

Simazine RED

April 6, 2006

SEPA

Reregistration Eligibility Decision for Simazine

$Reregistration \ Eligibility \ Decision \ (RED) \ Document \ for \ Simazine$

List A

Case Number 0070

Approved by:		Date: April 6, 2006
	Debra Edwards, Ph. D.	
	Director	
	Special Review and Reregistra	tion Division

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Glossary of Terms and Abbreviations

AGDCI Agricultural Data Call-In

ai Active Ingredient

aPAD Acute Population Adjusted Dose

BCF Bioconcentration Factor
CFR Code of Federal Regulations
cPAD Chronic Population Adjusted Dose
CSF Confidential Statement of Formulation

CSFII USDA Continuing Surveys for Food Intake by Individuals

DCI Data Call-In

DEEM Dietary Exposure Evaluation Model

DFR Dislodgeable Foliar Residue
DNT Developmental Neurotoxicity

EC Emulsifiable Concentrate Formulation
EDWC Estimated Drinking Water Concentration
EEC Estimated Environmental Concentration
EPA Environmental Protection Agency

EUP End-Use Product

FDA Food and Drug Administration

FIFRA Federal Insecticide, Fungicide, and Rodenticide Act

FFDCA Federal Food, Drug, and Cosmetic Act

FQPA Food Quality Protection Act

GLN Guideline Number IR Index Reservoir

LC₅₀ Median Lethal Concentration. A statistically derived concentration of a

substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of a substance per weight or volume of

water, air, or feed, e.g., mg/l, mg/kg, or ppm.

LD₅₀ Median Lethal Dose. A statistically derived single dose that can be

expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight

of substance per unit weight of animal, e.g., mg/kg.

LOC Level of Concern

LOAEL Lowest Observed Adverse Effect Level

MATC Maximum Acceptable Toxicant Concentration

μg/g Micrograms Per Gram μg/L Micrograms Per Liter

mg/kg/day Milligram Per Kilogram Per Day

mg/L Milligram Per Liter MOE Margin of Exposure

MRID Master Record Identification Number. EPA's system for recording and

tracking studies submitted.

MUP Manufacturing-Use Product

NOAEL No Observed Adverse Effect Level OPP EPA Office of Pesticide Programs

OPPTS EPA Office of Prevention, Pesticides, and Toxic Substances

PAD Population Adjusted Dose

PCA Percent Crop Area

PDP USDA Pesticide Data Program
PHED Pesticide Handler's Exposure Data

PHI Pre-harvest Interval ppb Parts Per Billion

PPE Personal Protective Equipment

ppm Parts Per Million

PRZM/EXAMS Pesticide Root Zone Mode/Exposure Analysis Modeling System, Tier II

Surface Water Computer Model

Q* 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-GROW2 Tier I Ground Water Computer Model

SAP Science Advisory Panel

SF Safety Factor

SLC Single Layer Clothing

TGAI Technical Grade Active Ingredient
USDA United States Department of Agriculture

USGS United States Geological Survey

UF Uncertainty Factor

UV Ultraviolet

WPS Worker Protection Standard

Abstract

This document presents EPA's decision regarding the reregistration eligibility of the currently registered uses of the active ingredient simazine. The Agency has conducted human health and environmental fate and effects risk assessments for simazine and has made tolerance reassessment decisions for existing tolerances. Simazine has also been determined to share a neuroendocrine mechanism of toxicity with two other structurally-related chlorinated triazines, atrazine and propazine, and their three chlorinated degradates. The Agency has completed its cumulative risk assessment for the chlorinated triazine class of pesticides, concluding that with the mitigation measures in this document and in the 2003 IRED for atrazine the cumulative risks associated with these pesticides are below the Agency's level of concern. The Agency has determined that, with label amendments and changes as specified in this document and the 2003 IRED for atrazine, there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers, from the use of simazine, atrazine, and propazine. The Agency has determined that simazine will be eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

EPA has identified potential human health risks of concern associated with the current registered uses of simazine from dietary exposure from drinking water, residential exposure, and occupational exposure. EPA has also identified potential ecological risks of concern to non-target organisms. To reduce these exposures and to address subsequent risks of concern, EPA is requiring a number of mitigation measures such as prohibiting specific uses, formulations, and application methods; reducing maximum application rates to typical rates; establishing a performance standard for raw water concentrations; requiring appropriate PPE for occupational handlers; and adding setbacks from wells and waterways. The Agency is also requiring appropriate data to confirm the decisions presented in this RED. The Agency has determined that simazine is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions (REDs). The Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the Environmental Protection Agency (hereafter 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 hazards arising from the currently registered uses of a pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food; by August 3, 2006, EPA must review all tolerances in effect as of August 2, 1996. 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 among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment would be accomplished through the reregistration process.

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 exposure 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 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 classified the structurally-related chlorinated triazines atrazine, simazine, and propazine, and their three chlorinated degradates, as sharing a common neuroendocrine mechanism of toxicity. The Agency has completed its cumulative risk assessment for the chlorinated triazine class of pesticides and has concluded that with the mitigation measures in this document and in the 2003 Interim Reregistration Eligibility Decision (IRED) for atrazine the cumulative risks associated with these pesticides are below the Agency's level of concern. The cumulative risk assessment and supporting documents are available in the public docket EPA-

HQ-OPP-2005-0481 located on-line in the Federal Docket Management System (FDMS), http://www.regulations.gov.

