



# Reregistration Eligibility Decision (RED) for Ametryn

**REREGISTRATION ELIGIBILITY DECISION (RED)**  
**for**  
**AMETRYN**

(2-ethylamino)-4-(isopropylamino)-6-(methylthio)-s-triazine,

CASE 2010

Approved by:

\_\_\_\_\_  
Debra Edwards, Ph. D.  
Director  
Special Review and Reregistration Division

Date:

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## **Ametryn Team List**

### **Office of Pesticide Programs:**

#### **Health Effects Risk Assessment**

William Donovan

John Doherty

Robert Travaglini

#### **Environmental Fate Risk Assessment**

Kevin Costello

John Ravenscroft

Roxolana Kashuba

Brian Kiernan

#### **Biological and Economics Division**

Julie Heflin

Nicole Zinn

Steve Smearman

#### **Registration Division**

Jim Tompkins

#### **Risk Management**

Mark Howard

Neil Anderson

## Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ASAE	American Society of Agricultural Engineers
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII USDA	Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FAO	Food and Agricultural Organization of the United Nations (UN)
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC <sub>50</sub>	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 substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	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
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
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	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Groundwater Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c)) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WHO	World Health Organization of the United Nations (UN)
WPS	Worker Protection Standard



## Executive Summary

EPA has completed its review of public comments on the revised ametryn risk assessments and is issuing its risk management decision for ametryn. There are currently 14 tolerances being reassessed for ametryn. The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and additional information received. After considering the risks identified in the revised risk assessment, comments, and mitigation suggestions from interested parties, EPA developed its risk management decision for uses of ametryn that pose risks of concern. As a result, the Agency has determined that ametryn containing products are eligible for reregistration provided that data needs are addressed, risk mitigation measures are adopted, and labels are amended accordingly. The decision is discussed fully in this document.

Ametryn was first registered for use to control broadleaf weeds and annual grasses in sugarcane fields in 1964. In 1969, use for general weed control in corn fields, currently the largest use of ametryn, was added. Other crop uses added to the registration include bananas, grapefruit, oranges, pineapple, plantains, and potatoes for broadleaf weed, annual grass, and general weed control and as a desiccant. Ametryn has also been used as a general herbicide in uncultivated areas, rights of way, and industrial areas and aquatic weeds. Over time, the uses of ametryn have been cancelled so that only four use sites remain: field corn, popcorn, pineapple, and sugarcane. EPA estimates up to 380,000 lbs of ametryn active ingredient are used per year. Sixty percent of the annual use of ametryn is used with corn, 20% with pineapple, and 20% with sugarcane. However, in terms of percent crop treated, nearly 100% of the pineapple crop is treated, 30% of sugarcane, and less than 1% of corn is treated.

Ametryn is a member of the broad class of triazine herbicides. However, EPA has determined that there is no known mechanism of toxicity that would support grouping ametryn, a thiomethyl-s-triazine, with the chloro-s-triazines (atrazine, simazine, propazine and their chloro-s-triazine metabolites). In addition to a different functional group attached to the triazine ring, (i.e., thiomethyl versus chloro), ametryn does not exhibit the same toxicity profile as the chloro-s-triazines. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA is assuming that ametryn does not share a common mechanism of toxicity with other compounds.

### Overall Risk Summary

Ametryn occupational and dietary risks from food and drinking water sources are low and not of concern. Since there are no registered residential uses of ametryn, no residential risks were assessed. Aggregate risks, based on combined food and drinking water exposures are low and not of concern. For ecological risks, ametryn poses some chronic risk to birds, mammals, estuarine/marine invertebrates, and acute risk to plants, which will be reduced with various application reductions.

### Dietary Risk

Acute and chronic dietary (food only) risk from ametryn from all sources are low and below the Agency's level of concern. Estimated concentrations of ametryn and its metabolites, in surface and groundwater sources of drinking water, are low resulting in risks below EPA's level of concern.

### Residential Risk

The Agency is not considering residential exposures from ametryn, since there are no existing or proposed residential or other non-occupational sources of exposure, and ametryn is not used in or around public buildings, schools or recreational areas where children or others might be exposed.

### Aggregate Risk

Aggregate risk for ametryn refers to the combined risk from food and drinking water. Aggregate risk estimates are also negligible, therefore, no mitigation measures are needed.

### Occupational Risk

Workers can be exposed to ametryn through mixing, loading, and/or applying (handlers) the pesticide to field corn, popcorn, pineapple, and sugarcane. The lowest margin of exposure (MOE) from handling ametryn wearing baseline clothing is 250. Based on the acute toxicity studies, a 12-hour REI is required for ametryn use, although the ametryn use patterns make early re-entry unlikely.

### Ecological Risk

For terrestrial species, short-term or acute ametryn risks are low to mammals, birds, and non-target insects. However, the screening-level ecological risk assessment for terrestrial species indicates some risk quotient (RQ) exceedance of the chronic levels of concern (LOCs), especially to mammals that rely on grasses and broadleaf plants/insects for their diet and birds that rely on short grasses.

In aquatic species acute and chronic risks are low, with the exception of the chronic risk for estuarine/marine invertebrates. Both the estuarine/marine fish and invertebrates chronic values estimates are based on extrapolation using a acute to chronic ratio from the test data on the freshwater species. The Agency is requiring additional chronic estuarine/marine species toxicity data and vascular plant studies as a part of this RED to address these data gaps.

Consistent with its chemical use as an herbicide, ametryn is toxic to plants, including dicots which are much more sensitive to ametryn than monocots. The RQs for dicot plants all exceed the LOCs for uses of ametryn in all exposure scenarios (adjacent areas, semi-aquatic, and spray drift). The RQs for monocots also exceed in almost all uses in the adjacent areas and semi-aquatic exposure. For aquatic plants, based on limited data, the RQs exceed the level of concern for both vascular and non-vascular plants for uses of ametryn.

Therefore, to be more protective of plants and the mammals, birds, and the aquatic species that may be exposed on a chronic basis, the technical registrant has agreed to additional label changes to reduce potential risk, including reducing maximum application rates and maximum number of applications to all the remaining crops.

## Endangered Species

Based on available screening-level information, there is a potential concern for acute and chronic effects on listed mammals; chronic effects on listed birds; and effects to terrestrial and aquatic listed plants should exposure actually occur. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any specific listed species. If the Agency determines use of ametryn "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

## Mitigation Summary

To address assessed risks of concern, the following mitigation measures will be implemented:

### *Corn:*

- Reduce field corn and popcorn maximum single application rate from 2.0 to 1.6 lbs ai/A
- Eliminate sweet corn use

### *Sugarcane:*

- Reduce sugarcane maximum single application rate from 7.2 to 2.4 lbs ai/A in HI
- Reduce sugarcane maximum seasonal rate from 12.0 to 7.2 lbs ai/A in HI
- Reduce sugarcane maximum application rate from 2.4 to 1.2 lbs ai/A in FL, LA, & TX
- Reduce sugarcane maximum number of applications from  $\leq 5$  to 2 per year in FL, LA, & TX
- Reduce sugarcane maximum season rate from 11.6 to 2.4 lbs ai/A in FL, LA, & TX
- Eliminate aerial application on sugarcane in HI, LA, & TX
- Eliminate (sugarcane) use of ametryn in PR

### *Pineapple:*

- Reduce pineapple maximum single application rate from 2.4 to 1.2 lbs ai/A (HI)
- Reduce pineapple maximum seasonal rate from 7.2 to 3.2 lbs ai/A (HI)
- Reduce pineapple maximum application number from unlimited to 2 per year (HI)

### *Other:*

- Eliminated use on bananas, plantains, and non-cultivated areas
- Restrict application methods to reduce spray drift

## Next Steps

The Agency is issuing this RED document for ametryn as announced in a Notice of Availability published in the *Federal Register*. In the future, EPA will issue the generic DCI for additional data necessary to confirm the conclusions of this RED for the active ingredient ametryn. EPA will also issue a product-specific DCI for data necessary to complete product reregistration for products containing ametryn.

## 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. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency, henceforth referred to as EPA or "the 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 risks arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether 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 amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996 by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA 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 EPA 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. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered, because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA'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 EPA'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/>.

The Agency has found no information indicating ametryn shares a common mechanism of toxicity with other substances. Based on the Agency's review of the available toxicity information, EPA has determined that there is no known mechanism of toxicity that would support grouping ametryn with chloro-s-triazines (atrazine, simazine, propazine and their chloro-s-triazine metabolites). Ametryn has a different functional group attached to the triazine ring, i.e., thiomethyl versus chloro. Further, ametryn does not exhibit the same toxicity profile as the chloro-s-triazines. Although there were several tumors induced by ametryn in a rat bioassay, they were only at an excessive dose which confounds the interpretation of this response. Moreover, the Agency has found no information

indicating ametryn shares a common mechanism of toxicity with other substances, nor does ametryn appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has not assumed that ametryn shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests ametryn shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary. Information specific to the grouping of triazines for cumulative risk assessment including the March 2002 report, “The Grouping of a Series of Triazine Pesticides Based on a Common Mechanism of Toxicity” can be found at: <http://www.epa.gov/oppsrrd1/cumulative/triazines/triazinescommonmech.pdf>.

This document presents EPA’s revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for ametryn. The document consists of six sections. Section I contains the regulatory framework for reregistration/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 environmental effects 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. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The preliminary and revised risk assessments for ametryn are available in the Public Docket, under docket number OPP-2004-0411 and on the Agency’s web page, <http://www.epa.gov/edockets>.

## **II. Chemical Overview**

### **A. Regulatory History**

Ametryn was first registered for use to control broadleaf weeds and annual grasses in sugarcane fields in 1964. In 1969, use for general weed control in corn fields, currently the largest use of ametryn, was added. Other food crop uses added to the registration include bananas, grapefruit, oranges, pineapple, plantains, and potatoes for broadleaf weed, annual grass; general weed control; and as a desiccant. Ametryn has also been used as a general herbicide in uncultivated areas, rights of way, industrial areas, and aquatic weeds.

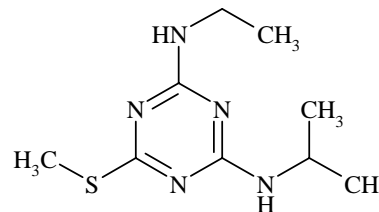
Ametryn has been subject to several data call-ins (DCIs), including: 1983 Toxicology DCI; 1984 Groundwater DCI; 1989 FIFRA 88 Reregistration Process (Phase 1-III) DCI; 1991 Reregistration Phase 4 DCI; and 1992 Hexachlorobenzene/Pentachlorobenzene Special DCI.

In response to the 1983 Toxicology DCI, a number of technical products and their associated end-use products were cancelled. In addition, the use of ametryn on grapefruit, oranges, and as a vine desiccant on potatoes was no longer supported by the remaining technical registrant. Adequate data was provided for all the subsequent DCIs.

In 2003, technical registrant Syngenta Crop Protection decided to no longer support uses on bananas, plantains, and the non-agricultural/general herbicide uses (uncultivated fields, rights of ways, and industrial areas). These uses were voluntarily cancelled in 2004 (see 69 *FR* 39467, June 30, 2004). In addition, neither the technical registrant nor the USDA's IR-4 program are supporting tolerances on cassava, taniars, and yams, nor regional uses for these crops in Puerto Rico.

## B. Chemical Identification

<b>Chemical Name:</b>	(2-ethylamino)-4-(isopropylamino)-6-(methylthio)-s-triazine
<b>Common Name:</b>	Ametryn
<b>Chemical family:</b>	methylthio-s-triazine
<b>Case number:</b>	2010
<b>CAS registry number:</b>	834-12-8
<b>OPP chemical code:</b>	080801
<b>Empirical formula:</b>	C <sub>9</sub> H <sub>17</sub> N <sub>5</sub> S
<b>Molecular weight:</b>	227.35
<b>Trade &amp; other names:</b>	Evik, Ametryne, Ametrex
<b>Basic manufacturer:</b>	Syngenta Crop Protection, Inc. (formerly Ciba-Geigy)



Technical grade ametryn (95% pure) is a white powder with a melting point of 84-85°C, octanol/water partition coefficient ( $K_{ow}$ ) of 676 at pH 7 (log P 2.63), and vapor pressure of  $2.74 \times 10^{-6}$  mm Hg at 25°C. Ametryn is slightly soluble in water (185 mg/100 mL), and soluble in most organic solvents (56.9 g/100 mL in acetone, 61.4 g/100/mL in methylene chloride, 51.6 g/100 mL in methanol, 46.0 g/100 mL in toluene, 24.2 g/100 mL in n-octanol, and 1.4 g/100mL in n-hexane).

## C. Use Profile

The following information is based on current registered uses of ametryn:

**Type of Pesticide:** Herbicide

**Mode of Herbicidal Action:** Like other triazines, ametryn inhibits photosynthesis and other enzymatic processes. It is a selective systemic herbicide, absorbed by the leaves and roots, with translocation acropetally in the xylem, and accumulation in the apical meristems.

**Summary of Use Sites:** Corn (field & pop), Pineapple, and Sugarcane

**Public Health Uses:** None

**Target Pests:** Weeds consisting of: *Ageratum*, alexandergrass, amaranth, annual broadleaf weeds, annual grasses, annual sowthistle, barnyardgrass, *Brachiaria*, broadleaf carpetgrass, broadleaf weeds, browntop panicum, cocklebur, common chickweed, common lambsquarters, common purslane, crabgrass, dallisgrass, fall panicum, fingergrass, fireweed, flora's paintbrush, Florida pusley, foxtail species, goosegrass, grasses, guineagrass, henbit, itchgrass, japanese tea, junglerice, kukaipuaa, lambsquarters, milkweed, morning glory, nutsedge, paleseed plantain, panicum, paspalum, pigweed, proso millet, purpletop, purslane, ragweed, raoulgrass, rattlebox, richardia, sandbur, shattercane, signalgrass, smartweed, sowthistle, spanishneedles, spreading dayflower, sunflower, swinecress, swollen fingergrass, texas millet, texas panicum, velvetleaf, wild mustard, wild pea bean, and wild proso millet.

**Formulation Types Registered:** Ametryn is formulated as a 80% water dispersible granule (WDG), which is also referred to as dry flowable (DF).

**Method of Application:** Ametryn can be applied by groundboom sprayers and by aerial equipment (in FL for sugarcane only). For corn (field and pop), ametryn is used as a directed spray for soil treatment (post-emergence). For sugarcane, ametryn is used as a band treatment (ratoon) or as a broadcast spray (pre-emergence, ratoon, and post-emergence). For pineapple, ametryn is used as a blanket (i.e., broadcast) spray.

