	Preliminary Analysis	A,B,C,E, F, G,J,K	43423702
830.1750	62-2	Certification of limits	A,B,C,E, F, G,J,K	46274402
830.1800	62-3	Analytical Method	A,B,C,E, F, G,J,K	44102801
830.6302	63-2	Color	A,B,C,E, F, G,J,K	00145872
830.6303	63-3	Physical State	A,B,C,E, F, G,J,K	00145872

830.6304	63-4	Odor	A,B,C,E, F, G,J,K	00145872
830.6313	63-13	Stability - temp and ions	A,B,C,E, F, G,J,K	00145872
830.7000	63-12	pH	A,B,C,E, F, G,J,K	00145872
830.7050	N/A	UV/Visible absorption	A,B,C,E, F, G,J,K	Data Gap
830.7200	63-5	Melting point/melting range	A,B,C,E, F, G,J,K	00145872
830.7220	63-6	Boiling point/range	A,B,C,E, F, G,J,K	N/A
830.7300	63-7	Density	A,B,C,E, F, G,J,K	00145872
830.7370	63-10	Dissociation Constants in Water	A,B,C,E, F, G,J,K	00145872
830.7550	63-11	Partition Coefficient, shake flask method	A,B,C,E, F, G,J,K	00145872, 00133555
830.7560	63-11	Partition Coefficient, generator column method	A,B,C,E, F, G,J,K	See 830.7550
830.7570	63-11	Partition Coefficient, estimation by liquid chromatography	A,B,C,E, F, G,J,K	See 830.7550
830.7840	63-8	Water Solubility, column elution method; shake flask method	A,B,C,E, F, G,J,K	See 830.7860
830.7860	63-8	Water Solubility, generator column method	A,B,C,E, F, G,J,K	00145872

830.7950	63-9	Vapor Pressure	A,B,C,E, F, G,J,K	00145782
ECOLOGICAL EFFECTS				
850.2100	71-1(a)	Avian Oral LD50 Quail/Duck	A,B,C,E, F, G,J,K	00131633, 00131634
850.2200	71-2(a)	Avian Dietary LC50 Quail	A,B,C,E, F, G,J,K	00131635, 0013552, 00133553
850.2200	71-2(b)	Avian Dietary LC50 Duck	A,B,C,E, F, G,J,K	00131636, 00131551
850.2300	71-4(a)	Avian Reproduction Quail	A,B,C,E, F, G,J,K	45119714, 43831401
850.2300	71-4(b)	Avian Reproduction Duck	A,B,C,E, F, G,J,K	43831402
850.1075	72-1(a)	Freshwater Fish LC50 Bluegill (warm water)	A,B,C,E, F, G,J,K	00133549
850.1075	72-1(b)	Freshwater Fish LC50 Channel Catfish	A,B,C,E, F, G,J,K	00131631
850.1075	72-1(c)	Freshwater Fish LC50 Rainbow trout (cold water)	A,B,C,E, F, G,J,K	45119713
850.1010	72-2(a)	Freshwater Invertebrate LC50 *Daphnia magna*	A,B,C,E, F, G,J,K	00131632, 01133550
850.1045	72-3(a)	Estuarine/Marine Fish LC50	A,B,C,E, F, G,J,K	41315801
850.1025	72-3(b)	Estuarine/Marine Mollusk EC50	A,B,C,E, F, G,J,K	41315802, 45119709, 45119710
850.1035	72-3(c)	Estuarine/Marine Shrimp EC50	A,B,C,E, F, G,J,K	41315803