This document presents EPA's revised human health and environmental fate and effects risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for simazine. The document consists of six sections. Section I contains the regulatory framework for reregistration and tolerance reassessment. Section II provides a description of the chemical and a profile of the use and usage of the chemical. Section III provides a summary of the human health and ecological risk assessments which have been revised based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's risk management, reregistration eligibility, and tolerance reassessment decisions. Section V summarizes the data requirements necessary to confirm the reregistration eligibility decision as well as label changes and language necessary to implement the risk mitigation measures outlined in Section IV. Section VI, the Appendices, provides related information and supporting documents. The preliminary and revised risk assessments for simazine are available in the public docket EPA-HQ-OPP-2005-0151 located on-line in FDMS, https://www.regulations.gov.

II. Chemical Overview

A. Chemical Identity

Chemical Structure:

3HC2HCHN N NHCH2CH3

Empirical Formula: $C_7N_5H_{12}C1$

Common Name: Simazine

CAS Name: 6-chloro-N,N'-diethyl-1,3,5-Triazine-2,4-diamine

CAS Registry Number: 122-34-9

OPP Chemical Code: 080807

Case Number: 0070

Technical Registrants: Drexel Chemical Co., Oxon Italia S.P.A./Sipcam Agro USA, Inc.,

and Syngenta Crop Protection, Inc.

Simazine is a chlorinated triazine herbicide, a class of herbicides that also includes the pesticides atrazine and propazine. The Registration Standard was completed for simazine on August 1, 1984. The Registration Standard also required the submission of generic and product-specific data to support the continued registration of simazine. A Data Call-In (DCI) was issued for simazine in September 1991. Subsequent DCIs were issued in August 1992, March 1995 and October 1995. This RED reflects an assessment of all data submitted to date.

In 1994 EPA's Office of Water (OW) established a Maximum Contaminant Level (MCL) for simazine in finished drinking water of 4.0 parts per billion (ppb). OW established this MCL under the Safe Drinking Water Act (SDWA) and simazine has been subject to compliance monitoring at Community Water Systems (CWS) since 1993. This compliance monitoring typically consists of samples taken quarterly at CWS in simazine use areas.

In November 1994, EPA initiated a Special Review for the triazine pesticides, which at that time included atrazine, simazine, and cyanazine, as announced in a *Federal Register* Notice, 59 *FR* 60412. The basis for the Special Review included the potential for cancer risks of concern resulting from dietary or occupational exposure as well as the potential for human health risks of concern resulting from drinking water exposure caused from ground and surface water contamination. At the time that the Special Review was initiated, atrazine and the other triazines were classified as Group C carcinogens, or possible human carcinogens. Cyanazine registrations were cancelled effective December 1999 and atrazine and simazine were later reclassified as "not likely to be carcinogenic to humans." The Agency expects to be able to close out the Special Review after considering comments from a Scientific Advisory Panel that will meet in 2007 to review currently available data and pending data from the National Cancer Institute concerning the carcinogenic potential of atrazine.

B. Use and Usage Profile

The following is information on the currently registered uses of simazine. Sections IV and V include information on those currently registered uses which are not eligible for reregistration and Appendix A provides a detailed table of those uses which are eligible for reregistration.

Type of Pesticide: Simazine is a systemic herbicide that is usually applied to soil,

absorbed through leaves and roots, and acts by inhibiting photosynthesis within the targeted plant. It is widely used as a selective herbicide to control most annual grasses and broadleaf weeds before they emerge or after removal of weed growth.

Formulations: Simazine is formulated as granules, pellets/tablets, dry flowables,

wettable powders, emulsifiable concentrates, flowable concentrates,

and ready-to-use liquids.

Methods of Application:

End-use products containing simazine may be applied on the ground by broadcast across an area, as a spot treatment, or in rows, which is also referred to as band treatment. Some products can also be applied by aerial broadcast.

Use Sites:

Simazine is registered for pre-plant use or use in established fields of a variety of food and feed crops including, but not limited to, fruit and nut crops, such as apples, oranges, and almonds, in addition to corn. Simazine can also be applied at forestry sites and on turfgrass grown commercially for sod. Nonagricultural uses for simazine include application as nonselective weed control on noncrop land, which consists of industrial sites, highway medians and shoulders, railroad rights-of-way, lumberyards, petroleum tank farms, and noncrop areas on farms such as around buildings, equipment and fuel storage areas, along fences, road-sides, and lanes. Simazine is also registered for residential use on turfgrass including both commercial use on recreational lawns such as golf courses and commercial or homeowner use on home lawns. There is an additional registration for simazine as an algaecide in ornamental ponds and aquariums of 1,000 gallons or less.

Application Rates:

For agricultural uses, the maximum use or application rates range from 1 to 9.6 pounds active ingredient per acre (lbs ai/A). For noncrop land, maximum application rates are 40 lbs ai/A, and for use specifically on turfgrass, 4 lbs ai/A.

Estimated Usage:

An estimated 5 to 7 million pounds of simazine are applied domestically to agricultural crops each year, and an additional 1.2 million pounds are applied for nonagricultural uses. Of these totals, nearly 2 million pounds of simazine are applied each year in the Midwest (more than 90% on corn); more than 1 million pounds are applied in California on fruits and nuts (90% on almonds, grapes, oranges, and walnuts); and more than 1 million pounds are applied in Florida on citrus (more than 85% on oranges and nearly 15% on grapefruit). Simazine is also used on a variety of other crops including, but not limited to, apples, peaches, filberts (i.e., hazelnuts), pecans, blackberries, and raspberries.