**Application Equipment:** Groundboom sprayers (all uses) and aircraft (sugarcane only in FL).

**Application Rates:** At the time of preparation and release of the preliminary risk assessments for Phase 3 public comment, the use pattern information in Table 1, including maximum application rates and number of applications, specified on the labels were used to assess ametryn risks.

**Table 1. Maximum Application Rates Used for Preliminary Risk Assessment**

Crop	Maximum Single Application Rate (lbs ai/A)	Applications per Year	Maximum Seasonal Application Rate (lbs ai/A)
Corn (Field, Sweet, Pop)	2.0	1	2.0
Pineapple (HI)	7.2	NS	7.2
Sugarcane (FL, LA, TX)	1.2-2.4	3-5	3.6-11.6
Sugarcane (HI)	7.2	3	12.0
Sugarcane (PR)	8.0	3	16.0

**Table 1. Maximum Application Rates Used for Preliminary Risk Assessment**

Crop	Maximum Single Application Rate (lbs ai/A)	Applications per Year	Maximum Seasonal Application Rate (lbs ai/A)
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\* NS - Not specified

In June 2005, the technical registrant amended its master product label to eliminate ametryn use on sweet corn and use on sugarcane in Puerto Rico, and reduce the application rates and number of applications to the levels specified in Table 2. This label was stamped and approved in August 2005.

**Table 2. Proposed Revised Maximum Use Patterns**

Crop	Maximum Single Application Rate (lbs ai/A)	Applications per Year	Maximum Seasonal Application Rate (lbs ai/A)
Corn (Field and Pop)	1.6	1	1.6
Pineapple (HI)	1.6	2	3.2
Sugarcane (FL, LA, TX)	1.2	2	2.4
Sugarcane (HI)	2.4	3	7.2

The Agency has revised its risk assessment to reflect the reduction of risk based on the revised application rates and use patterns. The risk assessment summarized and presented in this RED document reflects the reduced application rates and sites specified in Table 2.

**Application Timing:** Post emergence; post harvest; post plant; pre-emergence; ratoon.

**Use Classification:** General use

**D. Estimated Usage of Pesticide**

This section summarizes available pesticide usage information for the current supported uses of ametryn. EPA estimates up to 380,000 lbs of ametryn active ingredient are used per year. In terms of pounds active ingredient (ai) applied annually in the U.S., ametryn usage is allocated to corn (60%), sugarcane (20%), and pineapple (20%). However, in terms of percent crop treated, nearly 100% of the pineapple crop is treated, 30% of sugarcane, and less than 1% of corn is treated. Uses are concentrated in, but not limited to, the following regions: GA, SC, & NC (corn); FL, HI, LA, & TX (sugarcane); and HI (pineapple).

**III. Summary of Ametryn Risk Assessment**



The following is a summary of EPA's human health and ecological effects risk findings and conclusions for the herbicide, ametryn as presented fully in the documents: *Revised Memo to Incorporate Responses to Phase 3 Public Comments. Ametryn: HED Chapter of the Reregistration Eligibility Decision Document (RED)*, dated June 15, 2005 and the *Environmental Fate and Ecological Risk Assessment for the Re-registration of Ametryn*, dated June 9, 2005.

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. While the risk assessments and related addenda are not included in this RED document, they are available from the Office of Pesticide Programs (OPP) Public Docket: OPP-2004-0411 and may also be accessed on the Agency's website at <http://www.epa.gov/edockets>. Paper copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room 119, Crystal Mall II, 1801 South Bell Street, Arlington, VA. The public docket is open Monday through Friday, excluding Federal holidays, from 8:30 AM to 4:00 PM.

As part of the public participation process for the RED, EPA released its preliminary dietary, occupational, and environmental risk assessments for ametryn for public comment on February 25, 2005 (Phase 3 of the public participation process). In response to comments received and new studies submitted during Phase 3, the human health and environmental risk assessments were updated and refined. A complete listing of support documents used in preparation of this RED can be found in Appendix C.

Major revisions to the human health and environmental and ecological risk assessments as a result of the Phase 3 public comments include the following:

- A change in the cancer determination.
- A reduction in crop application rates, which result in lower dietary, occupational, and environmental exposures.
- Eliminating the use on sweet corn.
- Removing aerial application on sugarcane in Hawaii and eliminating use in Puerto Rico.
- A reduction in the soil half-life calculation, resulting in lower environmental and drinking water exposure estimates.

#### **A. Human Health Risk Assessment**

The human health risk assessment incorporates potential exposure risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine exposures to the U.S. population.

##### **1. Toxicity Assessment of Ametryn**

Toxicity assessments are designed to predict if a pesticide could cause adverse health effects in humans (including short-term or acute effects, such as skin or eye damage, and lifetime or chronic effects such as cancer, development and reproduction deficiencies, etc.) and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for ametryn and has determined that the toxicological database is sufficient for reregistration. Further details on the toxicity of ametryn can be found in the technical support documents cited in Appendix C. For the purposes of this RED, ametryn and its degradates are assumed to be of equal toxicity.

### a. Acute Toxicity Profile for Ametryn

The toxicology data base is adequate to characterize the toxicity of ametryn. Ametryn is of low acute toxicity with respect to acute oral and dermal exposure (Toxicity Category III for both) and the acute inhalation exposure (Category IV). Ametryn is also non-irritating to the eye (Category III) and skin (Category IV) and did not demonstrate sensitization. The acute toxicity profile for ametryn is summarized in Table 3.

**Table 3. Acute Toxicity Profile - Ametryn**

Guideline	Study Type	MRID(s)	Results	Tox Cat
870.11	Acute oral - rat	40995814	LD <sub>50</sub> = 1356 (1164-1581) mg/kg ♂ LD <sub>50</sub> = 1009 (829-1229) mg/kg ♀	III
870.12	Acute dermal - rabbit	40995815	LD <sub>50</sub> > 2020 mg/kg	III
870.13	Acute inhalation - rat	42470902	LC <sub>50</sub> > 5.03 mg/L	IV
870.24	Acute eye irritation - rabbit	40995817	No corneal involvement, mild conjunctiva irritation (redness, chemosis and discharge) reversed by 72 hours in washed eyes.	III
870.25	Acute dermal irritation - rabbit	40995818	Essentially non-irritating.	IV
870.26	Skin sensitization - guinea pig	40995819	Not a sensitizer	N/A

LD<sub>50</sub> or LC<sub>50</sub> = Median Lethal Dose or Concentration. A statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).

### b. FQPA Safety Factor Considerations for Ametryn

The Federal Food, Drug, and Cosmetics Act, as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional tenfold (10X) safety factor to take into account the potential for pre- and post-natal toxicity, and the completeness of data with respect to the toxicity and exposure to infants and children. This is referred to as the Special FQPA Safety Factor (SF). The statute authorizes EPA to reduce or remove this default 10X FQPA SF only if, based on reliable data, the resulting margin would be safe for infants and children.

EPA reduced the ametryn Special FQPA SF to 1X based on the following: (1) there are no concerns and no residual uncertainties with regard to pre- and post-natal toxicity based on the rat and rabbit developmental toxicity studies and the rat two-generation reproduction study; (2) there were no indications of immunotoxicity or direct neurotoxicity in the standard studies with rats, dogs, mice or rabbits; (3) the quality of the dietary exposure data (crop field trial data); and (4) the conservatism in the drinking water models are also considered adequately protective to infants and children to support the reduction of the Special FQPA SF to 1X.

### **c. Carcinogenicity**

In the ametryn risk assessments initially made available for public comment, the Agency determined that it would be appropriate to estimate, on a trial basis, the cancer risk to humans associated with the various uses of ametryn by using a *provisional*  $Q_1^*$  based on the mammary tumors seen in a rat carcinogenicity study. That decision was made in part because of some uncertainty around the high doses of ametryn which elicited the formation of tumors. Upon review of comments and additional data, EPA has reconsidered the carcinogenicity issues associated with ametryn.

EPA conducted another review of the available information in the rat chronic/cancer study, considered additional information provided by the registrant, and also considered cancer information on structurally similar analogues. As a result of this EPA review, the rat carcinogenicity study has now been determined to have been assessed at an adequate dose, an additional rat cancer study is not necessary for ametryn, and a  $Q_1^*$  approach for risk assessment is no longer considered appropriate. The Agency reconsidered the data from the 500 ppm dose in the rat study; effects seen at various dose levels in the recently received 90-day subchronic (conducted on ametryn in 1998 and submitted to the Agency in March 2005); and the cancer reviews of two structurally similar methylthio-s-triazines, prometryn and terbutryn.

In reviewing the chronic/cancer study data and the additional 90-day subchronic toxicity study, there are minimal effects (slight decrease in body weight gain) at the 500 ppm dose level. Although there were no statistical differences reported at 500 ppm, the males were from about 2.6% to 6% lower in weight than the controls for each week of the 13 weeks of the study. The females were also similarly lower in weight (from about 3.2% to 6.3%) for each week of the 13 weeks of the study.

The cancer studies on prometryn and terbutryn support the conclusion that methylthio-s-triazines either do not induce tumors in rats (prometryn) or do so only at higher doses where the body weight is more drastically affected (terbutryn). Terbutryn is thus similar to ametryn (2-(ethylamino)-4-isopropylamino-6-methylthio-s-triazine), since both chemicals show liver, thyroid and testicular tumors at doses that have excessive body weight reductions. EPA's Science Advisory Panel in December 23, 1987 did not advise that the  $Q_1^*$  approach for risk assessment was appropriate for terbutryn because "positive tumor data occurred only at a dose that exceeded the MTD." Similarly, since the positive tumor data for ametryn occur only at a dose considered excessive, a  $Q_1^*$  quantitative risk assessment is not appropriate for ametryn.

### **d. Toxicological Endpoints for Ametryn**

The toxicological endpoints used in the human health risk assessment for ametryn are listed in Table 4. Also included in the table are the uncertainty factors (UFs) used in the ametryn risk assessments to account for interspecies extrapolation (10X), intraspecies variability (10X), and the Special FQPA SF (1X). An endpoint attributable to a single dose for females age 13 - 49 and the general population was not identified from available oral studies including the developmental toxicity studies. Therefore, an acute dietary endpoint was not selected.

**Table 4. Summary of Toxicological Doses and Endpoints for Ametryn for Use in Human Risk Assessments**

Exposure Scenario	Dose Used in Risk Assessment and UF/MOE	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49) & (general pop.)	No toxicological effect attributable to a single dose was identified.		
Chronic Dietary (all populations)	NOAEL = 7.2 mg/kg/day  UF = 100 (inter and intraspecies)  Chronic RfD = 0.072 mg/kg/day	FQPA SF = 1X  cPAD = $\frac{\text{Chronic RfD}}{\text{FQPA SF}}$  cPAD = 0.072 mg/kg/day	Dog chronic feeding study  LOAEL = 70 mg/kg/day with indications of degenerative and inflammatory liver effects.
Dermal Short-Term (1 - 30 days) & Intermediate-Term (1 - 6 months)	NOAEL = 100 mg/kg/day  MOE = 100	FQPA SF = 1X  LOC = 100	Rabbit 21-day dermal toxicity study.  LOAEL = 1000 mg/kg/day with body weight gain decrease.
Inhalation Short-Term (1 - 30 days) & Intermediate-Term (1 - 6 months)	NOAEL = 10 mg/kg/day  MOE = 100	FQPA SF = NA  LOC = 100	Oral rabbit developmental toxicity.  LOAEL = 60 mg/kg/day with body weight and decreased feed consumption and increased liver weight.  Assume 100% absorption from inhalation exposure.
Cancer (oral, dermal, inhalation)	Carcinogenic responses occur only at doses exceeding the maximum tolerated dose. (No quantitative carcinogenicity risk assessment is 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; NA = Not Applicable

#### e. Ametryn Metabolites and Degradates

The food and occupational risk estimates summarized in this document are for ametryn *per se*. However, risk estimates for drinking water include ametryn *per se* and the degradates 2-amino-4-

isopropylamino-6-methylthio-s-triazine (GS-11354) and 2-ethylamino-4-amino-6-methylthio-s-triazine (GS-11355). These degradates are formed primarily by soil metabolism and therefore are only likely to be found in drinking water sources from run off to streams or leaching to groundwater . These degradates are significantly similar in structure to the parent ametryn and are found to be present in sufficient abundance in some environmental degradation studies to warrant inclusion as residues of concern in the risk assessment. In addition, estimated contributions from the sulfoxide [NOA423271] and sulfone [NOA428383] forms of ametryn were also considered to account for possible reformation of ametryn from these two degradates through reduction reactions. No degradates of concern were found in the crop metabolism studies. As a result, no degradates are expected in food items from treated crops. A summary of the ametryn metabolites and degradates used in the human health risk assessment and tolerance expression is provided in Table 5.

**Table 5. Summary of Metabolites and Degradates Included in the Risk Assessment and Tolerance Expression**

Matrix		Residues included in Risk Assessment	Residues included in Tolerance Expression
Plants	Primary Crop	ametryn <i>per se</i>	ametryn <i>per se</i>
	Rotational Crop	ametryn <i>per se</i>	ametryn <i>per se</i>
Livestock	Ruminant	Not Applicable - no residues expected	Not Applicable - no tolerances required
	Poultry	Not Applicable - no residues expected	Not Applicable - no tolerances required
Drinking Water		ametryn, GS-11354, GS-11355, NOA423271*, and NOA428383*	Not Applicable

\* Oxidized forms of ametryn: NOA423271 = N-ethyl-N-isopropyl-6-methanesulfinyl-[1,3,5]triazine-2,4-diamine; NOA428383 = 4-ethylamino-6-isopropyl-6-isopropylamino-[1,3,5]triazine-2-sulfinic acid sodium salt (D307097 & D307105, K. Costello, 07-JUN-2005)

#### **f. Endocrine Effects**

EPA 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 such endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA 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. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA 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 of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on ametryn, there was no estrogen, androgen, and/or thyroid mediated toxicity. When additional appropriate screening and/or testing protocols being considered under the Agency’s EDSP have been developed, ametryn may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

## 2. Dietary Exposure and Risk from Food

Dietary (food) exposure assessments were conducted for ametryn using Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.0) and Lifeline™ (ver. 2.0) for the general U.S. population and all population sub-groups. Both of these models use food consumption data from the USDA’s Continuing Surveys of Food Intake by Individuals (CSFII) from 1994-1996 and 1998. Since the toxicity database for ametryn did not indicate any potential acute effects in the available short-term studies, an acute dietary risk assessment was not conducted. Furthermore, for the revised risk assessment, a cancer dietary exposure assessment was not conducted in light of the change in the Agency’s view of the carcinogenicity of ametryn. Therefore, only a chronic dietary (food) risk assessment was conducted for ametryn.