850.1400	72-4(a)	Fish Early Life-Stage Rainbow Trout (freshwater)	A,B,C,E, F, G,J,K	41315804
850.1400	72-4(a)	Fish Early Life-Stage Fathead Minnow (estuarine/marine)	A,B,C,E, F, G,J,K	45119711
850.1350	72-4(b)	Aquatic Invertebrate Life-Cycle (freshwater)	A,B,C,E, F, G,J,K	41315805
850.1500	72-5	Freshwater Fish Full Life-Cycle	A,B,C,E, F, G,J,K	45119712
850.171	72-6	Aquatic Organism Accumulation	A,B,C,E, F, G,J,K	00147120
850.4225	122-1	Seed Germ./Seedling Emergence (Tier 2)	A,B,C,E, F, G,J,K	40003711, Data Gap
850.4400	122-2	Aquatic Plant Growth (Tier 2)	A,B,C,E, F, G,J,K	43889102, 40811802
850.4250	123-1	Vegetative Vigor (Tier 2)	A,B,C,E, F, G,J,K	43889101, 40811801, 40811802Data Gap
850.4450	124-2	Aquatic Field	A,B,C,E, F, G,J,K	40811802, 00131628, 00131629, 00131637, 00133554, 00147114
850.3020	141-1	Honey Bee Acute Contact LD50	A,B,C,E, F, G,J,K	00131637
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A,B,C,E, F, G,J,K	41551002, 93048016
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A,B,C,E, F, G,J,K	41551003, 93048017
870.1300	81-3	Acute Inhalation Toxicity-Rat	A,B,C,E, F, G,J,K	00132032, 93048018

870.2400	81-4	Primary Eye Irritation-Rabbit	A,B,C,E, F, G,J,K	41551001, 93048019, Accession# 252004
870.2500	81-5	Primary Skin Irritation	A,B,C,E, F, G,J,K	41551004, 93048020
870.2600	81-6	Dermal Sensitization	A,B,C,E, F, G,J,K	00131607, 93048021
870.3100	82-1(a)	90-Day Feeding - Rodent	A,B,C,E, F, G,J,K	42774401
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A,B,C,E, F, G,J,K	00131609, 93048022
870.3700a	83-3(a)	Developmental Toxicity (Teratogenicity) - rat	A,B,C,E, F, G,J,K	00131611, 93048023
870.3700b	83-3(b)	Developmental Toxicity (Teratogenicity) - rabbit	A,B,C,E, F, G,J,K	00131613, 93048024
870.3800	83-4	2-Generation Reproduction - Rat	A,B,C,E, F, G,J,K	41039505
870.4100a	83-1	Chronic Toxicity - Rat	A,B,C,E, F, G,J,K	N/A; see 870.4300
870.4100b	83-1	Chronic Toxicity - Dog	A,B,C,E, F, G,J,K	41039502
870.4200a	83-2	Carcinogenicity - Rat	A,B,C,E, F, G,J,K	N/A; see 870.4300
870.4200b	83-2	Carcinogenicity - Mouse	A,B,C,E, F, G,J,K	41038505, 42774401
870.4300	83-5	Combined Chronic/Carcinogenicity	A,B,C,E, F, G,J,K	41039503

870.5100	84-2	Bacterial Reverse Mutation (Ames Assay)	A,B,C,E, F, G,J,K	00131615, 93048025
870.5300	84-2	*In vitro* Mammalian Cell Gene Mutation	A,B,C,E, F, G,J,K	00151641, 93048028
870.5375	84-2	*In vitro* Mammalian Chromosome Aberration (CHO)	A,B,C,E, F, G,J,K	00151640, 93048026
870.5450	84-2	Rodent Dominant Lethal	A,B,C,E, F, G,J,K	00151638
870.5500	84-2	Unscheduled DNA Synthesis	A,B,C,E, F, G,J,K	00151639, 93048027
870.7485	85-1	Metabolism and Pharmacokinetics - Rat	A,B,C,E, F, G,J,K	43861501
870.7600	85-3	Dermal Absorption – Rat	N/A	N/A
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A,B,C,E, F, G,J,K	00132359, 00131617, 00131639, 00133557
835.2240	161-2	Photodegradation - Water	A,B,C,E, F, G,J,K	00131617
835.4100	162-1	Aerobic Soil Metabolism	A,B,C,E, F, G,J,K	00131619, 41002301, 00131618, 00133557, 45119701
835.4200	162-2	Anaerobic Soil Metabolism	A,B,C,E, F, G,J,K	00131619, 41023201, 45119701
835.4400	162-3	Anaerobic Aquatic Metabolism	A,B,C,E, F, G,J,K	40003712
835.4300	162-4	Aerobic Aquatic Metabolism	A,B,C,E, F, G,J,K	41002301, 45119702