C. Tolerances

Currently there are 62 tolerances listed in 40 CFR 108.213 for simazine on agricultural crops and animal commodities. With the exception of tolerances set for bananas and fish, tolerances for simazine residues are currently expressed in terms of the parent compound (simazine) only. In addition to bananas and fish, tolerances for simazine currently exist for alfalfa, alfalfa (forage and hay), almond, almond (hulls), apple, avocado, Bermuda grass, Bermuda grass (forage and hay), blackberry, blueberry, boysenberry, cattle (fat, meat

byproducts, and meat), cherry, corn (forage, sweet, grain, and stover), cranberry, currant, dewberry, egg, filbert (i.e., hazelnut), goat (fat, meat byproducts, and meat), grapefruit, grape, grass, grass (forage and hay), hog (fat, meat byproducts, and meat), horse (fat, meat byproducts, and meat), lemon, loganberry, milk, macadamia nut, olive, orange, peach, pear, pecan, plum, poultry (fat, meat byproducts, and meat), raspberry, sheep (fat, meat byproducts, and meat), strawberry, sugarcane (molasses), and walnut. Section IV includes a summary of the tolerance reassessment decision for simazine and lists those tolerances the Agency will propose to revoke, decrease, increase, maintain, reassign, and establish.

III. Summary of Risk Assessments

A. Human Health Risk Assessment

1. Hazard Profile

Historically, EPA's Office of Pesticide Programs (OPP) has classified pesticides into four acute toxicity categories ranging from Toxicity Category I (most toxic) to Toxicity Category IV (least toxic). These toxicity categories reflect the doses or concentrations that, in an acute toxicity study, are lethal to at least 50% of the test animals in the group or are severely irritating. Non-lethal endpoints, such as those observed in histophathological evaluations or through clinical chemistry measurements, are not reflected in the toxicity categories. OPP uses six separate studies to determine the toxicity category classification for a pesticide – an acute oral study, an acute dermal study, an acute inhalation study, an eye irritation study, a skin irritation study, and a dermal sensitization study. Simazine is not acutely toxic and is classified as Toxicity Category IV via the oral route of exposure and Toxicity Category III via the dermal and inhalation routes of exposure. Simazine is not an eye or skin irritant, nor is the compound a dermal sensitizer. This information is summarized in Table 1.

Table 1. Summary of Acute Toxicity Categorization for Simazine

Guideline Number	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute Oral	00148897	LD ₅₀ > 5 g/kg (males and females combined)	IV
870.1200	Acute Dermal	00148898	$LD_{50} > 2 g/kg$	III
870.1300	Acute Inhalation	00148899	$LC_{50} > 1.71 \text{ mg/L}$	III
870.2400	Primary Eye Irritation	00148900	Slight irritant	IV
870.2500	Primary Dermal Irritation	00148901	PIS = 0.2	IV
870.2600	Dermal Sensitization	41184501	Negative	N/A

In a sub-chronic developmental toxicity study, incomplete or absent bone formation or ossification was observed in fetal rats following exposure of pregnant rats to simazine. These developmental effects are presumed to occur after a single exposure and are therefore appropriate for consideration in the acute exposure scenario for dietary risk from food and drinking water.

After subchronic and chronic exposure to simazine, a variety of species were shown to exhibit neuroendocrine effects resulting in both reproductive and developmental consequences that are considered relevant to humans. These effects are biomarkers of a neuroendocrine mechanism of toxicity that is shared by several other structurally-related chlorinated triazines including atrazine, propazine, and three chlorinated degradates – G-28279 (des-isopropyl atrazine or DIA), and G-30033 (des-ethyl atrazine or DEA), and G-28273 (diaminochlorotriazine or DACT) – the first and last of which can result from the degradation of simazine. These six compounds disrupt the hypothalamic-pituitary-gonadal (HPG) axis, part of the central nervous system, causing cascading changes to hormone levels and developmental delays. These neuroendocrine effects are considered the primary toxicological effects of regulatory concern for all subchronic and chronic exposure scenarios including dietary risk from food and drinking water, residential risk, and occupational risk.

Simazine's two chlorinated degradates, DIA and DACT, are considered to have toxicity equal to the parent compound in respect to their common neuroendocrine mechanism of toxicity. Another degradate, G-30414 (hydroxy-simazine), was identified, which is expected to have a different toxicological profile from simazine based on the toxicological data available for an analogous metabolite for atrazine, hydroxy-atrazine. On the basis of the results of a risk assessment for hydroxy-atrazine that showed minimal exposure and risk, anticipated exposure, and consequently risk, to hydroxy-simazine in the diet would be expected to be very small. Therefore the degradate hydroxy-simazine was not included in the human health risk assessment.

Simazine was originally classified in 1989 as a Group C carcinogen, or possible human carcinogen, and was considered to have a non-threshold mechanism for tumor formation. In other words, a threshold, or dose below which the risk of developing cancer is negligible, had not been identified for simazine. Mode of action data were later received and examined by the Agency in regards to the ability of atrazine to induce mammary tumors in female rats through the neuroendocrine mechanism of toxicity the compound shares with simazine. As a result of evidence that the events leading to the tumor formation are species/strain specific and not operative in humans, atrazine was reclassified in 2000 as "not likely to be carcinogenic to humans." Simazine was similarly reclassified in 2005 based on weight-of-evidence that it is not genotoxic and operates via a mode of action for the development of mammary and pituitary tumors in female rats similar to atrazine. Consequently, cancer risks have not been assessed in the human health risk assessment.