Estimated dietary (food) risks less than 100% of the Population Adjusted Dose (PAD), either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The PAD is the reference dose (RfD) adjusted for the FQPA safety factor (PAD = RfD/FQPA SF). The cPAD is the dose at which an individual could be exposed over the course of a lifetime and not expect an adverse health effect.

### Chronic Dietary Risk from Food

The Lifeline™ and DEEM-FCID™ chronic exposure estimates were less than 0.1% of the cPAD for all population subgroups (including children ages 1 - 2, the highest potentially exposed population). These exposures are well below EPA’s level of concern. Table 6 summarizes the results of the chronic dietary analyses. A refined chronic analysis was conducted for ametryn using average residue levels from applicable field trials, percent crop treated information and DEEM (ver. 7.76) default processing factors. Maximum application rates have been reduced and anticipated residues are not expected to increase as a result of the new, lower use rates. Residue levels at the old higher rates were all < 0.02 ppm, which is less than the level of quantitation (LOQ).

**Table 6. Summary of Chronic Dietary (Food) Exposure and Risk Estimates for Ametryn**

Population Subgroup	Dietary Exposure (mg/kg/day)		% cPAD	
	DEEM-FCID™	Lifeline™	DEEM-FCID™	Lifeline™
General U.S. Population	0.000004	0.000004	< 0.1	< 0.1
Children 1-2 years old	0.000018	0.000018	< 0.1	< 0.1

### 3. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and groundwater contamination. EPA considers chronic (lifetime) drinking water risks and uses modeling to estimate those exposures, or monitoring data, if available. For ametryn, estimated drinking water concentrations (EDWCs) were generated using the screening-level computer models PRZM/EXAMS-Index Reservoir for surface water and SCI-GROW2 for groundwater sources of drinking water. Potential contaminants of concern considered in the drinking water exposure assessment are parent ametryn, the degradates 2-amino-4-isopropylamino-6-methylthio-s-triazine (GS-11354), 2-ethylamino-4-amino-6-methylthio-s-triazine (GS-11355), NOA-423271, and NOA-428383.

Given its persistence and mobility, transport of ametryn to surface and groundwater is expected from normal agricultural use. However, based on the new reduced maximum use patterns (rates and number of applications) supported by the registrant and a revised half-life, modeled EDWCs have been reduced from those presented in the preliminary risk assessments initially made available for public comment. The EDWCs for ametryn in groundwater and surface water based on the reduced application rates are summarized in Table 7.

**Table 7. Ametryn EDWCs for Surface Water and Groundwater**

Exposure Duration	Ametryn	
	Surface Water Conc., ppb <sup>a</sup>	Groundwater Conc., ppb <sup>b</sup>
Chronic	14	1.4

<sup>a</sup> From the Tier II PRZM-EXAMS - Index Reservoir model. Input parameters are based on the physical properties of ametryn, and assuming 2 separate applications of ametryn to sugarcane in LA, for a total rate of 2.4 lb ai/A/year.

<sup>b</sup> From the SCI-GROW model assuming a maximum seasonal use rate of 3.2 lb ai/A [pineapple in HI], a  $K_{oc}$  of 96, and a half-life of 40.1 days.

Monitoring of ametryn concentrations in groundwater and surface water is limited. Ametryn was not included among analytes in the US Geological Survey's National Water-Quality Assessment (NAWQA) program, for instance. Monitoring in Hawaii of groundwater in pineapple use areas in the mid-1990s resulted in a maximum concentration similar in magnitude to that predicted with the groundwater screening model SCI-GROW. In addition, quarterly surface water monitoring on the borders of the Everglades Agricultural Area (EAA) has resulted in surface water concentrations well below those estimated from maximum application rates by the PRZM/EXAMS models.

### 4. Residential Exposure and Risk

Ametryn uses are being supported only for the following agricultural crops: field corn, popcorn, sugarcane, and pineapple. There are no residential uses and there are no anticipated exposures in or around homes or recreational areas. Therefore, a residential risk assessment was not conducted.

### 5. Aggregate Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require “that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information.” Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

In accordance with the FQPA, the Agency must consider and aggregate (combine) pesticide exposures and risks from three major sources or pathways: food, drinking water and, if applicable, residential or other non-occupational exposures. For aggregate risk, EPA combines exposures from food and residential sources and calculates a drinking water level of comparison (DWLOC), which represents the maximum allowable exposure through drinking water after considering food and residential exposures. If the EDWCs are less than the DWLOCs, EPA does not have concern for aggregate exposure. If EDWCs are greater than DWLOCs, EPA will conduct further analysis to characterize the potential for aggregate risk of concern.

In the case of ametryn, the aggregate risk estimates only consider combined food and drinking water exposures because there are no registered residential uses. An acute aggregate risk assessment was not conducted because an endpoint of concern attributable to a single dose was not identified.

#### Chronic Aggregate Risk

A long-term (chronic) aggregate risk assessment was conducted for ametryn. The chronic assessment considered exposures from food and drinking water only. As indicated in Table 8, the EDWCs for chronic exposures for the U.S. general population or for the most highly exposed group (Children ages 1 - 2 years old) are less than the corresponding DWLOCs; therefore, estimated aggregate risks for these exposure durations are below EPA’s level of concern.

**Table 8. Ametryn Chronic Aggregate Risk Assessment**

<b>Population Subgroup</b>	<b>Groundwater EDWC* (ppb)</b>	<b>Surface Water EDWC* (ppb)</b>	<b>Chronic DWLOC (ppb)</b>
U.S. Population	1.4	14	2520
Children 1-2 years			720

\*The EDWC levels are based on the reduced rates: 1.6 lbs ai/acre, 2X per crop cycle for pineapple use in HI (groundwater ) and 1.2 lbs ai/acre, 2X per year for sugarcane use in LA (surface water).

## **6. Occupational Exposure and Risk**

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and re-entering a treated site. For dermal and inhalation exposures, worker risk is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to the No Observed



Adverse Effect Level (NOAEL) selected from animal toxicity studies. For ametryn, MOEs that are greater than 100 do not exceed the Agency’s level of concern.

Ametryn exposures occurs in a variety of patterns. Occupational exposures to ametryn can occur for a single day, or up to weeks at a time for commercial applicators that are completing a number of applications for several different clients. This is an upper bound assessment, which presents handler risk estimates for both short-term (1 to 30 days) and intermediate-term (1 month to 6 months) exposure durations. No long-term exposure (>6 months) is expected from applications of ametryn.

**a. Occupational Handler Risk**

EPA determines potential exposures to pesticide handlers by identifying exposure scenarios from various types of application equipment that are recommended on ametryn labeling. Based on the product labeling, agricultural use patterns specific to ametryn are associated with the following types of application equipment: groundboom sprayers for sugarcane, pineapple, and corn and aerial (sugarcane in FL only). As a result, EPA has identified 9 occupational handler scenarios for which short-term (1 - 30 days) and intermediate-term (1 - 6 months) exposures to ametryn may occur. Exposure estimates were conducted using the reduced maximum application rates for each of the crops.

In the absence of chemical-specific handler data, EPA used unit exposure values from the Pesticide Handlers Exposure Database (PHED) to estimate exposures for a variety of occupational scenarios and combinations of personal protective equipment (PPE) and engineering controls. For most handler scenarios, EPA used standard assumptions for the number of acres treated, body weight, and hours worked. EPA derived information about use patterns, application methods, and the range of application rates used in the exposure assessment from the current ametryn labels. The dermal and inhalation toxicological endpoints used in assessing the risks from occupational exposures to ametryn and the target MOEs are listed in Table 4. The application rates specified on the ametryn labels range from 1.6 to 2.4 lbs a.i./A in agricultural settings. The Agency typically uses acres treated per day values that are thought to represent eight hours of application work for specific types of application equipment. Table 9 summarizes the exposure scenarios, use patterns assessed and associated risk estimates (MOEs) for occupational handlers wearing baseline attire when handling ametryn products. All scenarios for occupational handlers wearing baseline attire (long-sleeved shirts, long pants, shoes and socks, no gloves, and no respirator) have combined dermal and inhalation MOEs greater than 100 and, therefore, are not of concern. The PPE on the current product label includes: long-sleeve shirt and long pants; chemical resistant gloves made of any waterproof material; and shoes plus socks.

**Table 9. Summary of Occupational Handler Exposure Estimates - Baseline PPE\***

Exposure Scenario (Scenario #)	Crop	App. Rate (lb ai/A)	Daily Area Treated (acres)	Dermal MOE	Inhalation MOE	Total MOE
Mixer/Loader						

**Table 9. Summary of Occupational Handler Exposure Estimates - Baseline PPE\***

Exposure Scenario (Scenario #)	Crop	App. Rate (lb ai/A)	Daily Area Treated (acres)	Dermal MOE	Inhalation MOE	Total MOE
Mixing/Loading Dry Flowables for Groundboom application (1)	Corn	1.6	200	330	2800	300
Mixing/Loading Dry Flowables for Groundboom application (2)	Pineapple	1.6	40	1700	14000	1500
Mixing/Loading Dry Flowables for Groundboom application (3)	Sugarcane	2.4	80	550	4700	490
Mixing/Loading Dry Flowables for Aerial application (4)	Sugarcane	1.2	350	250	2200	230
Applicator						
Sprays for Groundboom application (5)	Corn	1.6	200	1600	3000	1000
Sprays for Groundboom application (6)	Pineapple	1.6	80	3900	7400	2600
Sprays for Groundboom application (7)	Sugarcane	2.4	80	2600	4900	1700
Sprays for Aerial application (8)	Sugarcane	1.2	350	No Data	No Data	No Data
Flagger						
Flagging for Sprays application (9)	Sugarcane	1.2	350	1500	4800	1100

\* Baseline PPE = All handlers are wearing long-sleeved shirts, long pants, socks & shoes, no gloves, and no respirator.

**b. Occupational Post-Application Risk**

Ametryn product labeling specifies application as either a directed spray at weeds or as a pre-emergent broadcast spray, and includes instructions to avoid application to the crop foliage. Additionally, for corn and pineapples, the label specifies the last ametryn application be made 30 and 160 days prior to harvesting, respectively. For sugarcane, the label specifies “Avoid wetting sugarcane

foliage, or injury may occur” and also recommends against application after “close-in” - when the sugarcane grows over the planting beds, generally months prior to harvesting. For these reasons, EPA does not anticipate any foliar residues on the ametryn treated crops. Therefore, the Agency does not expect there to be any post-application foliar exposures to occur and post-application occupational exposures were not assessed.

## **7. Incident Reports**

Relatively few incidents of illness (four) have been reported due to ametryn. Four exposures to ametryn products were reported to Poison Control Centers from 1993 through 2001. Two of the four cases, all adults, involved minor symptoms. One of the cases was seen in a health care facility and was not hospitalized and another case reported diarrhea and drowsiness/lethargy. There were no other reports of incidences in the other poisoning databases.

### **B. Environmental Risk Assessment**

A summary of the Agency’s environmental risk assessment for ametryn is presented below. More detailed information associated with the environmental risk from the use of ametryn can be found in the *Final EFED Chapter for Ametryn*, dated June 9, 2005. The complete environmental risk assessment is not included in this RED document, but may be accessed in the OPP Public Docket OPP-2004-0411 and on the Agency’s website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

Aquatic and terrestrial organisms may be exposed to ametryn residues from areas on or adjacent to treated fields. The Tier II screening-level model PRZM/EXAMS was used to estimate surface water concentrations of ametryn to assess risks to aquatic organisms. Terrestrial organisms may be exposed to ametryn from consuming plants, seeds, and insects with ametryn residues. Only the toxicity of the ametryn parent is assessed, as no toxicity data is available to assess the degradates separately. However, additional risk from potential degradates is covered by the conservative assumptions built into the model for assessing risk to terrestrial organisms and is not expected to significantly change the RQs for aquatic organisms.

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic exposure estimates by ecotoxicity values for various animal and plant species. RQs are then compared to levels of concern (LOCs); the higher the RQ, the greater the potential risk. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed. A summary of the Agency’s environmental risk assessment for ametryn is presented below.

### **1. Environmental Fate and Transport**

The environmental fate database is sufficient to characterize the environmental exposure associated with ametryn use. However, an anaerobic aquatic metabolism study and a foliar dissipation study will be required to verify assumptions about risk. These studies will be part of a Data Call-In (DCI) EPA intends to issue as a result of this RED for the parent ametryn and its degradates, to address areas of uncertainty. These data are expected to confirm the conclusions of this environmental risk assessment.

The environmental fate of ametryn varies based on the site-specific properties of the soil to which it is applied. Based on packed soil column leaching studies, ametryn *per se* and its degradates exhibit moderate to high mobility in most sandy to loamy soils, except for clay where its mobility is low. The major route of degradation of ametryn *per se* is aerobic soil metabolism, with an observed half-life range of 9.6 days to 38 days. Ametryn *per se* is stable to hydrolysis, with an observed half-life of 368 days. Ametryn has a low vapor pressure at room temperature, and is unlikely to significantly volatilize from soil surfaces. Ametryn degradates of concern include NOA-423271, NOA428383, GS-11354, and GS-11355. The total amount of ametryn degradate residues can vary depending on environmental conditions. In the case of NOA-423271 and NOA-428383, environmental conditions conducive to redox reactions can allow the oxidized forms of degradates to reduce back to the ametryn parent. Similar to the parent, ametryn's degradation products are persistent and relatively mobile in many soils. Given its persistence and mobility, transport of ametryn *per se* and its degradates to surface water and groundwater is expected from labeled agricultural uses. Additional information on the environmental fate of ametryn can be found in the supporting documents referenced in Appendix C.

## 2. Environmental Effects (Ecotoxicity)

### a. Toxicity to Terrestrial Organism

Ametryn is slightly toxic to mammals on an acute oral exposure basis ( $LD_{50} = 1162$  mg/kg body weight); following chronic exposure, reduced growth (NOEC = 13 mg/kg) was observed. Ametryn is practically nontoxic to bees based on an acute contact study. No mortality was observed in subacute dietary toxicity studies with mallard ducks and bobwhite quail ( $LC_{50} > 5620$  ppm). Both surrogate species responded similarly (NOEC = 300 mg/kg diet) with reduced growth and reproduction following chronic exposure (Table 10).