835.1240	163-1	Leaching/Adsorption/Desorption	A,B,C,E, F, G,J,K	00131620, 00131620, 00133557, 43423703, 45119705
835.6100	164-1	Terrestrial Field Dissipation	A,B,C,E, F, G,J,K	00131621, 42192101,42192102, 45119705, 45119706, 00131622, 00131623, 00131624, 0013357, 00147119
835.6200	164-2	Aquatic Field Dissipation	A,B,C,E, F, G,J,K	41891501, 45119707, 45119708
835.6500	164-5	Long Term Soil Dissipation	A,B,C,E, F, G,J,K	45119706
N/A	165-4	Accumulation in Fish	A,B,C,E, F, G,J,K	00147120
N/A	165-5	Accumulation – Aquatic Non-target	A,B,C,E, F, G,J,K	45119722
835.7100	166-1	Ground Water Monitoring	A,B,C,E, F, G,J,K	44746701, 44746702, 44746703, 44865101, 44865102, 44975001, 45035201, 45139101, 45139102, 45212601, 45212602, 45335301, 45335302, 45410001, 45410002, 45498201, 45212602, 45335301, 45335302, 45410001, 45410002, 45498201, 45498202, 45663801, 45663802, 45677401
840.1100	201-1	Spray Droplet Size Spectrum	A,B,C,E, F, G,J,K	41516301
840.2100	202-1	Spray Drift Field Deposition	A,B,C,E, F, G,J,K	41516301

RESIDUE CHEMISTRY				
860.1300	171-4(a)	Nature of Residue in Plants	A,B,C,E, F, G,J,K	45119715
860.1300	171-4(b)	Nature of Residue in Livestock	A,B,C,E, F, G,J,K	45119716
860.1340	171-4(c)	Residue Analytical Method - plant	A,B,C,E, F, G,J,K	45119718
860.1340	171-4(d)	Residue Analytical Method - livestock	A,B,C,E, F, G,J,K	45119718
860.1340	171-4(d)	Residue Analytical Method – Water/fish	A,B,C,E, F, G,J,K	Data Gap
860.1360	171-4(m)	Multiple Residue Methods	N/A	N/A
860.1380	171-4(e)	Storage Stability Data	A,B,C,E, F, G,J,K	45119719, Data Gap
860.1400	171-4(h)	Fish, water, & irrigated crops	A,B,C,G,J,K	45119709, 45119722, 4519707, Data Gap
860.1480	171-4(j)	Milk, Meat, Poultry, & Eggs	A,B,C,E, F, G,J,K	45119721
860.1500	171-4(k)	Cropfield Residue (Grass, Forage, & Hay)	A,B,C,E, F, G,J,K	45119720, Data Gap
860.1520	171-4(l)	Processed Food/Feed	N/A	N/A

860.1650	171-13	Submittal of Analytical Reference Standards	A,B,C,E, F, G,J,K	Submitted to EPA National Pesticide Standards Repository
860.1850	165-1	Confined rotational crops	A,B,C,E, F, G,J,K	45119717
860.1900	165-2	Field rotational crops	A,B,C,E, F, G,J,K	45119717

HED concludes that there are no outstanding residue chemistry data requirements that would preclude the reassessment of tolerance levels for reregistration purposes, provided that:

- the registrant submits an acceptable fish metabolism study,
- the registrant submits adequate corn or grass storage stability information,
- the registrant specifies the identity and quantity of spray additives used in all of the grass field trials,
- the analytical enforcement method is determined to be adequate, and
- labels are revised to prohibit use of treated waters on irrigated crops for 120 days after treatment or residue data is provided for irrigated crops.

A few data gaps were identified for imazapyr in a few different use areas that include:

- applying sprayers to aquatic sites via helicopters (PHED data for fixed wind aerial spray applications were used as a reasonable surrogate); and
- mixing/loading/applying liquids to trees via injection equipment (no surrogate data are available at this time).

For all agricultural postapplication exposure scenarios, data gaps exist such as a lack of imazapyr specific postapplication studies.