Following the 2000 reclassification of atrazine and during the reregistration process for atrazine, the Agency reviewed subsequent cancer epidemiology studies regarding atrazine's potential link to cancer and convened a Scientific Advisory Panel (SAP) to further review the studies. Results of these studies did not alter EPA's conclusion that atrazine is "not likely to be carcinogenic to humans." EPA has recently received three new pieces of information concerning atrazine and its possible association with carcinogenic effects: a report from the National Cancer Institute (NCI) re-analyzing previous epidemiologic studies of atrazine and non-Hodgkin's lymphoma, an epidemiological study of all cancers related to atrazine exposure from NCI's Agricultural Health Study, and a nested case-control study conducted for Syngenta Crop Protection, Inc. of workers at an atrazine manufacturing plant in St. Gabriel, Louisiana. These studies are currently undergoing review. At this time there are two other studies pending in the near future from NCI's Agricultural Health Study that will include atrazine. EPA expects to

receive and review in 2006 or early 2007 an updated epidemiological study and analysis concerning the potential connection between multiple pesticides and prostate cancer as well as a similar study on non-Hodgkin's lymphoma, although completion of the latter study depends upon identification by NCI of enough cases of this relatively rare cancer.

After the two pending studies have been received and reviewed, the Agency plans to convene another SAP meeting in 2007 concerning atrazine and its possible association with carcinogenic effects. At that meeting, EPA intends to present the SAP with all of the data bearing on atrazine and cancer, including old and new epidemiology studies and laboratory animals studies. In the meantime, EPA will continue to review all new data submissions in addition to the NCI studies. If at any time results from any of these submissions raise significant questions that would benefit substantially from SAP review prior to submission of all of the data, the Agency will hold a SAP meeting before all aspects of NCI's Agricultural Health Study are completed. EPA intends to thoroughly review any SAP report from any future meeting, once issued, and to review its determinations regarding the carcinogenic potential of atrazine, and simazine, as necessary. EPA will also continue to review any future additional studies performed by NCI that include atrazine or simazine.

Based on the toxicity profile and major exposure routes of simazine and its two chlorinated degradates, toxicological endpoints (based on critical health effects observed in toxicity studies on animals) and corresponding doses or concentrations, were derived for the following exposure durations: acute (1 day) for females ages 13 to 49 only, short-term (1-30 days), intermediate-term (1 month-6 months), and long-term or chronic (more than 6 months). All endpoints, aside from the acute endpoint used for females ages 13 to 49 derived from a toxicity study on animals exposed to simazine, were derived from toxicity studies on animals exposed to atrazine in lieu of simazine-specific studies. Because the database for simazine's potential neuroendocrine effects is less robust than the atrazine database, particularly for the young, the Agency concluded that atrazine data could be used as bridging data for simazine due to the fact that simazine and atrazine share the neuroendocrine mechanism of toxicity described above and that these neuroendocrine effects are considered the primary toxicological effects of regulatory concern for the relevant exposure durations. These effects are considered to be applicable to the general U.S. population, including infants and children.

Table 2 presents a summary of the toxicological endpoints and corresponding doses or concentrations for each exposure scenario considered. The vocabulary and calculations in this table are further explained below.

Table 2. Summary of toxicological endpoints and corresponding doses and concentrations for simazine

Exposure Scenario	Dose or Concentration used in Human Health Risk Assessment, Uncertainty Factor (UF) and Level of Concern (LOC) of Occupational Assessment	Special FQPA Safety Factor (SF) and LOC for Dietary and Human Health Risk Assessment	Study and Toxicological Effects/Endpoints
Acute Dietary (females ages 13-49)	Developmental NOAEL ^a = 30 mg/kg/day UF = 100 aRfD ^b = 0.3 mg/kg/day	3X for residual exposure-based uncertainty when monitoring data were used to estimate drinking water exposure. aPAD ^c = aRfD/FQPA SF aPAD = 0.1 mg/kg/day	MRID 40614403 Developmental study in rats w/ simazine LOAEL ^d = 300 mg/kg/day based on increased incidence of unossified teeth, head, centra vertebrae, sternabrae, and also on rudimentary ribs
Acute Dietary (general U.S. population)	N/A	N/A	No toxic effect attributable to a single dose was identified for the general U.S. population
Chronic Dietary (all populations)	NOAEL = 1.8 mg/kg/day UF = 100 cRfD = 0.018 mg/kg/day	10X: 3X for residual hazard- based uncertainty and an additional 3X for uncertainty when monitoring data were used to estimate drinking water exposure. cPAD = cRfD/FQPA SF cPAD = 0.0018 mg/kg/day	MRID 44152102 6-month LH surge study in rat w/ atrazine LOAEL = 3.65 mg/kg/day based on estrous cycle alterations and LH surge suppression
Incidental Oral Short-Term	NOAEL = 6.25 mg/kg/day UF = 100	3X for residual hazard-based uncertainty LOC = 300 (MOE°)	No MRID (Stoker, Laws, Guidici, and Cooper, 2000) 28-day Pubertal study in rats w/ atrazine LOAEL = 12.5 mg/kg/day based on delayed preputial separation
Incidental Oral Intermediate- Term	NOAEL = 1.8 mg/kg/day UF = 100	3X for residual hazard-based uncertainty LOC = 300 (MOE) residential	MRID 44152102 6-month LH surge study in rat w/ atrazine LOAEL = 3.65 mg/kg/day based on estrous cycle alterations and LH surge suppression
Dermal Short- Term	NOAEL = 6.25 mg/kg/day UF = 100 LOC = 100 (MOE) occupational	3X for residual hazard-based uncertainty LOC = 300 (MOE) residential	No MRID (Stoker, Laws, Guidici, and Cooper, 2000) 28-day Pubertal study in rats w/ atrazine LOAEL = 12.5 mg/kg/day based on delayed preputial separation