**Table 10. Summary of Acute and Chronic Toxicity Data for Terrestrial Organisms Exposed to Ametryn.**

Species	Acute Toxicity				Chronic Toxicity	
	LD <sub>50</sub> (mg/kg bw)	Acute Oral Toxicity	5-day LC <sub>50</sub> (ppm)	Subacute Dietary Toxicity	NOEC/LOEC	Affected Endpoints
Birds	>2250	practically non-toxic	>5620	practically non-toxic	300 / 900 ppm	growth and reproduction
Honey bees	>0.1 (mg/bee contact)	practically non-toxic	--	--	--	--

**Table 10. Summary of Acute and Chronic Toxicity Data for Terrestrial Organisms Exposed to Ametryn.**

Species	Acute Toxicity				Chronic Toxicity	
	LD <sub>50</sub> (mg/kg bw)	Acute Oral Toxicity	5-day LC <sub>50</sub> (ppm)	Subacute Dietary Toxicity	NOEC/LOEC	Affected Endpoints
Rat	1162	slightly toxic	–	–	13 / 130 mg/kg/d	pup weights and reduced weight gain

LD<sub>50</sub> or LC<sub>50</sub> = Median Lethal Dose or Concentration. NOEC/LOEC = No/lowest observed effect concentration

Consistent with its chemical use as an herbicide, ametryn is toxic to terrestrial plants; dicots are more sensitive to ametryn than monocots, with lettuce (EC<sub>25</sub> = 0.006 lb ai/acre) and cucumbers (EC<sub>25</sub> = 0.002 lb ai/acre) being the most sensitive indicators in the vegetative vigor and seedling emergence tests, respectively. Table 11 summarizes the most sensitive toxicity endpoints calculated or observed in terrestrial plant toxicity studies.

**Table 11. Summary of Nontarget Terrestrial Phytotoxicity Using Both Monocotyledon and Dicotyledon Plant Species Exposed to Ametryn.<sup>a</sup>**

Study Type	Species	EC <sub>25</sub> (lb ai/A)	EC <sub>50</sub> (lb ai/A)	NOEC (lb ai/A)
Vegetative Vigor	Monocot - onion	0.105 dw	0.209 ph	0.05 dw
	Dicot - lettuce	<b>0.006</b> dw	<b>0.015</b> dw	<b>&lt;0.006</b> dw
Seedling Emergence	Monocot - oat	0.083 dw	0.335 dw	0.05 dw
	Dicot - cucumber	<b>0.002</b> pe	<b>0.016</b> pe	<b>&lt;0.002</b> pe
	Dicot - lettuce	0.027 dw	0.093 dw	0.013 ph, dw
Seed Germination	Monocot - onion	25.9 pg	644 pg	<b>2.0</b> pg
	Dicot - cabbage	ND pg	ND pg	≥8.0 all

EC<sub>50</sub>/EC<sub>25</sub> = Effect concentration to 50%/25% of the test population.

<sup>a</sup> For each toxicity endpoint, the parameter in which these concentrations were observed are listed. dw = dry weight; ph = plant height; pr = phytotoxicity rating; pe = percentage of seedlings emerged; rl = radicle length measurements; pg = percentage of seed germinated; all = all parameters measured; ND = not determined.

## b. Toxicity to Aquatic Organisms

Ametryn is slightly to moderately toxic to freshwater fish and invertebrates, and moderately toxic to estuarine/marine fish and invertebrates on an acute exposure basis. Following chronic exposure, freshwater fish exhibited reduced growth (NOEC = 0.7 mg/L) while freshwater invertebrates exhibited reduced reproduction (*Daphnia* NOEC = 0.24 mg/L). Table 12 summarizes the most sensitive endpoints used in the hazard assessment of aquatic animals.

No chronic toxicity data were required or made available for estuarine/marine fish. A chronic toxicity value for sheepshead minnow is estimated from the results of the acute toxicity study, assuming that the acute/chronic toxicity ratio (ACR) is the same as that seen in the freshwater fathead minnow study ( $16 \text{ mg L}^{-1}/0.7 \text{ mg L}^{-1} = 22.9$ ). Based on this ACR, the estimated chronic toxicity to sheepshead minnow is 0.25 mg/L. Similarly, the ACR from the freshwater invertebrate study is used to estimate a chronic toxicity for estuarine/marine invertebrates. Using the ACR from the *Daphnia* studies ( $28 \text{ mg L}^{-1}/0.24 \text{ mg L}^{-1} = 116.7$ ), a chronic toxicity value of 0.02 mg/L is estimated for mysid shrimp.

**Table 12. Summary of Acute and Chronic Aquatic Toxicity Estimates Using Ametryn.**

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC <sub>50</sub> (mg/L)	48-hr EC <sub>50</sub> (mg/L)	Acute Toxicity	NOEC/LOEC (mg/L)	Affected Endpoints
Rainbow trout	3.6	--	moderately toxic	--	--
Fathead minnow	16	--	slightly toxic	0.7 / 1.4	Growth
Water flea	--	28	slightly toxic	0.24 / 0.32	Reduced reproduction
Sheepshead minnow	5.8	--	moderately toxic	0.25*	--
Mysid shrimp	2.3	--	moderately toxic	0.02**	--

\* based on fathead minnow ACR of 22.9

\*\* based on daphnid ACR of 116.7

Only one submitted study was available to evaluate the toxicity of ametryn to nonvascular aquatic plants, which is summarized in Table 13. Also, toxicity information from a study available from the ECOTOX (Ecotoxicology Database System) on-line database of ametryn and other herbicides on their effects on duckweed *Lemna perspusilla* were used to assess non-endangered vascular plants ( $EC_{50} = 10 \mu\text{g/L}$ ).

**Table 13. Summary of the Toxicity of Ametryn to Aquatic Plants**

Species	EC <sub>50</sub> (μg/L)	Acute toxicity
Green algae <i>Pseudokirchneriella subcapitata</i>	3.67 (NOEC = 1.14)	very highly toxic

### 3. Exposure and Risk Assessment

The pesticide use profile, exposure data, and toxicity information are used to determine risk estimates to non-target aquatic and terrestrial organisms. The estimated environmental concentration (EEC) is calculated based on the maximum single application rate(s) of ametryn, which would yield the maximum exposure estimate. To calculate acute risk exposure, the EEC is then divided by the LC<sub>50</sub> or LD<sub>50</sub>, which is a statistically-derived lethal concentration or dose of chemical that can be expected to cause death in at least 50% of test animals. To calculate chronic risk exposure, the EEC is divided by the No Observed Adverse Effect Level or No Observed Effects Concentration, NOAEL or NOEC, respectively. The EECs calculated for the ecological risk assessment are based solely on data for ametryn *per se*, as no ecotoxicity data is available for the degradates. However, the addition of degradates is not expected to significantly increase the RQs for ametryn. The EECs are used to calculate RQs. An RQ is the estimated ratio of exposure concentration (EEC) to the toxicity endpoint (LC<sub>50</sub>/LD<sub>50</sub> or NOAEL/NOEC). The RQ is then compared to the LOC to determine if exposure to ametryn would pose a risk to non-target organisms. Table 14 outlines the Agency's LOCs and the corresponding risk presumptions.

**Table 14. Agency's LOCs and Risk Presumptions**

If RQ > LOC value given below.....			Then EPA presumes .....
Terrestrial Organisms	Aquatic Organisms	Plants	Risk Presumption
0.5	0.5	1	<b>Acute Risk</b> - there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.
0.2	0.1	N/A	<b>Acute Restricted Use</b> - there is potential for acute risk, but may be mitigated through restricted use classification.
0.1	0.05	1	<b>Acute Endangered Species</b> - endangered species may be adversely affected; regulatory action may be warranted.
1	1	N/A	<b>Chronic Risk</b> - there is potential for chronic risk; regulatory action may be warranted.

#### a. Fish and Aquatic Invertebrates Exposure and Risk

For exposure to fish and aquatic invertebrates, EPA considers potential concentrations of ametryn in surface water. The Tier II PRZM/EXAMS models were used to estimate surface water concentrations of ametryn in freshwater and estuarine/marine environment. Exposure to aquatic invertebrates in sediment is not assessed, since a benthic invertebrate toxicity study was not required nor voluntarily submitted to the Agency for ametryn. This model was also used to derive EECs to measure potential exposures to aquatic organisms in surface water. The peak EECs for ametryn are calculated based on the reduced application rates of a single application at 1.6 lb a.i./A for corn, and two applications of 1.2 lb a.i./A sugarcane (total applied 2.4 lbs a.i./A), which are the highest labeled application rates that would yield the maximum EECs. All modeled EECs for fish and aquatic

invertebrates are less than those presented in the preliminary risk assessments because those in the preliminary assessments were based on maximum use patterns which are no longer supported by the technical registrant. The available acute and chronic toxicity data on ametryn and the EECs for ametryn residues in surface water indicate that RQs for both freshwater organisms are below the Agency's LOCs. The highest freshwater acute RQ for fish or invertebrates is 0.02. This is well below the Agency's 0.5 threshold for a level of concern. The highest chronic RQ for freshwater fish or invertebrates is 0.31, which is also well below the Agency's 1.0 chronic level of concern.

For all application scenarios, acute toxicity to estuarine/marine organisms is below the Agency's LOC. The highest acute RQs are 0.014 for fish and 0.034 for invertebrates. There were no estuarine/marine fish or invertebrates chronic toxicity studies required and none were voluntarily submitted to assess the chronic toxicity of ametryn. Estuarine/marine fish and invertebrates chronic toxicity studies will be required in the Data Call-In (DCI) resulting from this RED. The chronic assessment was based on the assumption that the acute-to-chronic NOEC ratio for estuarine/marine organisms is the same as that for freshwater organisms. There is potential chronic risk to estuarine/marine invertebrates for all corn and sugarcane scenarios modeled, with RQs ranging from 1.2 to 3.8. Some uncertainty exists in the chronic assessment for estuarine/marine organisms, because quantifiable taxonomic sensitivity factors between the two organism categories do not exist. The available acute and chronic RQs for estuarine/marine organisms are outlined in Table 15 below.

**Table 15. Chronic RQs for Estuarine/Marine Organisms Exposed to Ametryn in Surface Water**

- Crop, State - Application Rate	EECs ( $\mu\text{g/L}$ ) - 21-day Average - 60-day Average	Chronic RQs	
		Fish NOEC = 250 $\mu\text{g/L}$	Invertebrate NOEC = 20 $\mu\text{g/L}$
Corn, NC (east) 1.6 lbs a.i./A	24	—	<b>1.2</b>
	23	0.092	—
Corn, NC (west) 1.6 lbs a.i./A	26	—	<b>1.3</b>
	24	0.096	—
Sugarcane, FL 1.2 lbs a.i./A (2 applications)	75	—	<b>3.8</b>
	67	0.268	—
Sugarcane, LA 1.2 lbs a.i./A (2 applications)	50	—	<b>2.5</b>
	48	0.192	—

Bolded text indicates exceedance of LOC (chronic = 1.0) for estuarine/marine organisms.

## b. Terrestrial Organism Exposure and Risk



The Agency assessed potential risk to non-target terrestrial organisms based on residues on different types of food items that may be sources of exposure. The Agency expects exposure to residues of ametryn on food and forage items, because treated fields provide a habitat rich in food sources attractive to various avian and mammalian species. All modeled EECs for terrestrial organisms are less than those presented in the preliminary risk assessments because those in the preliminary risk assessments were based on maximum use patterns which are no longer supported by the technical registrant. Additional information on the terrestrial organism exposures can be found in the supporting documents referenced in Appendix C.

### Avian Exposure and Risk

Based on no observed mortality from the highest test dosage on birds, acute risks for birds were assessed, but RQs were not calculated, as there were not acute risks of concern for birds. The chronic RQs are based on the highest labeled application rates that would yield the maximum EECs. Chronic LOCs were exceeded for some feed items in the modeled crops, with the greatest exceedance resulting from use on sugarcane in Hawaii. Mean EECs were also used to calculate chronic RQs. Table 16 details the maximum chronic avian exposures for each use site for both the maximum and mean EECs, based on the short grass food item only (other food items result in lower chronic risk).

**Table 16. Chronic RQs for Avian Species Exposed to Ametryn\***

Site	Application Rate (state) lbs a.i./A	Food Item	EEC (ppb)	Chronic RQs
<b>MAXIMUM EECs</b>				
Corn	1.6	Short grass	384	<b>1.28</b>
Pineapple	1.6 (2 apps., 30 day interval)	Short grass	596	<b>1.99</b>
Sugarcane	1.2 (FL, LA, TX) (2 apps., 30 day interval)	Short grass	447	<b>1.49</b>
	2.4 (HI) (3 apps., 30 day interval)	Short grass	1070	<b>3.57</b>
<b>MEAN EECs</b>				
Corn	1.6	Short grass	136	0.45
Pineapple	1.6 (2 apps., 30 day interval)	Short grass	211	0.7
Sugarcane	1.2 (FL, LA, TX) (2 apps., 30 day interval)	Short grass	158	0.53
	2.4 (HI) (3 apps., 30 day interval)	Short grass	379	<b>1.26</b>

**Table 16. Chronic RQs for Avian Species Exposed to Ametryn\***

Site	Application Rate (state) lbs a.i./A	Food Item	EEC (ppb)	Chronic RQs
------	--	-----------	-----------	-------------

Bolded text indicates exceedance of chronic LOC (1.0) for avian species.

\* Based on a bobwhite quail NOEC of 300 ppm.

Mammalian Exposure and Risk

Ametryn is practically nontoxic to mammals on an oral acute basis, so RQs do not exceed the LOC for acute exposures. The highest acute RQ is 0.4 from short grass exposure to small mammals in Hawaii. However, consumption of food and forage items treated with ametryn may pose chronic risks to mammalian species. The chronic risk assessment is based on maximum EECs and a 2-generation rat reproduction study with a NOAEL of 13 mg/kg/day, based on reduction in growth in the F<sub>2</sub> generation. Resulting RQs exceed chronic LOCs for some feed items from all modeled uses of ametryn. See Table 17 for a summary of the maximum chronic mammalian exposure for each use site, based on the short grass food item only (other food items result in lower chronic risk). Mean EECs were not used to calculate chronic mammalian risks, but would result in RQ reductions similar to those shown for avian chronic risks.