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

http://docket.epa.gov/edkpub/index.jsp

These documents include:

1. Federal Register Notice: Imazapyr Reregistration Eligibility Decision; Notice of Availability

2. Reader's Guide to the Imazapyr EDOCKET OPP-2005-495

3. Imazapyr Reregistration Eligibility Decision

4. Imazapyr: Chronic Dietary Exposure Assessment for the Section 3 Registration Action on Grasses and Aquatic Sites, PC Code: 128821, DP Barcode D288806 (March 26, 2003).

5. Imazapyr: Revised Health Effects Division (HED) Chapter of the Reregistration Eligibility Document (RED), PC Code: 128821, CAS Reg 81334-34-1, Case #3078, DP Barcode D324106 (December 8, 2005).

6. Imazapyr: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document, PC Code: 128821, DP Barcode D320582, (August 31, 2005).

7. Response to Error Only Comments on the EFED Ecological Risk Assessment Supporting the RED for the Herbicide, Imazapyr, PC Code: 128821, DP Barcodes: 324101, 324103, (December 9, 2005).

8. Imazapyr: Summary of Product Chemistry Data for Reregistration Eligibility Decision (RED) Document, PC Code: 128821, DP Barcode: D320579 (August 29, 2005).

9. Level I Screening Ecological Risk Assessment for the Reregistration of Imazapyr, CAS Number: 81334-34-1.

Appendix D. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION DECISION (BIBLIOGRAPHY)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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45119715	Wu, D. (1997) AC 243997: Metabolism in Bermuda Grass Under Field Conditions: Lab Project Number: MET 96-007: RPT0084: XBL 91041. Unpublished study prepared by American Cyanamid Company, Pan-Agricultural Lab Inc., and XenoBiotic Labs Inc. 221 p. {OPPTS 860.1300}
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45119718	Bixler, T.; Fletcher, J.; Gross, J. et al. (1999) Validations of Methods of Analysis of Imazapyr Residues in Grass, Cattle Tissue and Milk, Fish, and Shellfish: Lab Project Number: RES 99-001: RES98-108: RES 99-002. Unpublished study prepared by American Cyanamid Company, ABC Labs Inc., and Maxim Tech Inc. 422 p. {OPPTS 860.1340}
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46274400	BASF Corporation (2004) Submission of Product Chemistry Data In Support of the Registration of Arsenal Herbicide Technical. Transmittal of 3 Studies.
46274401	Birk, J. (2004) Analysis of Imazapyr Herbicide Technical. Unpublished study prepared by BASF Corporation. 7 p.
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46559102	Gorban, I. (2005) Imazapyr Technical (Agan) - Five Lots Analysis and Method Validation. Project Number: 04/11/3, 90007751. Unpublished study prepared by Agan Chemical Manufacturers, Ltd. 95 p.
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46624602	Jian, Y. (2005) Preliminary Analysis of Imazapyr Technical. Project Number: NC/2005/002. Unpublished study prepared by Nutrichem Laboratory Co. Ltd. 65 p.
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46624607	Mukherjee, A. (2005) Acute Inhalation Toxicity Study of Imazapyr Technical in Rats. Project Number: 5269. Unpublished study prepared by Jai Research Foundation. 54 p.
46624608	Mukherjee, A. (2005) Acute Eye Irritation Study of Imazapyr Technical in Rabbits. Project Number: 5267. Unpublished study prepared by Jai Research Foundation. 37 p.
46624609	Mukherjee, A. (2005) Acute Dermal Irritation Study of Imazapyr Technical in Rabbits. Project Number: 5266. Unpublished study prepared by Jai Research Foundation. 34 p.
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46633301	Mukherjee, A. (2005) Skin Sensitization Study of Imazapyr Technical in Guinea Pigs (Guinea Pig Maximization Test). Project Number: 5268. Unpublished study prepared by Jai Research Foundation. 53 p.
46683900	PBI/Gordon Corporation (2005) Submission of Product Chemistry Data in Support of the Amended Registration of EH 1135 PGR. Transmittal of 1 Study.
46683901	Sanson, D. (2005) Product Identity and Composition of EH 1135 PGR. Unpublished study prepared by PBI/Gordon Corp. 10 p.
46731400	Agan Chem MFG, Ltd (2006) Submission of Product Chemistry Data in Support of the Application for Registration of Imazapyr Technical. Transmittal of 1 Study.
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46775503	Sanders, A. (2005) Acute Oral Toxicity in the Rat - Up and Down Procedure: Mohave 7 EG: AGN-SAH02. Project Number: 008/596. Unpublished study prepared by Safepharm Laboratories Ltd. 16 p.