Exposure Scenario	Dose or Concentration used in Human Health Risk Assessment, Uncertainty Factor (UF) and Level of Concern (LOC) of Occupational Assessment		Special FQPA Safety Factor (SF) and LOC for Dietary and Human Health Risk Assessment	Study and Toxicological Effects/Endpoints
Dermal Intermediate- Term	UF = 10	100 (MOE)	3X for residual hazard-based uncertainty LOC = 300 (MOE) residential	MRID 44152102 6-month LH surge study in rat w/ atrazine LOAEL = 3.65 mg/kg/day based on estrous cycle alterations and LH surge suppression
Dermal Long- Term	NOAEL = 1.8 mg/kg/day UF = 100 LOC = 100 (MOE) occupational		UF = 100 uncertainty $LOC = 300 (MOE) residential$ $LOC = 100 (MOE)$	
Inhalation Short- Term	NOAEL = 6.25 mg/kg/day UF = 100 LOC = 100 (MOE) occupational		3X for residual hazard-based uncertainty LOC = 300 (MOE) residential	surge suppression No MRID (Stoker, Laws, Guidici, and Cooper, 2000) 28-day Pubertal study in rats w/ atrazine LOAEL = 12.5 mg/kg/day based on delayed preputial separation
Inhalation Intermediate- Term	NOAEL = 1.8 mg/kg/day UF = 100 LOC = 100 (MOE) occupational		3X for residual hazard-based uncertainty LOC = 300 (MOE) residential	MRID 44152102 6-month LH surge study in rat w/ atrazine LOAEL = 3.65 mg/kg/day based on estrous cycle alterations and LH surge suppression
Inhalation Long- Term	NOAEL = 1.8 mg/kg/day UF = 100 LOC = 100 (MOE) occupational		3X for residual hazard-based uncertainty LOC = 300 (MOE) residential	MRID 44152102 6-month LH surge study in rat w/ atrazine LOAEL = 3.65 mg/kg/day based on estrous cycle alterations and LH surge suppression
Dermal absorption Cancer (oral, derminhalation)	,		*	ted in April 14, 2005 CARC Report, to mon mode of toxicity with atrazine.

^a NOAEL = no observed adverse effect level
^b aRfD and cRfD = acute (a) and chronic (c) Reference Dose
^c aPAD and cPAD = acute (a) and chronic (c) population adjusted dose
^d LOAEL = lowest observed adverse effect level
^e MOE = margin of exposure

2. Dietary Exposure and Risk from Food

EPA considers acute, chronic, and, if relevant, cancer dietary risks from food. Acute dietary risk from food is calculated considering what is eaten in one day and maximum, or highend, residue values in food. An acute risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD), the dose at which an individual could be exposed on any given day and no adverse health effects would be expected, is not of concern to the Agency. Chronic dietary risk from food is calculated using the average food consumption values for each population subgroup and average residue values in/on those foods over a 70 year lifetime to determine average exposure. A chronic risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD), the dose at which an individual could be exposed over the course of a lifetime and no adverse health effect would be expected, is not of concern to the Agency.

The aPAD and cPAD are the acute reference dose (aRfD) and the chronic reference dose (cRfD), respectively, adjusted for the Food Quality Protection Act (FQPA) safety factor, a method of accounting for the potential for increased susceptibility of infants and children to toxic effects. The Agency determined it was unnecessary to retain a safety factor in the acute dietary assessment to account for hazard-based uncertainty because open literature data demonstrate that any neuroendocrine effect, the primary toxicological effects of regulatory concern, that could result from a single dose would only occur at a very high dose. However, when available water monitoring data were used to estimate drinking water exposure, a 3X FQPA safety factor was retained to account for exposure-based uncertainty due to limitations in the monitoring database. The full 10X FQPA safety factor was retained and applied to the chronic dietary assessment to account for both exposure-based uncertainty in the water monitoring data and because of residual uncertainty regarding the effects of the neuroendocrine mechanism of action on the developing child. When drinking water exposure estimates were calculated using modeling, a conservative approach likely to overestimate actual exposure, the FQPA Safety Factor was reduced to 1X for acute assessments and 3X for chronic assessments.

The aRfD and cRfD are derived from toxicity studies on animals and are based on the highest dose or level of exposure at which no adverse effects were observable ("no observed adverse effect level" or NOAEL). For simazine, a developmental endpoint was identified for acute exposure based on adverse effects of incomplete or absent bone formation observed in a developmental study on female rats exposed to simazine. A neuroendocrine endpoint was identified for chronic exposure based on adverse effects of estrous cycle alterations and luteinizing hormone (LH) surge suppression observed in an LH surge study on female rats exposed to atrazine. Neuroendocrine effects such as these are the primary toxicological effects of regulatory concern for simazine. Corresponding NOAELs are listed below. A total uncertainty factor of 100X is applied to the NOAELs in calculating the aRfD and cRfD to account for both intraspecies variability (i.e., differences among humans) at 10X and interspecies extrapolation (i.e., uncertainty in extrapolating from animal data to humans) at 10X.

Potential residues of concern in food are simazine plus its two chlorinated degradates DIA and DACT. Existing field trial data, the United States Department of Agriculture's (USDA) Pesticide Data Program (PDP), and the Food and Drug Administration's (FDA) monitoring data indicate non-detectable residues (less than 0.05 ppm) of simazine. Given that simazine is an

herbicide applied mostly pre-plant by broadcast or by band treatment (where pesticide is applied to the field in bands or rows) to soil, the lack of detections in edible portions of crops is not surprising. Dietary exposure to simazine from food is estimated to be essentially zero, resulting in a risk estimate of 0% of the aPAD and cPAD which is not of concern to the Agency.