**Table 17. Chronic RQs for Mammalian Species Exposed to Ametryn\***

Site	Application Rate (state) lbs a.i./A	Body Weight (grams)	Food Item	Chronic RQs
Corn	1.6	15	Short grass	<b>13</b>
		35		<b>11</b>
		1000		<b>6</b>
Pineapple	1.6 (2 apps., 30 day interval)	15	Short grass	<b>20</b>
		35		<b>17</b>
		1000		<b>9</b>
Sugarcane	1.2 (FL, LA, TX) (2 apps., 30 day interval)	15	Short grass	<b>5</b>
		35		<b>5</b>
		1000		<b>2</b>
	1.6 (HI) (3 apps., 30 day interval)	15	Short grass	<b>36</b>
		35		<b>31</b>
		1000		<b>16</b>

Bolded text indicates exceedance of chronic LOC (1.0) for mammalian species.

\* Based on a 2-generation rat reproduction study with a NOAEL = 13 mg/kg/day and maximum EECs.

### c. Non-Target Plant Exposure and Risk

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from runoff, spray drift, or volatilization. Like terrestrial plants, non-target aquatic plants may be exposed to pesticides from the same routes. EECs were calculated using the highest estimated surface water concentrations based on the reduced maximum use patterns for ametryn. As with the other organisms assessed in the environmental risk assessment, estimated RQs are lower than those presented in the preliminary risk assessments because of the reduced maximum use patterns.

#### Terrestrial Plant Exposure and Risk

Acute RQs for terrestrial plant exposure were calculated using the TerrPlant model. Currently, the Agency is not assessing chronic effects on plants. Consistent with its use as an herbicide, ametryn may pose a risk of concern to terrestrial plants. Spray drift exposure risk estimates using AgDrift modeling indicates potential risk to plants. Table 18 details acute risks to terrestrial plants. Note that the predicted risk to semi-aquatic plants appears approximately 10 times higher than the risk to plants in adjacent area or exposed to spray drift. However, the model input for the surface watershed for the semi-aquatic areas is 10 hectares as compared to an input of one hectare for the watershed for adjacent areas. Unlike runoff from an adjacent area, semi-aquatic areas (i.e., wetlands) tend to be low lying areas and would typically collect field runoff from a larger area.

**Table 18. Acute RQs for Terrestrial Plants Exposed to Ametryn**

Crop	Application Rate (lbs a.i./A)	Application Method	Acute RQs					
			Adjacent Area		Semi-Aquatic Area		Spray Drift	
			Monocot <sup>1</sup>	Dicot <sup>2</sup>	Monocot <sup>1</sup>	Dicot <sup>2</sup>	Monocot <sup>3</sup>	Dicot <sup>3</sup>
Corn	1.6	Ground spray	<b>1.16</b>	<b>48</b>	<b>9.83</b>	<b>408</b>	0.15	<b>2.67</b>
Pineapple	1.6	Ground spray	<b>1.16</b>	<b>48</b>	<b>9.83</b>	<b>408</b>	0.15	<b>2.67</b>
Sugarcane	1.2 (FL, LA, TX) (2 apps., 30 day interval)	Ground spray	<b>0.87</b>	<b>36</b>	<b>7.37</b>	<b>306</b>	0.11	<b>2</b>
		Aerial Spray	<b>1.16</b>	<b>48</b>	<b>5.06</b>	<b>210</b>	0.57	<b>10</b>
	2.4 (HI) (3 apps., 30 day interval)	Ground Spray	<b>1.73</b>	<b>72</b>	<b>14.75</b>	<b>612</b>	0.23	<b>4</b>

<sup>1</sup> Seedling Emergence EC<sub>25</sub>: Monocot = 0.083 lb ai/A (oat) <sup>2</sup> Seedling Emergence EC<sub>25</sub>: Dicot = 0.002 lb ai/A (cucumber)

<sup>3</sup> Vegetative Vigor EC<sub>25</sub>: Monocot = 0.105 lb ai/A (onion); Dicot = 0.006 lb ai/A (lettuce)

Bolded text indicates exceedance of acute LOC (1.0) for terrestrial plants.

Acute endangered terrestrial nontarget plant RQs in adjacent and semi-aquatic areas (see Table 19) exceed the LOC for all crops modeled. Endangered species dicot spray drift RQs exceeded the LOC in all uses. As indicated in Table 11, the actual NOEC for the most sensitive dicot (cucumber) in both vegetative vigor and seedling emergence studies is lower than the lowest treatment level tested.

As a result, actual RQs for dicot endangered species are greater than the values reported in Table 19. Endangered species monocot spray drift RQs are less than the LOC for all application scenarios, except for aerial sugarcane applications of ametryn.

Crop	Application Rate (lbs a.i./A)	Application Method	Acute RQs					
			Adjacent Area <sup>1</sup>		Semi-Aquatic Area <sup>1</sup>		Spray Drift <sup>2</sup>	
			Monocot	Dicot	Monocot	Dicot	Monocot	Dicot
Corn	1.6	Ground spray	1.92	>48	16.32	>408	0.32	>2.67
Pineapple	1.6	Ground spray	1.92	>48	16.32	>408	0.32	>2.67
Sugarcane	1.2 (FL, LA, TX) (2 apps., 30 day interval)	Ground spray	1.44	>36	12.20	>306	0.24	>2.0
		Aerial Spray	1.92	>48	8.40	>210	1.2	>10
	2.4 (HI) (3 apps., 30 day interval)	Ground Spray	2.88	>72	24.48	>612	0.48	>4.0

<sup>1</sup> RQ = EEC/Seedling Emergence NOEC

<sup>2</sup> RQ = Drift EEC/Vegetative Vigor NOEC

### Aquatic Plant Exposure and Risk

Acute RQs for aquatic plant exposure were calculated using the Tier II PRZM/EXAMS model. Currently, the Agency is not assessing chronic effects on plants. Consistent with its use as an herbicide, ametryn may pose a risk to both vascular and non-vascular aquatic plants from all modeled crop scenarios. Acute risk to endangered vascular plants is not assessed, as no data is available. Plant testing will be required in the Data Call-In as part of this RED. Based on the higher application rate, it is possible that RQs for aquatic endangered vascular plants in Hawaii would be higher. Table 20 summarizes acute risks to aquatic plants.

**Table 20. Acute RQs for Non-Endangered and Endangered Aquatic Plants**

Crop State	Application Rate (lbs a.i./A)	EECs Peak ( $\mu\text{g/L}$ )	Acute RQs Non-Endangered		Acute RQs Endangered	
			Vascular EC <sub>50</sub> = 10 $\mu\text{g/L}$	Non-vascular EC <sub>50</sub> = 3.67 $\mu\text{g/L}$	Vascular	Non-vascular NOEC = 1.14 $\mu\text{g/L}$
Corn NC (east)	1.6	25	3	7	—	22
Corn NC (west)	1.6	27	3	7	—	24

**Table 20. Acute RQs for Non-Endangered and Endangered Aquatic Plants**

Crop State	Application Rate (lbs a.i./A)	EECs Peak ( $\mu\text{g/L}$ )	Acute RQs Non-Endangered		Acute RQs Endangered	
			Vascular $\text{EC}_{50} = 10 \mu\text{g/L}$	Non-vascular $\text{EC}_{50} = 3.67 \mu\text{g/L}$	Vascular	Non-vascular $\text{NOEC} = 1.14 \mu\text{g/L}$
Sugarcane FL	1.2 (2 applications)	81	<b>8</b>	<b>22</b>	—	<b>71</b>
Sugarcane LA	1.2 (2 applications)	52	<b>5</b>	<b>14</b>	—	<b>46</b>

Bolded text indicates exceedance of acute LOC (1.0) for aquatic plants.

#### 4. Ecological Incidents

EPA’s Ecological Incident Information System contains no reports of wildlife poisoning incidents attributed to ametryn.

#### IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

##### A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products 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 to support reregistration of products containing ametryn as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing ametryn.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient ametryn. Based on a review of these data and on public comments on the Agency’s assessments for the active ingredient ametryn, the Agency has sufficient information on the human health and ecological effects of ametryn to make decisions as part of the tolerance reassessment process under FFDCFA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that ametryn containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of ametryn that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of ametryn, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of ametryn, the Agency has determined that ametryn 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 ametryn. If all changes outlined in this document are incorporated into the product labels, then all current risks for ametryn will be adequately mitigated for the purposes of this determination.

## **B. Public Comments and Responses**

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for ametryn. During the public comment period on the risk assessments, which closed on April 26, 2005, the Agency received 6 submissions of public comments, one from Syngenta Crop Protection, Inc., three from commodity and research groups, one from a private citizen, and one from the University of Hawaii. These comments in their entirety are available in the public docket (OPP-2004-0411) at <http://www.epa.gov/edockets>. An individual response to these comments is being prepared by EPA and will be made available in the public docket (OPP-2004-0411).

## **C. Regulatory Position**

### **1. Food Quality Protection Act Findings**

#### **a. "Risk Cup" Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to ametryn is within its own "risk cup." An aggregate assessment was conducted for exposures through food and drinking water (ametryn has no registered residential uses). The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for ametryn meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the potential sensitivity of infants and children, as well as aggregate exposure from food and drinking water.

#### **b. Determination of Safety to U.S. Population**

The Agency has determined that the established tolerances for ametryn, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of ametryn. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of ametryn.

As discussed in Section III, acute dietary risk was not assessed as no acute oral endpoint was observed. Further, the ametryn chronic dietary risk for the U.S. general population from both food and

drinking sources is not of concern. Screening-level models were used to estimate concentrations of ametryn in surface water and groundwater sources of drinking water. All drinking water model estimates were low and below the Agency's level of concern.

### **c. Determination of Safety to Infants and Children**

EPA has determined that the established tolerances for ametryn, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of ametryn residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of ametryn, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. Based on this information, EPA reduced the ametryn Special FQPA SF to 1x. There are no concerns and no residual uncertainties with regard to pre- and post-natal toxicity based on the rat and rabbit developmental toxicity studies and the rat two-generation reproduction study. There were no indications of immunotoxicity or direct neurotoxicity in the standard studies with rats, dogs, mice or rabbits. Further, the quality of the dietary exposure data (crop field trial data and the conservatism in the drinking water models) are also considered adequately protective to infants and children to support the reduction of the Special FQPA SF to 1x.

## **2. Endocrine Disruptor Effects**

EPA 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), EPA 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. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA 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 of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on ametryn, there was no estrogen, androgen, and/or thyroid mediated toxicity. When additional appropriate screening and/or testing protocols being considered

under the Agency's EDSP have been developed, ametryn may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

### 3. Cumulative Risks

Risks summarized in this document are those that result only from the use of ametryn. The FQPA requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually.

The Agency has found no information indicating ametryn shares a common mechanism of toxicity with other substances. Based on the Agency's review of the available toxicity information, EPA has determined that there is no known mechanism of toxicity that would support grouping ametryn with chloro-s-triazines (atrazine, simazine, propazine and their chloro-s-triazine metabolites). Ametryn has a different functional group attached to the triazine ring, i.e., thiomethyl versus chloro. Further, ametryn does not exhibit the same toxicity profile as the chloro-s-triazines. Although there were several tumors induced by ametryn in a rat bioassay, they were only at an excessive dose which confounds the interpretation of this response. Moreover, the Agency has found no information indicating ametryn shares a common mechanism of toxicity with other substances, nor does ametryn appear to produce a toxic metabolite produced by other substances.

Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has not assumed that ametryn shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests ametryn shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary. Information specific to the grouping of triazines for cumulative risk assessment including the March 2002 report, "The Grouping of a Series of Triazine Pesticides Based on a Common Mechanism of Toxicity" can be found at:

<http://www.epa.gov/oppsrrd1/cumulative/triazines/triazinescommonmech.pdf>.

#### D. Tolerance Reassessment Summary

The tolerances listed in 40 CFR §180.258 (a and c) are currently expressed in terms of ametryn (2-ethylamino)-4-(isopropylamino)-6-(methylthio)-s-triazine *per se*. The Agency has determined that the residues of concern for the tolerance expression consists of ametryn *per se*. The current tolerance expression allowing for residues of ametryn are established under 40 CFR §180.258, as listed in Table 21 below.



Tolerances Listed Under 40 CFR §180.258 (a and c):

Adequate residue data are available to reassess the established tolerances on corn, pineapples, and sugarcane. The available residue data indicate that tolerances can be lowered for all commodities. Tolerances on corn grain, forage, and stover should be split to include field and pop corn (e.g. *Corn, field, grain* and *Corn, pop, grain*)

Based on the available livestock metabolism and feeding studies, there is no reasonable expectation of finite residues occurring in livestock commodities. Therefore, tolerances for livestock commodities are not currently required.

The tolerances on forage and fodder of pineapples and sugarcane should be revoked as these commodities are no longer regulated; and the tolerances on sweet corn, banana, cassava, tanager, and yams should be revoked as uses on these crops are not being supported.

**Table 21. Tolerance Reassessment Summary for Ametryn.**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)		Comment
<b>Tolerances Listed Under 40 CFR §180.258(a):</b>				
Banana	0.25	--	Revoke	Technical registrant is deleting this use from the label (use is not being supported).
Corn, forage	0.5	Corn, field, forage	0.1	Field corn and pop corn should have separate tolerances for grain, forage, and stover.
		Corn, pop, forage		
Corn, grain	0.25	Corn, field, grain	0.05	
		Corn, pop, grain		
Corn, stover	0.5	Corn, field, stover	0.05	
		Corn, pop, stover		
Corn, fresh, kernel plus cob with husks removed	0.25	---	Revoke	Technical registrant is deleting this use from the label (use is not being supported).
Pineapple	0.25	---	0.05	---
Pineapple, fodder	0.25	---	Revoke	Commodity is no longer regulated livestock feed items.
Pineapple, forage	0.25			
Sugarcane, cane	0.25	---	0.05	---
Sugarcane, fodder	0.25	---	Revoke	Commodity is no longer regulated livestock feed items.
Sugarcane, forage	0.25			
Tanager	0.25	---	Revoke	No active registrations include this use (technical registrant does not support this use).
Yam, true, tuber	0.25			
<b>Tolerances Listed under 40 CFR 180.258(c):</b>				

**Table 21. Tolerance Reassessment Summary for Ametryn.**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)		Comment
Cassava, root	0.1	---	Revoke	No active registrations include this use (technical registrant does not support this use).