46775504	Sanders, A. (2005) Acute Dermal Toxicity (Limit Test) in the Rat: Mohave 70 EG: AGN-SAH02. Project Number: 008/598. Unpublished study prepared by Safepharm Laboratories Ltd. 19 p.
46775505	Griffiths, D. (2005) Acute Inhalation Toxicity (Nose Only) Study in the Rat: AGN-SAH02. Project Number: 008/597. Unpublished study prepared by Safepharm Laboratories Ltd. 32 p.
46775506	Sanders, A. (2005) Acute Eye Irritation in the Rabbit: Mohave 7 EG: AGN-SAH02. Project Number: 008/600. Unpublished study prepared by Safepharm Laboratories Ltd. 18 p.
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Appendix E. GENERIC DATA CALL-IN

Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

Appendix F. PRODUCT SPECIFIC DATA CALL-IN

Note that a complete Data Call-In (DCI), with all pertinent instructions, will be sent to registrants under separate cover.

Appendix G. EPA'S BATCHING OF IMAZAPYR PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing IMAZAPYR as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a

registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirty eight products were found which contain Imazapyr as the active ingredient. These products have been placed eight batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	241-286	95.0
	11603-42	95.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	241-387	75.0
	241-402	75.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	228-480	53.1
	241-299	53.1
	241-401	53.1
	34704-908	53.1
	61202-1	53.1

Batch 4	EPA Reg. No.	Percent Active Ingredient
	241-346	28.7
	241-426	28.7
	34704-896	28.7

Batch 5	EPA Reg. No.	Percent Active Ingredient
	241-273	27.6
	241-296	27.6
	241-336	27.6
	241-398	27.6
	34704-905	27.6

Batch 6	EPA Reg. No.	Percent Active Ingredient
	241-308	5.0
	34913-24	5.0

Batch 7	EPA Reg. No.	Percent Active Ingredient
	228-307	0.5
	241-295	0.5
	34913-23	0.5

Batch 8	EPA Reg. No.	Percent Active Ingredient
	228-308	Imazapyr: 0.5 Diuron: 2.0
	241-344	Imazapyr: 0.5 Diuron: 2.0
	13283-19	Imazapyr: 0.5 Diuron: 2.0
	34913-22	Imazapyr: 0.5 Diuron: 2.0

No Batch	EPA Reg. No.	Percent Active Ingredient
	239-2622	Imazapyr: 0.080 Oxyfluorfen: 0.700
	239-2657	Imazapyr: 0.080 Glyphosate: 5.000
	239-2686	Imazapyr: 0.016 Glyphosate: 1.000
	241-294	14.200
	241-330	3.600
	241-372	Imazapyr: 7.780 Diuron: 62.220
	241-377	Imazapyr: 17.500 Imazethapyr: 52.500
	241-384	Imazapyr: 4.000 Imazethapyr: 12.000 Benzoic Acid: 58.900
	241-400	Imazapyr: 5.050 Imazethapyr: 15.150
	241-414	Imazapyr: 8.360 Glyphosate: 22.130
	2217-802	Imazapyr: 0.150 Acetamide: 21.450 Imazethapyr: 4.090
	62719-526	Imazapyr: 2.390 Glyphosate: 31.380

Appendix H. LIST OF REGISTRANTS SENT THIS DATA CALL-IN NOTICE

1. BASF Corporation.

2. Nufarm Americas, Inc.

3. PBI/Gordon Corporation.

4. Agan Chemical MFG, Ltd.

5. Rainbow Technology Corporation.

7. SSI Maxim Company, Inc.

8. Vegetation Management, LLC.

9. Etigra, LLC.

Appendix I. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions:

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the Internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendmentb. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   b. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   c. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   d. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   e. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

   - Date of receipt
   - EPA identifying number
   - Product Manager assignment

   Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

   To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.

2. Detailed Luis Report.