- Estimated acute dietary risk from food for females ages 13 to 49 only is 0% of the aPAD.
 - o aPAD of 0.1 mg/kg/day = 0.3 mg/kg/day (aRfD) \div 3 (FQPA safety factor)
 - o aRfD of 0.3 mg/kg/day = 30 mg/kg/day (NOAEL) ÷ 100 (uncertainty factor for intraspecies variability and interspecies extrapolation)
- Estimated chronic dietary risk from food for the general U.S. population and all subgroups is 0% of the cPAD.
 - o cPAD of 0.0018 mg/kg/day = 0.018 mg/kg/day (cRfD) \div 10 (FQPA safety factor)
 - o cRfD of 0.018 mg/kg/day = 1.8 mg/kg/day (NOAEL) ÷ 100 (uncertainty factor for intraspecies variability and interspecies extrapolation)

3. Dietary Exposure and Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers acute, chronic, and, if relevant, cancer dietary risks from drinking water and uses either modeling or monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution from water in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then calculates a "drinking water level of comparison" (DWLOC) using the acute or chronic PAD as described above. The DWLOC represents the maximum contribution to the human diet (in ppb) that may be attributed to residues of a pesticide in drinking water after dietary exposure from food is considered. Acute and chronic risks from drinking water are assessed by determining if the DWLOC is exceeded by monitored or modeled concentrations in both surface and ground water. Concentrations that are less than the DWLOC are below the Agency's level of concern.

For simazine, the DWLOCs are based on 100% of the aPAD and cPAD because dietary exposure from food has been estimated at zero. Simazine is persistent and mobile and detected in both surface and ground water. Potential residues of concern in drinking water are simazine plus its two chlorinated degradates, DIA and DACT. DWLOCs were calculated for various subpopulations for comparison against concentrations of simazine and its two chlorinated degradates as monitored in drinking water and as predicted through modeling which the Agency believes to be conservative and protective. For those DWLOCs calculated for comparison to concentration values generated through conservative modeling, the 3X FQPA safety factor included in the calculation to account for exposure-based concerns for inadequate monitoring data was removed because the models are protective and provide upper-bound concentrations.

DWLOCs for comparison against concentrations as monitored in drinking water:

- Acute DWLOC for females ages 13 to 49 only for comparison against maximum peak water concentration based on monitoring data = 3000 ppb
- Chronic DWLOC for comparison against 90-day average and annual average concentrations based on monitoring data:
 - o Infants and children less than 1 year old = 12.5 ppb
 - o Children ages 1 to 6 = 23 ppb
 - o Children ages 7 to 12 = 53 ppb
 - \circ Females ages 13 to 49 = 60 ppb
 - o General U.S. population = 68 ppb

DWLOCs for comparison against concentrations as predicted though modeling:

- Acute DWLOC for females ages 13 to 49 only for comparison against maximum peak water concentrations based on models = 9000 ppb
- Chronic DWLOC for comparison against 90-day average and annual average concentrations based on models:
 - o Infants and children less than 1 year old = 37.5 ppb
 - o Children ages 1 to 6 = 69 ppb
 - o Children ages 7 to 12 = 159 ppb
 - o Females ages 13 to 49 = 180 ppb
 - o General U.S. population = 204 ppb

The human health risk assessment used both monitoring and modeling data to estimate concentrations and focused on five regions where simazine is used – the Midwest (corn), the Mid-Atlantic (corn and fruit trees), Washington (fruit trees), California (nuts, fruit trees, and citrus), and Florida (citrus). Monitoring data were used to identify maximum peak, 90-day average, and annual average concentrations of simazine for the Midwest, the Mid-Atlantic, and Washington. Monitoring data for simazine are available from the Population-Linked Exposure Database (PLEX), which contains data initially collected to comply with monitoring requirements in SDWA, and from the registrant-supported monitoring programs Voluntary Monitoring Program (VMP) and Atrazine Monitoring Program (AMP). PLEX includes measurements taken primarily on a quarterly basis (i.e., a maximum of four per year) for concentrations of simazine only in finished (treated) water in CWS with both surface and ground water sources. The VMP/AMP database includes more frequent measurements for concentrations of simazine and its two chlorinated degradates in both raw and finished water in select CWS where there is a history of atrazine use. The Agency used a simple linear regression analysis to derive an equation representing the relationship between the sum of the parent compound (simazine) plus its two chlorinated degradates and levels of the parent compound alone. The regression equation is (simazine + DACT + DIA) = 0.364 + 1.378 * (simazine).This analysis allowed EPA to derive conservative estimates of concentrations for total simazine plus its two chlorinated degradates when these data were not available in the databases.

Estimated maximum peak, 90-day average, and annual average concentrations of simazine in surface water for California and Florida were generated using the predictive model Pesticide Root Zone Mode/Exposure Analysis Modeling System (PRZM/EXAMS) because sufficient monitoring data were not available for areas where simazine use is most intensive in these states. PLEX contains infrequent and sparse measurements from California and Florida and the VMP/AMP database does not include measurements from these states. Modeling was performed to estimate concentrations in drinking water derived from surface water sources which might occur near nut, fruit tree, and citrus growing areas of these regions as well as nationwide, representing the three sites with the highest simazine use in California and Florida.