### 1. Codex/NAFTA Harmonization

There are no ametryn Maximum Residue Limits (MRLs) in the FAO/WHO *Codex Alimentarius* nor are there MRLs for ametryn in Canada.

### 2. Residue Analytical Methods

Adequate methods are available for enforcing tolerances and/or collecting data on ametryn residues in/on plant and livestock commodities. Two gas chromatography (GC) methods are available for enforcing tolerances of ametryn in plant commodities and are listed as Methods I and A in PAM Vol. II (section 180.258). Method I is a GC/microcoulometric (MC) detection method for determining ametryn *per se*, with a limit of quantitation (LOQ) of 0.05 ppm. Method A is a GC/flame photometric detection (sulfur mode, FPD-S) method for determining residues of ametryn and its three thiomethyl metabolites (GS-11354, GS-11355, and GS-26831), with a LOQ of 0.05 ppm for parent and 0.1 ppm for each metabolite.

### E. Regulatory Rationale

The Agency has determined that ametryn containing products are eligible for reregistration provided that: current data gaps and confirmatory data needs be addressed; the risk mitigation measures outlined in this document are adopted; and label amendments are made to reflect these measures.

Based on the following mitigation measures agreed to by the technical registrant and certain commodity groups including, reduced maximum use patterns and other use restrictions, risks from ametryn exposures to humans and the environment have been reduced.

- Reduction in maximum application rates and number of applications (see Table 22).
- Cancellation of the use on sweet corn.
- Prohibition of aerial application on sugarcane in Hawaii, Louisiana, and Texas.
- Cancellation of use in Puerto Rico.
- Cancellation of use in non-crop areas such as uncultivated areas, rights of way, and industrial areas.

The following is a summary of the rationale for managing risks associated with the use of ametryn. Where labeling revisions are warranted, specific language is set forth in Table 23 in Section V of this document.

## **1. Human Health Risk Management**

### **a. Dietary and Aggregate Risk Summary**

In the case of ametryn, an acute dietary risk assessment was not conducted because an endpoint of concern attributable to a single dose was not identified. Therefore, only a chronic (non-cancer) dietary risk assessment was conducted. Chronic dietary (food only) estimates are less than 0.1% of the cPAD for all population subgroups and are therefore, not of risk concern. Also, ametryn drinking water concentrations from both groundwater and surface water sources based on screening-level models are low and not of risk concern.

Aggregate risk estimates for ametryn only consider combined food and drinking water exposures because there are no registered residential uses. A long-term (chronic) aggregate risk assessment was conducted for ametryn. As indicated in Table 8, the EDWCs for chronic exposures for the U.S. general population and the most highly exposed group (Children ages 1 - 2 years old) are less than the corresponding DWLOCs. Therefore, estimated chronic aggregate risk is below EPA's level of concern, and no measures are necessary to mitigate dietary risks from food and drinking water.

### **b. Occupational Risk Mitigation**

#### Handler Exposure

Handler exposure assessments are completed by EPA using a baseline (long-sleeved shirt; long pants; and shoes and socks) exposure scenario and, if required, increasing levels of mitigation (Personal Protective Equipment (PPE) and engineering controls) to achieve an adequate margin of exposure (MOE). For ametryn, the target MOE for workers is 100. The calculations indicate that the MOEs for all occupational handler scenarios are above 100 at the baseline level and are not of concern. Therefore, no additional measures are needed to mitigate risks to handlers.

#### Post-application Risk Mitigation

Ametryn product labeling specifies application as either a directed spray at weeds or as a pre-emergent broadcast spray, and includes instructions to avoid application to the crop foliage. Additionally, for corn and pineapples, the label specifies the last ametryn application be made 30 and 160 days prior to harvesting respectively. For sugarcane, the label specifies "Avoid wetting sugarcane foliage, or injury may occur" and also recommends against application after "close-in" - when the sugarcane grows over the planting beds prior to harvesting. For these reasons, EPA does not anticipate any foliar residues on the ametryn treated crops. Therefore, the Agency does not expect any post-application foliar exposures to occur and post-application occupational exposures were not assessed. As a result, no mitigation measures are necessary.

## 2. Environmental Risk Mitigation

It is the Agency's policy to mitigate ecological risks to the greatest extent necessary and feasible. Mitigation measures may include lowering application rates, reducing the number of applications, restricting the timing of applications, minimizing runoff potential, and others.

### Fish and Aquatic Invertebrate Risk

EPA has low risk concerns about the potential acute or chronic risk to freshwater aquatic organisms (fish and invertebrates) or the acute risk to estuarine/marine aquatic organisms potentially exposed to ametryn via runoff or drift.

EPA completed a high end screening-level assessment incorporating the reduced maximum use patterns to predict chronic risk to estuarine/marine aquatic invertebrates. There were no chronic toxicity studies available to assess the chronic toxicity of ametryn to estuarine/marine invertebrates or fish. Therefore, an extrapolation of available data from freshwater aquatic organisms was used to estimate risks for estuarine/marine organisms which resulted in slight chronic risk for estuarine/marine invertebrates. There is uncertainty associated with this extrapolation, therefore, chronic studies for estuarine/marine fish (Guideline # 850.1400) and invertebrates (Guideline # 850.1350) will be required as part of this RED.

### Avian Risk

There are low acute risk concerns for avian species. Minimal predicted chronic risks to birds were based on maximum modeled EECs using high-end exposure feed items. When mean EECs are used to assess potential chronic risk to birds, only one use scenario, sugarcane grown in Hawaii, and one feed item, short grass, resulted in an RQ in excess of the LOC (RQ = 1.26).

The Agency had to rely on default assumptions when predicting foliar dissipation of ametryn residues on feed items. Refinement of the exposure estimate with actual foliar dissipation data for ametryn would replace the conservative default assumption utilized in the assessment and is expected to lead to a significant reduction in predicted risk to birds through ingestion of feed items contaminated with ametryn residues. Therefore, a foliar dissipation study (Guideline # 860.1500) is required in order to refine the assumptions used for assessing risks to birds.

### Mammalian Risk

Although ametryn is practically nontoxic to mammals on an acute oral exposure basis, screening-level EECs slightly exceed acute restricted use and acute endangered species LOCs for some feed items on several modeled uses. Acute RQ values range from 0.06 to 0.4 with the highest values resulting from mammals feeding on short grass.

Estimated chronic risks to mammals from ametryn exposures exceed LOCs for some feed items from all modeled use patterns for ametryn. Based on maximum EECs, chronic RQ values range

from 0.04 to 36 with the highest values also resulting from mammals feeding on short grass. Use of mean EECs to assess chronic mammalian risks would result in lower RQs.

As with the avian risk estimates, EPA had to rely on default assumptions when predicting foliar dissipation of ametryn residues on feed items. Refinement of the exposure estimate with actual foliar dissipation data (Guideline # 860.1500) for ametryn would replace the conservative default assumption utilized in the screening-level assessment and is expected to lead to a significant reduction in predicted acute and chronic risk to mammals through ingestion of feed items contaminated with ametryn residues.

### Non-Target Terrestrial and Aquatic Plant Risk

Based on high end screening-level assessments for ametryn exposures via runoff or drift, RQs for non-target and endangered/threatened aquatic plants range from 3 to 71. RQs for terrestrial non-target plants range from 0.11 to 612, while RQs for endangered or threatened non-target plants range from 0.24 to >612. As stated previously, the registrant had agreed to reduced maximum application rates and other use pattern restrictions (see Table 22) which reduced environmental exposure, including exposures to plants. As an example, RQs for terrestrial non-target plants, based on the previous higher rates, were as high as 4080. With the agreed to mitigation measures, this RQ was significantly reduced to 612, with similar results for the other plant risk estimates.

In general, monocot species are less sensitive to ametryn than dicot species. For terrestrial non-target plants, including endangered and threatened species, RQs estimated from spray drift exposures were not of concern for monocot species from all modeled scenarios except for aerial application to sugarcane where the RQ for endangered/threatened plants was 1.2.

Ametryn is applied to corn only as a post-emergence directed spray below the leaf canopy in order to prevent injuring the corn plant. This type of application procedure minimizes the opportunity for sprays to drift off-site. Similarly, when used as a directed spray on sugarcane the likelihood for off-site drift is also minimized. Furthermore, the product label directs that aerial applications to sugarcane have a minimum upwind distance of 800 feet to sensitive non-target plants. These restrictions to the application methods are not reflected in the screening-level risk assessment and, therefore, the Agency believes that the RQs summarized above may be overestimates.

Nevertheless, to further minimize the potential for drift, the Agency is requiring that strict use restrictions to minimize spray drift be placed on the labels for all ametryn products. These include: limits to droplet size, wind speed limitations, and spray boom heights. The Agency believes that the specific drift language amendments proposed in this RED will further reduce potential risks to all non-target plants below that already achieved through rate reductions.

### **3. Significance of Ametryn**

Ametryn is widely used within certain regions. In Hawaii it is used on nearly 100% of the pineapple and sugarcane crops. In the southeastern US ametryn is used extensively on sugarcane in

Florida and up to 15% on the field corn in South Carolina, North Carolina and Georgia. Ametryn use on popcorn is minimal. Ametryn has some niche uses in Texas and Louisiana for sugarcane.

There are several other herbicides that are also registered for the same use sites (field corn, popcorn, pineapple, and sugarcane) as ametryn. In terms of price, ametryn is at the lower end of cost measured in dollars/acre. In terms of weed control, ametryn, when compared to its competitors, often has similar effectiveness in controlling weeds but controls a different spectrum of weeds than many of its competitors. Ametryn is more effective in controlling grasses than some of the alternatives. In pineapple, it is the only herbicide available to control morning glory species. Nevertheless, herbicides such as ametryn are commonly mixed with other herbicides to achieve a broader spectrum of weed control than with a single active ingredient. It is not unusual for ametryn to be tank mixed with complementary herbicides such as 2,4-D, atrazine, or diuron.

## **F. Other Labeling Requirements**

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing ametryn. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

### **1. Endangered Species Considerations**

Based on available screening level information there is a potential concern for ametryn's chronic effects on listed birds; acute and chronic effects on listed mammals; and effects on listed terrestrial and aquatic plants should exposures actually occur. The Agency expects ametryn poses a low acute risk to nontarget insects because ametryn is practically nontoxic to honeybees (acute contact LD<sub>50</sub> was greater than the highest dose tested (>100 µg/bee)). However, the Agency does not assess risk to bees using RQs because a screening-level RQ assessment method for estimating the risk to bees is not available. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act (ESA) for any listed species.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. The ESA 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, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. If the Agency determines use of ametryn "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until

that 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 ametryn at levels of concern.

## 2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of ametryn, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for ametryn. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 24) in Chapter V of this RED document. In the future, ametryn product labels may need to be revised to include additional or different drift label statements.

### G. Mitigation Summary

At this time EPA is not specifying additional specific mitigation measures for ametryn other than the spray drift reduction measures mentioned above and acceptance of the reduced maximum use patterns submitted by the technical registrant. A comparison of the previous (old) and reduced (new) rates are summarized below in Table 22. The registrant has also agreed to voluntarily cancel the use on sweet corn; aerial application to sugarcane in Hawaii, Louisiana, and Texas; and all use in Puerto Rico.

**Table 22. Pre-RED and Post-RED Maximum Use Patterns for Ametryn<sup>1</sup>**

Crop	Max Single Rate (lbs ai/A)		Applications per Yr		Maximum Seasonal Rate (lbs ai/A/Yr)		Application Method
	Old	New	Old	New	Old	New	
Corn (Field and Pop)	2.0	1.6	1	1	2.0	1.6	Ground
Corn (sweet)	2.0	Canc	1	Canc	2.0	Canc	Ground
Pineapple (HI)	7.2	1.6	NS	2	7.2	3.2	Ground
Sugarcane (FL, LA, TX)	1.2-2.4	1.2	3-5	2	3.6-11.6	2.4	Ground
Sugarcane (HI)	7.2	2.4	3	3	12.0	7.2	Ground
Sugarcane (PR)	8.0	Canc	3	Canc	16.0	Canc	Ground
Sugarcane (FL)	1.2	1.2	3	2	3.6	2.4	Aerial

**Table 22. Pre-RED and Post-RED Maximum Use Patterns for Ametryn<sup>1</sup>**

Crop	Max Single Rate (lbs ai/A)		Applications per Yr		Maximum Seasonal Rate (lbs ai/A/Yr)		Application Method
	Old	New	Old	New	Old	New	
Sugarcane (LA, TX)	1.2-2.4	Canc	3-5	Canc	3.6-11.6	Canc	Aerial

<sup>1</sup> Information taken from Syngenta letters of April 26, 2005; June 22, 2005, and August 16, 2005 with revised label language.

NS = Not Specified

Canc = Use Cancelled

## V. What Registrants Need to Do

The Agency has determined that ametryn is eligible for reregistration provided that: (i) additional data are submitted to confirm this decision; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table (Table 24) in Section C below. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data and additional 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 eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for ametryn to be eligible for reregistration.

### A. Manufacturing-Use Products

#### Additional Generic Data Requirements

The generic data base supporting the reregistration of ametryn for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below in Table 22 are necessary to confirm the reregistration eligibility decision documented in this RED.

**Table 23. Generic Data Requirements for the Reregistration Eligibility Decision on Ametryn**

Test Series	OPPTS Number	Study Title
Health Effects/ Toxicology	870.5300	<i>In vitro</i> mammalian cell gene mutation test



**Table 23. Generic Data Requirements for the Reregistration Eligibility Decision on Ametryn**

Test Series	OPPTS Number	Study Title
Product Use Chemistry	830.1550	Product identity and composition
	830.1700	Preliminary analysis
	830.1750	Certification of limits
	830.1800	Analytical method
	830.6314	Oxidation/Reduction Potential
	830.6315	Flamability
	830.6318	Viscosity
	830.6319	Miscibility
	830.6321	Dielectric breakdown voltage
	830.7370	Dissociation constants in water
Residue Chemistry	860.1200	Directions for use
	860.1500	Foliar dissipation: there is no set guidance for this test at this time; a modified protocol of EPA's magnitude of residue study is the preferred baseline. The registrant is encouraged to consult with EPA regarding the appropriate modifications to ensure suitability.
	860.1520	Processed food/feed
Environmental Fate	old 160-5	Chemical identity
	835.4300	Aerobic aquatic metabolism
	835.4400	Anaerobic Aquatic Metabolism
Ecological Effects	850.1350	Estuarine/marine Mysid chronic toxicity test
	850.1400	Estuarine/marine fish early life stage toxicity test
	850.4400	Aquatic plant toxicity test using <i>Lemna sp.</i> , Tiers I and II

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 24.

## **B. End-Use Products**

### 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 pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that 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 Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

### Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 24. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

## **C. Labeling Changes Summary Table**

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table (Table 24) describes how language on the labels should be amended.

**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	“Only for formulation into an water dispersible granule, herbicide for the following uses: field corn, popcorn, pineapple, and sugarcane.”	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	<p>“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).”</p> <p>“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).”</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
<b>End Use Products Intended for Occupational Use</b>		
PPE Requirements Established by the RED <sup>1</sup> for water-dispersible granules Formulations	<p>“Personal Protective Equipment (PPE):”</p> <p>“Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers, loaders, applications and other handlers must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt,</li> <li>- long pants,</li> <li>- shoes and socks”</li> </ul> <p>“See engineering controls for additional options and requirements”</p> <p>“Human flagging is prohibited”</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Control Requirements:	<p>“Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR §170.240(d)(6)]:-</p>	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals. (Immediately following PPE and User Safety Requirements.)
User Safety Requirements	<p>“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.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p>“This pesticide is toxic aquatic organisms. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate. Apply this product only as specified on the label.</p>	<p>Precautionary Statements immediately following the User Safety Recommendations</p>
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	<p>Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Coveralls</li> <li>• Chemical-resistant gloves made of any waterproof material</li> <li>• Shoes plus socks</li> </ul>	<p>Direction for Use</p> <p>Agricultural Use Requirements box</p>
General Application Restrictions	<p>“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.”</p>	<p>Place in the Direction for Use directly above the Agricultural Use Box.</p>

**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
<p>Other Application Restrictions (Note: The maximum allowable application rate and maximum allowable rate per year must also be listed as pounds of formulated product per acre, not just as pounds active ingredient per acre.)</p>	<p>Corn (Field and Pop) - Maximum application rate is 1.6 lb ai/acre; 1 application per year.</p>	<p>Directions for Use</p>
<p>Other Application Restrictions (Note: The maximum allowable application rate and maximum allowable rate per year must also be listed as pounds of formulated product per acre, not just as pounds active ingredient per acre.)</p>	<p>Pineapple - Maximum application rate is 1.6 lb ai/acre; 2 applications per crop cycle; maximum 3.2 lbs ai/acre/crop cycle;  For use in HI only</p>	<p>Directions for Use</p>

**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
<p>Other Application Restrictions                      (Note: The maximum allowable application rate and maximum allowable rate per year must also be listed as pounds of formulated product per acre, not just as pounds active ingredient per acre.)</p>	<p>Sugarcane -                       FL, LA, TX - 1.2 lb ai/acre, 2 applications per crop cycle; maximum 2.4. lbs ai/acre/crop cycle.                       HI - 2.4 lb ai/acre 3 applications per crop cycle; maximum 7.2 lbs ai/acre/crop cycle.</p>	<p>Directions for Use</p>
<p>Other Application Restrictions</p>	<p>Aerial application is prohibited except for use on sugarcane in FL.</p>	<p>Directions for Use</p>

**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
<p>Spray Drift Label Language for Products Applied as a Spray</p>	<p><b>"SPRAY DRIFT MANAGEMENT"</b>            "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product."</p> <p><b>Wind Speed</b>            "Do not apply at wind speeds greater than 10 mph."</p> <p><b>"Controlling Droplet Size"</b>            "Use a nozzle type according to manufacturer's specifications that is designed for the intended application and produces a Medium or coarser spray (ASAE standard 572) or a volume mean diameter of 300 microns or greater for spinning atomizer nozzles under application conditions. Applicators must consider nozzle orientation, nozzle pressure, and flight speed in determining droplet size. Nozzles should always be oriented in the manner that minimizes the effects of air shear. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."</p> <p>"Do not exceed the nozzle manufacturer's recommended pressures. When higher flow rates are needed, use a higher-capacity nozzle instead of increasing pressure."</p> <p><b>"Temperature Inversions"</b>            "If applying at wind speeds less than 2 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions."</p>	<p>Directions for Use under General Precautions or Restrictions and/or Application Instructions</p>



**Table 24. Summary of Labeling Changes for Ametryn**

Description	Amended Labeling Language	Placement on Label
<p>Spray Drift Label Language for Products Applied as a Spray</p>	<p><b>“Equipment”</b>                      “All aerial and ground application equipment must be properly maintained and calibrated using appropriate carriers or surrogates.”</p> <p><i>“Additional requirements for aerial applications:”</i></p> <ol style="list-style-type: none"> <li>1. “The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter.”</li> <li>2. “Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety.”</li> <li>3. “When applications are made with a crosswind, the swath must be displaced downwind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind.”</li> </ol> <p><i>“Additional requirements for groundboom application:”</i></p> <ol style="list-style-type: none"> <li>1. “Do not apply with a nozzle height greater than 4 feet above the crop canopy.”</li> <li>2. “Use low drift nozzles with a maximum pressure of 40 psi.”</li> </ol> <p><b>“Other State and Local Requirements”</b>                      “Applicators must follow all state and local pesticide drift requirements regarding application of ametryn. Where states have more stringent regulations, they must be observed.”</p>	<p>Directions for Use under General Precautions or Restrictions and/or Application Instructions</p>

<sup>1</sup> PPE that is established on the basis of Acute 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.



## **VI. Related Documents and How to Access Them**

A list of technical support documents for the ametryn RED is provided in Appendix C. All technical support documents for this RED may be viewed on paper in the Office of Pesticides Program Public Docket or electronically via the Internet. These documents may be found on the Agency's web page at [www.epa.gov.edockets](http://www.epa.gov.edockets) under docket OPP-2004-0411 (Documents from May 2002 to the present). Hard copies of these documents may be found in the OPP public docket, also under docket numbers OPP-2004-0411. The OPP public docket is located in Room 119, Crystal Mall II; 1801 South Bell Street; Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

### **List of Appendices:**

- Appendix A. Table of Use Patterns Eligible for Reregistration for Ametryn
- Appendix B. Generic Data Requirements and Studies Utilized to Make the RED for Ametryn
- Appendix C. Technical Support Documents Utilized to Make the RED for Ametryn
- Appendix D. Citations Supporting the RED for Ametryn (Bibliography)
- Appendix E. Batching of Ametryn Products
- Appendix F. List of Registrants to be sent the Data Call-In
- Appendix G. List of Available Related Documents and Electronically Available Forms

**Appendix A. Food/Feed Use Patterns Eligible for Reregistration for Ametryn**

Use Site Application Timing Application Type Application Equipment	Formulation	Max Single App Rate (lbs ai/acre)	Max No. of App Per Year	Minimum Retreatment Interval (days)	Max Annual Rate (lbs ai/cc or year)	Preharvest Interval (Days)	Use Directions and Limitations
<b>Food/Feed Uses</b>							
<b>Corn (Pop &amp; Field)</b>							
Postemergence Directed Spray Groundboom	80% WDG	1.6	1	Not Applicable	1.6	30	Apply directed spray to weeds after smallest corn is at least 12 in tall. Keep spray or drift from contacting leaves or whorl of corn. Apply at 30 psi to avoid spray from bouncing back and settling on corn leaves.
<b>Pineapple</b>							
Postplant, postharvest, broadcast/blanket spray Groundboom	80% WDG	1.6	2	30	3.2	160	HI
<b>Sugarcane</b>							
Preplant broadcast, band, interline Groundboom & aerial [FL only]	80% WDG [100-786]	1.2 2.4 [HI]	2 3 [HI]	30	2.4 7.2 [HI]	NS	Aerial application permitted only permitted in FL

## **Appendix B. Data Supporting Guideline Requirements for the Reregistration of Ametryn**

### **Guide to Appendix B**

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case ametryn covered by this RED. It contains generic data requirements that apply to ametryn 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 by Guideline Number. The Guideline Numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance 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            | H. Greenhouse Food     |
| B. Terrestrial Feed             | I. Greenhouse Non-Food |
| C. Terrestrial Non-Food         | J. Forestry            |
| D. Aquatic Food                 | K. Residential         |
| E. Aquatic Non-Food Outdoor     | L. Indoor Food         |
| F. Aquatic Non-Food Industrial  | M. Indoor Non-Food     |
| G. Aquatic Non-Food Residential | 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 (MRID) 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.

## Appendix B

### Data Supporting Guideline Requirements for the Reregistration of Ametryn

REQUIREMENT		Use Patterns	CITATION(S)
<b>PRODUCT CHEMISTRY</b>			
Guideline Number			
New	Old		
830.1550	61-1	Product Identity and Composition	All 408447-01, CSF 8/19/85, Data gap
830.1600	61-2A	Description of materials used to produce the product	All 408447-01
830.1620	61-2B	Description of production process	All 408447-01, 433359-01
830.1670	61-2B	Formation of Impurities	All 408447-01
830.1700	62-1	Preliminary Analysis	All 410679-01, Data Gap
830.1750	62-2	Certification of limits	All 40844701, 41067901, CSF 8/19/85, Data Gap
830.1800	62-3	Analytical Method	All 410679-01, Data Gap
830.6302	63-2	Color	All 408773-01
830.6303	63-3	Physical State	All 408773-01
830.6304	63-4	Odor	All 408773-01
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All 40877301, 42470901, 42631501
830.700	63-12	pH	All 408773-01
830.7050	None	UV/Visible Absorption	All 408773-01
830.7200	63-5	Melting Point	All 408773-01
830.7220	63-6	Boiling Point	All N/A
830.7300	63-7	Density	All 408773-01
830.7370	63-10	Dissociation constants in water	All 408773-01
830.7550	63-11	Partition coefficient, shake flask method	All 408773-01
830.7840	63-8	Solubility	All 408773-01
830.7950	63-9	Vapor Pressure	All 408773-01
830.6314	63-14	Oxidizing/Reduction Potential	All Data Gap
830.6315	63-15	Flamability	All Data Gap
830.6316	63-16	Explodability	All 408773-01, In Review
830.6317	63-17	Storage Stability	All 408773-01, In Review
830.6318	63-18	Viscosity	All Data Gap
830.6319	63-19	Miscibility	All Data Gap
830.6320	63-20	Corrosion Characteristics	All 408773-01, In Review
830.6321	63-21	Dielectric Breakdown Voltage	All Data Gap

**Appendix B**  
**Data Supporting Guideline Requirements for the Reregistration of Ametryn**

REQUIREMENT			Use Patterns	CITATION(S)
<b><u>ECOLOGICAL EFFECTS</u></b>				
850.2100	71-1A	Avian Acute Oral Toxicity	A, B	409958-01
850.2200	71-2A	Avian Dietary Toxicity - Quail	A, B	409958-03
850.2200	71-2B	Avian Dietary Toxicity - Duck	A, B	409958-02
850.2300	71-4A	Avian Reproduction - Quail	A, B	415476-01
850.2300	71-4B	Avian Reproduction - Duck	A, B	415476-02
850.1075	72-1A	Fish Toxicity Bluegill	A, B	409958-04 (supplemental)
850.1075	72-1A	Fish Toxicity Fathead Minnow	A, B	428616-01
850.1075	72-1C	Fish Acute Toxicity Rainbow Trout	A, B	428616-02 409958-05 (supplemental)
850.1010	72-2A	Invertebrate Acute Daphnid Toxicity	A, B	409958-06
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	A, B	411149-02
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk	A, B	411149-03
850.1035	72-3C	Estuarine/Marine Acute Toxicity - Shrimp	A, B	411149-01
850.1300	72-4B	Daphnid Chronic Toxicity (life cycle)	A, B	411897-02, 423252-01
850.1350	72-4B	Estuarine/Marine Invertebrate chronic (Mysid Shimp, Life Cycle)	A, B	Data Gap
850.1400	72-4A	Freshwater Fish- Early Life Stage	A, B	411897-03, 423252-03
850.1400	72-4D	Eustarine Fish- Early Life Stage	A, B	Data Gap
850.4100	122-1A	Terrestrial Plant Toxicity, Seedling Emergence	A, B	N/A
850.5400	122-2	Aquatic Plant Growth	A, B	409958-10
850.4225	123-1A	Seedling Germination & Seedling Emergence	A, B	409958-07 409958-08
850.4250	123-1B	Vegetative Vigor	A, B	409958-09
850.4400	123-2	Aquatic Plant Growth	A, B	Data Gap
850.3020	141-1	Honey Bee Acute Contact	A, B	409958-11

**Appendix B**  
**Data Supporting Guideline Requirements for the Reregistration of Ametryn**

REQUIREMENT		Use Patterns	CITATION(S)
<b><u>TOXICOLOGY</u></b>			
870.1100	81-1	Acute Oral Toxicity-Rat	A, B 40995814
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A, B 40995815
870.1300	81-3	Acute Inhalation Toxicity-Rat	A, B 42470902, 40995816
870.2400	81-4	Primary Eye Irritation-Rabbit	A, B 40995817
870.2500	81-5	Primary Skin Irritation	A, B 40995818
870.2600	81-6	Dermal Sensitization	A, B 40995819
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	A, B See 870.4300
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	A, B See 870.4100
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A, B 92002019
870.6200	81-8 82-7	Neurotox screening battery Acute & 90-Day Neurotox-mammal	A, B Reserved
	83-1A	Chronic Tox-Rodent	A, B 92002020
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	A, B 403499-02
	83-2A	Oncogenicity - Rat	A, B 40349906, 41184201, 92002020
870.3700	83-3A	Developmental Toxicity - Rat	A, B 00153215 and 92002024
870.3700	83-3B	Developmental Toxicity - Rabbit	A, B 00153214, 92002025
870.3800	83-4	2-Generation Reproduction - Rat	A, B 403499-05
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity: Rats	A, B 403499-06, 411842-01, 403820-01
870.4200	83-2B	Carcinogenicity Mice	A, B 403499-04
870.5395	84-2	erythrocyte (mouse) micronucleus	A, B 410679-03
870.5100	84-2	Bacterial Reverse Gene Mutation	A, B 409958-29, 411897-01
870.5375	84-2B	Cytogenetics chromosome aberration study	A, B 41067903
870.7485	85-1	General Metabolism	A, B 41463301, 41463302, 41463303