The modeled scenarios include the following and are listed in Table 3: almonds in California with a banded application rate (where the pesticide is applied to the field in bands or rows rather than broadcast) to represent use at this application rate on nuts in California; a second scenario for almonds in California with a higher broadcast application rate and a separate scenario for pecans and other nuts in Georgia (an area of more abundant rainfall) with a broadcast application rate, both scenarios together representing use on nuts grown nationwide including macadamia nut production in Hawaii and California; fruit in California with a banded application rate to represent use at this application rate on fruit trees (apples, cherries, nectarines, peaches, pears, and plums) in California; a second scenario for fruit in California with a higher broadcast application rate and a separate scenario for peaches in Georgia with a broadcast application rate, both scenarios together representing use on fruit trees grown nationwide; citrus in California with a broadcast application rate; and citrus in Florida with a broadcast application rate. As with monitoring data, the Agency used an equation representing the relationship between the sum of the parent compound (simazine) plus its two chlorinated degradates and levels of the parent compound alone to derive conservative estimates of concentrations for total simazine plus its two chlorinated degradates.

Modeling was also performed to provide estimates of simazine concentrations in ground water using the Screening Concentration in Ground Water model or SCI-GROW2. SCI-GROW2 provides estimated concentrations of the parent compound when the pesticide is used at a high application rate in areas where ground water is vulnerable to contamination. Estimates for use on citrus in Florida and citrus and grapes in Texas were generated. The Agency does not believe that the equation used to derive estimates of concentrations for total simazine plus its two chlorinated degradates in surface water can be reliably used for ground water, so only concentrations of the parent compound were estimated for ground water.

The Agency considered data from USDA's PDP, EPA's Chesapeake Bay Program, and the U.S. Geological Survey's National Water-Quality Assessment Program (NAWQA), as well as data from the states of California and Florida, to characterize results from both monitoring and modeling data. The data demonstrate that ambient concentrations are capable of reaching high levels under the proper combination of application timing and climatic conditions although indications of these concentrations were not evident in PLEX or VMP/AMP. The Agency also considered data from the Rural Well Survey that was submitted during atrazine's reregistration process to further address rural wells, a ground water source of drinking water of particular importance in Florida. In the Rural Well Survey, measurements of simazine were taken once from each of 402 wells across seven states and ranged up to 11 ppb for the parent compound (simazine) alone.

No surface or ground water concentrations generated from either monitoring or modeling data exceed the acute DWLOC; therefore, acute exposure to simazine plus its two chlorinated degradates in drinking water is below the Agency's level of concern.

No CWS in the Midwest with a ground water source was identified in the available monitoring data with concentrations that indicate the system may exceed the chronic DWLOC for infants and children less than 1 year old, the most sensitive subpopulation. However, one CWS in the Midwest with a surface water source, Hillsboro CWS of Illinois, had a maximum 90-day average concentration in 1994 of 25.2 ppb simazine plus its two chlorinated degradates, indicating the system may exceed the chronic DWLOC for infants and children less than 1 year old. While the human health risk assessment also identifies Defiance City CWS of Ohio as having a concentration of concern, upon further review of the monitoring data, the Agency has concluded that the maximum 90-day average concentration is lower than previously calculated, and no concentrations for this CWS are of concern to the Agency. No surface or ground water CWS in the Mid-Atlantic or Washington were identified in the monitoring data with concentrations indicating a potential exceedance of the chronic DWLOC for infants and children less than 1 year old.

Modeled surface water concentrations exceed the chronic DWLOC for infants and children and are of concern to the Agency for the following uses: nuts (mainly in California and Hawaii) when simazine is applied at a broadcast rate of 4 pounds active ingredient per acre (lbs ai/A); fruit trees (apples, cherries, nectarines, peaches, pears, and plums) in states other than California when applied at a broadcast rate of 4 lbs ai/A or higher; and citrus in Florida when simazine is applied at a broadcast rate of 9.6 lbs ai/A. Table 3 below presents all modeled scenarios with those concentrations bolded that exceed the chronic DWLOC of 37.5 ppb for infants and children less than 1 year old and/or 69 ppb for children ages 1 to 6.

Modeled surface water concentrations do not exceed the chronic DWLOC for any subpopulation, including infants and children less than 1 year old, for use on nuts when simazine is applied at a banded rate of 2 lbs ai/A; for use on fruit trees when simazine is applied at a banded rate of 2 lbs ai/A or when applied at a broadcast rate of 4 lbs ai/A in California; and for use on citrus in California when simazine is applied at a broadcast rate of 4 lbs ai/A.

Modeled ground water concentrations of the parent compound (simazine) alone also do not exceed the chronic DWLOC for any subpopulation, including infants and children less than 1 year old, for high rate uses in Florida (9.6 lbs ai/A on citrus = 11.7 ppb simazine) or Texas (4.8 lbs ai/A on grapes or citrus = 5.9 ppb simazine).

An additional national use that was not modeled but is also expected to exceed the chronic DWLOC of 204 ppb for the general U.S. population based on an application rate of 40 lbs ai/A, or a rate four times as high as the highest rate modeled, is nonselective weed control on noncrop land. This application rate is expected to produce modeled concentrations that are at least 4 times higher, and possibly much higher, than those for use on citrus in Florida. This use site includes, for instance, industrial sites, highway medians and shoulders, and noncrop areas around farms such as around buildings.