**Appendix B**  
**Data Supporting Guideline Requirements for the Reregistration of Ametryn**

REQUIREMENT			Use Patterns	CITATION(S)
<b>OCCUPATIONAL/RESIDENTIAL EXPOSURE</b>				
875.2100	132-1A	Dislodgable Foliar residue dissipation	A, B	Reserved
875.2200	132-1B	Soil residue dissipation	A, B	Reserved
875.2400	133-3	Dermal Passive Dosimetry Exposure	A, B	Reserved
875.2500	133-4	Inhalation Passive Dosimetry Exposure	A, B	Reserved
<b>ENVIRONMENTAL FATE</b>				
	160-5	Chemical identity	A, B	Data Gap
835.2120	161-1	Hydrolysis	A, B	408858-12
835.2240	161-2	Photodegradation - Water	A, B	411696-01
835.2410	161-3	Photodegradation - Soil	A, B	411696-02, 411696-03
	161-4	Photodegradation - air	A, B	Waived
835.4100	162-1	Aerobic Soil Metabolism	A, B	417524-01, 465338-01
835.4200	162-2	Anaerobic Soil Metabolism	A, B	417524-01
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B	428616-03, Data Gap
835.4300	162-4	Aerobic Aquatic Metabolism	A, B	Data Gap
835.1240	163-1	Leaching/Adsorption/Desorption	A, B	409958-13, 411696-04,
835.1410	163-2	Laboratory Volatilization	A, B	waived (low vapor pressure)
835.6100	164-1	Terrestrial Field Dissipation	A, B	417524-02, 418723-02, 418723-01
	165-1	Confined Rotational crop	A, B	419863-02, 433424-01
None	165-4	Bioaccumulation in Fish	A, B	420619-01
	165-5	Bioaccumulation in aquatic organisms	A, B	Reserved
	166-1	Groundwater - small prospective	A, B	Reserved

**Appendix B**  
**Data Supporting Guideline Requirements for the Reregistration of Ametryn**

REQUIREMENT			Use Patterns	CITATION(S)
<b>RESIDUE CHEMISTRY</b>				
860.1200	171-2	Directions for Use	A, B	Data Gap
860.1300	171-4A	Nature of Residue - Plants	A, B	41662301 41662302 44107901
860.1300	171-4B	Nature of Residue - Livestock	A, B	41662303 41662304 41662305 41662306 43931001
860.1340	171-4C	Residue Analytical Method - Plants	A, B	41557102, 41557103, 41872304 42391601
860.1340	171-4D	Residue Analytical Method - livestock	A, B	44477701, 44477702
860.1360		Multiresidue Method	A, B	41397201, 41423401
860.1380	171-4E	Storage Stability - Plants	A, B	41557101 43335902 43342401 44783701?
860.1380	171-4E	Storage Stability - Livestock	A, B	44477704
860.1480:	171-4J	Magnitude of the Residue - Meat, Milk, Poultry, Eggs	A,B	44477705, 44477706
860.1500	171-4K	Crop Field Trials (corn)	A, B	41909501
860.1500	171-4K	Crop Field Trials (pineapple)	A, B	41909502
860.1500	171-4K	Crop Field Trials (sugarcane)	A, B	41846601
860.1520	171-4L	Processed Food/Feed (corn)	A, B	42391602
860.1520	171-4L	Processed Food/Feed (pineapple)	A, B	41909502
860.1520	171-4L	Processed Food/Feed (sugarcane)	A, B	41846601
860.1650		Submittal of Analytical Reference Standards	A, B	Not Required
860.1850		Confined Accumulation in Rotational Crops	A, B	41986301, 41986302, 43342401
860.1900:	165-2	Field Accumulation in Rotational Crops	A, B	42391602, 44783702
<b>OTHER</b>				
840.1100	201-1	Droplet Size Spectrum	A, B	Reserved
840.1200	202-1	Drift Field Deposition Evaluation	A, B	Reserved

N/A = Not Applicable

## Appendix C. List of EPA's Technical Support Documents For Ametryn

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 am to 4:00 pm.

The preliminary and revised risk assessments for ametryn are available in the Public Docket, under docket number OPP-2004-0411 on the Agency's E-Dockets web page, <http://www.epa.gov/edockets>.

EPA released the preliminary risk assessments for ametryn on February 25, 2005. During and after the public comment period, the registrant submitted additional voluntary data for ametryn. EPA reviewed there data and incorporated them into the final revised risk assessments for ametryn. These final revised risk assessments form the basis of the regulatory decision described in the RED.

All final revised risk assessment and technical support documents may be viewed in the OPP docket room, in hard copy form, or downloaded or viewed electronically via the Internet at the following site: [www.epa.gov/edockets](http://www.epa.gov/edockets). These documents include the following:

### *Human Health Risk Assessment Documents*

- *Revised Memo to Incorporate Responses to Phase 3 Public Comments. Ametryn: HED Chapter of the Reregistration Eligibility Decision Document (RED).* June, 15, 2005. William H. Donovan, Ph.D. and John Doherty, Ph.D.
- *Revised Memo to Incorporate Responses to Phase 3 Public Comments. Ametryn. Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision.* May 24, 2005. William H. Donovan, Ph.D.
- *Corrected Ametryn ORE Chapter to Incorporate Responses to Phase 3 Public Comments- Ametryn. HED Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision Document.* June 13, 2005. Robert Travaglini.
- *Review of Ametryn Incident Reports.* Aug 26, 2004. Jerome Blondell, Ph.D. and Monica S. Hawkins, M.P.H.
- *Ametryn. Health Effects Division (HED) Phase 4 Response to Phase 3 Public Comments on the Ametryn Preliminary Reregistration Eligibility Decision (RED) and Supporting Memos.* May 25, 2005. William H. Donovan, Ph.D., John Doherty, Ph.D., and Robert Travaglini.
- *Revised Memo to Incorporate Responses to Phase 3 Public Comments. Ametryn. Residue Chemistry Considerations for Reregistration Eligibility Decision.* May 25, 2005. William H. Donovan, Ph.D.
- *AMETRYN: Report of the Cancer Assessment Review Committee.* September 17, 2004.

- *Revised as per 30-day Error Only Registrant Comments. Ametryn RED - Reregistration Eligibility Decision. Product Chemistry Considerations. December 22, 2004. William H. Donovan, Ph.D.*

#### ***Environmental Fate and Ecological Effects Assessment Documents***

- *Drinking Water Exposure Assessment for Proposed Reregistration of Ametryn Use on Corn, Pineapple and Sugarcane (Revised). June 9, 2005. Kevin Costello.*
- *Environmental Fate and Ecological Risk Assessment for the Re-registration of Ametryn June 9, 2005. Costello et al.*

#### ***Use and Usage / Economic Analysis Documents***

- *Use Closure Memo for Ametryn; PC Code: 080801; RED Case No.: 2010; CAS No.: 834-12-8 February 27, 2003. Mark Howard.*
- *Alternatives Analysis for Ametryn on Sugarcane, Pineapple, Field Corn, and Popcorn June 23, 2005. Nicole Zinn and Stephen Smearman.*

## **Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Decision (Bibliography)**

### GUIDE TO APPENDIX D

**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.

**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.

**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.

**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.

1. **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.
2. **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.

3. 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.

4. 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:

- A. Submission date. The date of the earliest known submission appears immediately following the word "received."
- B. 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.
- C. Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
- D. 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.

## **PRODUCT CHEMISTRY:**

<b>MRID #</b>	<b>Study Citations</b>
40844701	Lail, L. (1988) Product Chemistry: Technical Ametryn: Study No. PC-88-018. Unpublished study prepared by Ciba-Geigy Corp. 205 p.
40877301	Lail, L. (1988) Technical Ametryn: Product Chemistry: Study No. PC- 88-018. Unpublished study prepared by Ciba-Geigy Corp. 136 p.
41067901	Lail, L. (1989) Technical Ametryn: Product Chemistry: Study No. PC-89-002. Unpublished study prepared by Ciba-Geigy Corp. 108 p.
42470901	Stubbs, D. (1992) Product Chemistry: Ametryn Technical: Lab Project Number: PC-92-027. Unpublished study prepared by CIBA-GEIGY Corp. 5 p.

- 42583102 Lail, L.; Verma, M. (1992) Product Chemistry: Technical Ametryn: Lab Project Number: PC-92-039. Unpublished study prepared by CIBA-GEIGY Corp., Agricultural Division. 19 p.
- 42631501 Stubbs, D. (1993) Product Chemistry (Stability): Technical Ametryn: A Supplement. Unpublished study prepared by Ciba-Geigy. 17 p.
- 43335901 McCain, P. (1994) Technical Ametryn Product Chemistry (Manufacturing Process): Addendum: Lab Project Number. Unpublished study prepared by Ciba-Geigy Corp. 8 p.

### **Ecological Effects**

#### **MRID # Study Citations**

- 40995801 Grimes, J.; Jaber, M. (1988) Ametryn: An Acute Oral Toxicity Study with the Bobwhite: Final Report: Project No. 108-291. Unpublished study prepared by Wildlife International Ltd. 20 p.
- 40995802 Grimes, J.; Jaber, M. (1988) Ametryn: A Dietary LC50 Study with the Mallard: Project No. 108-290A. Unpublished study prepared by Wildlife International Ltd. 19 p.
- 40995803 Grimes, J.; Jaber, M. (1988) Ametryn: A Dietary LC50 Study with the Bobwhite: Project No. 108-289. Unpublished study prepared by Wildlife International Ltd. 18 p.
- 41547601 Beavers, J. (1990) Ametryn Technical: A One-Generation Reproduction Study with the Northern Bobwhite (*Colinus virginianus*): Lab Project Number: 108-303. Unpublished study prepared by Wildlife International Ltd. 116 p.
- 41547602 Beavers, J. (1990) Ametryn Technical: A One-Generation Reproduction Study with the Mallard (*Anas platyrhynchos*): Lab Project Number: 108-304. Unpublished study prepared by Wildlife International Ltd. 119 p.
- 40995804 Surprenant, D. (1989) Ametryn: Acute Toxicity of Ametryn Technical to Bluegill (*Lepomis macrochirus*) Under Static Conditions: Study No. 89-1-2917. Unpublished study prepared by Springborn Life Sciences, Inc. 43 p.
- 40995805 Surprenant, D. (1989) Ametryn: Acute Toxicity of Ametryn Technical to Rainbow Trout (*Salmo gairdneri*) Under Static Conditions: Study No. 89-1-2919. Unpublished study prepared by Springborn Life Sciences, Inc. 42 p.

- 42861601 Ward, T.; Kowalski, P. (1993) Acute Toxicity of Ametryn Technical to the Fathead Minnow, *Pimephales promelas*: Lab Project Number: 219-CG. Unpublished study prepared by T.R. Wilbury Labs, Inc. 31 p.
- 42861602 Ward, T.; Kowalski, P. (1993) Acute Toxicity of Ametryn Technical to the Rainbow Trout, *Oncorhynchus mykiss*: Lab Project Number: 220-CG. Unpublished study prepared by T.R. Wilbury Labs, Inc. 31 p.
- 40995806 Surprenant, D. (1989) Ametryn: Acute Toxicity of Ametryn Technical to Daphnids (*Daphnia magna*) under Static Conditions: Study No. 89-1-2912. Unpublished study prepared by Springborn Life Sciences, Inc. 44 p.
- 41114901 Surprenant, D. (1989) Acute Toxicity of Ametryn Technical To Mysid Shrimp (*Mysidopsis bahia*) under static Conditions: Study No. 893-2960. Unpublished study prepared by Springborn Life Sciences, Inc. 47 p.
- 41114902 Surprenant, D. (1989) Acute Toxicity of Ametryn Technical To Sheepshead Minnow (*Cyprinodon variegatus*) under Static Conditions: Study No. 89-4-2967. Unpublished study prepared by Springborn Life Sciences, Inc. 43 p.
- 41114903 Surprenant, D. (1989) Acute Toxicity of Ametryn Technical to Quahog Clam (*Mercenaria mercenaria*) Embryos-Larvae under Static Conditions: Study No. 89-4-2971. Unpublished study prepared by Springborn Life Sciences, Inc. 47 p.
- 41189702 McNamara, P. (1989) Ametryn: The Chronic Toxicity of Ametryn Technical to *Daphnia Magna* Under Flow-through Conditions: Study No. 89-6-3002. Unpublished study prepared by Springborn Laboratories, Inc. 50 p.
- 41189703 Surprenant, D. (1989) Ametryn: The Toxicity of Ametryn Technical to Fathead Minnow (*Pimephales Promelas*) Embryo and Larvae: Study No. 89-7-3022. Unpublished study prepared by Springborn Laboratories, Inc. 48 p.
- 42325202 McNamara, P. (1989) Supplement to the Chronic Toxicity of Ametryn Technical to *Daphnia magna* under Flow-through Conditions. Unpublished study prepared by Ciba-Geigy Corp. 55 p.
- 42325203 Surprenant, D. (1989) Supplement to the Toxicity of Ametryn Technical to Fathead Minnow (*Pimephales promelas*) Embryos and Larvae. Unpublished study prepared by Ciba-Geigy, Inc. 36 p.
- 40995807 Canez, V. (1988) Ametryn: Nontarget Phytotoxicity Test: Seed Germination Tier 2: Study No. LR88-55B. Unpublished study prepared by Pan-Agricultural Labs, Inc. 72 p.



- 40995808 Canez, V. (1988) Ametryn: Nontarget Phytotoxicity Test: Seedling Emergence Tier 2: Study No. LR88-55C. Unpublished study prepared by Pan-Agricultural Labs, Inc. 281 p.
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## **Appendix E. Batching of Ametryn Products**

There is only one ametryn technical product and only one ametryn end use product. Therefore no batching is required.

## **Appendix F. List of Registrants to be sent the Data Call-In**

There is only one registrant, Syngenta Crop Protection, Inc. for both the remaining ametryn technical (100-579) and remaining end use product (100-786). The contact information is:

Mr. John Abbot  
Syngenta Crop Protection, Inc.  
PO Box 18300  
Greensboro, NC 27419-8300  
[www.syngenta.com](http://www.syngenta.com)

**Appendix G. 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@epa.gov](mailto:williams.nicole@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	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product_	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>
8570-27	Formulator's Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>

8570-28	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>
8570-30	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-35	Data Matrix (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>

**Pesticide Registration Kit**

[www.epa.gov/pesticides/registrationkit/](http://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](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/Amendment
  - b. 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
  - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - c. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
  - g.. 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' website.
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.

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 website.
4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website: <http://npic.orst.edu>.

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:

- a. Date of receipt;
- b. EPA identifying number; and
- c. 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 chemical abstract system (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 Label Usage Information System (LUIS) Report.