Table 3. 90-day average and annual average surface water concentrations of simazine plus its two chlorinated degradates for modeled scenarios

Crop (Location – application method) Application Rate ^a	90-day averages (ppb) ^b	Annual average (ppb) ^b
Almonds (CA – ground)	15.5	4.5
2.0 banded (equal to 0.89 assuming application to a band 2 feet on each side		
of the tree row)		
Represents use at this banded application rate on nuts in California		
Almonds (CA – ground)	66.6	43.3
4.0		
Represents use at this broadcast application rate on nuts in California		
Almonds (CA – aerial)	79	51.9
4.0		
Represents use at this broadcast application rate on nuts in California		
Pecans/nuts (GA – ground)	128.5	55.5
4.0		
Represents use at this broadcast application rate on nuts in states receiving		
more rainfall than California		
Pecans/nuts (GA – aerial)	132	56.8
4.0		
Represents use at this broadcast application rate on nuts in states receiving		
more rainfall than California		
Fruit (CA – ground)	7.2	5.3
2.0 banded (equal to 0.89 assuming application to a band 2 feet on each side		
of the tree row)		
Represents use at this banded application rate on fruit trees in California		
Fruit (CA – aerial)	34.2	23.5
4.0		
Represents use at this broadcast application rate on fruit trees in California		
Peaches (GA – ground)	99.6	55.5
4.0		
Represents use at this broadcast application rate on fruit trees in states		
receiving more rainfall than California		
Peaches (GA – aerial)	114.7	63.8
4.0		
Represents use at this broadcast application rate on fruit trees in states		
receiving more rainfall than California		

Crop (Location – application method) Application Rate ^a	90-day averages (ppb) ^b	Annual average (ppb) ^b
Citrus (CA – ground)	15.5	11
4.0		
Represents use at this broadcast application rate on citrus in California		
Citrus (CA – aerial)	33.3	23.3
4.0		
Represents use at this broadcast application rate on citrus in California		
Citrus (FL – ground)	132	50
9.6		
Represents use at this broadcast application rate on citrus in Florida		
Citrus (FL – aerial)	135	53
9.6		
Represents use at this broadcast application rate on citrus in Florida		

^a Pounds active ingredient per acre (lbs ai/A)

4. Residential Exposure and Risk

Residential risk is expressed as a Margin of Exposure (MOE) which reflects a determination of how close the residential exposure comes to the NOAEL determined in toxicity studies on animals. For simazine, a neuroendocrine endpoint was identified for short-term exposure based on an adverse effect of delayed preputial separation observed in a pubertal study on male rats exposed to atrazine. Neuroendocrine effects such as this are the primary toxicological effects of regulatory concern for simazine. The NOAEL determined for short-term exposure is 6.25 mg/kg/day. The MOE level of concern includes an uncertainty factor of 100X which includes 10X each for intraspecies variability (i.e., differences among humans) and interspecies extrapolation (i.e., uncertainty in extrapolating from animal data to humans). The total FQPA safety factor applied to the residential assessment for simazine was reduced from the default 10X FQPA safety factor to 3X. A 3X FQPA safety factor was retained to account for residual uncertainty regarding the effects of the neuroendocrine mechanism of action on the developing child. The Agency determined that it was unnecessary to retain an additional FQPA safety factor in the residential assessment to account for exposure-based uncertainty because the assessment is based on EPA's Standard Operating Procedures using high-end default values and assumptions that would be protective of infants and children. For simazine, a short-term MOE of 300 or greater is below EPA's level of concern.

Simazine is registered for residential use on turfgrass including both commercial use on recreational lawns such as golf courses and commercial or homeowner use on home lawns. Simazine is also registered for use in ornamental ponds and aquariums of 1,000 gallons or less. Risks were calculated, based on exposure to the parent compound (simazine) alone, for homeowner handler tasks for dermal and inhalation routes of exposure. Risks were similarly calculated for adults, youths (children ages 7 to 12), and toddlers (children ages 1 to 6) entering areas of turfgrass after application of simazine (post-application) for the dermal route of exposure. Post-application risk for toddlers was also calculated for the incidental oral route of exposure. Exposure in all of these scenarios is expected to be short-termonly. Dermal and inhalation absorption rates of 6% and 100%, respectively, as well as maximum application rates and estimates of what area homeowners would typically treat in a day, were assumed for each scenario assessed.

^b 1-in-10 year estimates

Of the four homeowner handler scenarios assessed, one results in a risk that exceeds the Agency's level of concern. The task of loading/applying granules via a belly grinder to turfgrass when simazine is applied at a rate of 1.75 lbs ai/A results in an MOE of 76 for short-term dermal exposure. When dermal exposure and inhalation exposure are combined for this scenario, the MOE that results is 75. For the post-application scenarios assessed for toddlers, youths, and adults, no risks exceed the Agency's level of concern (i.e., all MOEs are greater than or equal to 300).

5. Aggregate Exposure and Risk

In accordance with FQPA, the Agency considers and aggregates pesticide exposures and risks for dietary exposure (from both food and drinking water) as well as residential exposure if applicable. Based on a common endpoint of toxicity, acute, short-term, intermediate-term, and chronic risk from dermal, inhalation, and oral routes of exposure may be aggregated. Because dietary exposure to simazine from food is estimated to be zero, aggregate risks for simazine are driven by dietary exposure from drinking water and/or residential exposure.

Risk estimates for aggregate acute exposure are based on acute dietary exposure from drinking water only. As discussed above, no surface or ground water concentrations generated from either monitoring or modeling data exceed the acute DWLOC or the Agency's level of concern; therefore, acute exposure to simazine plus its two chlorinated degradates in drinking water is below the Agency's level of concern. Risk estimates for aggregate acute exposures to simazine and its two chlorinated degradates are also, therefore, below the Agency's level of concern.

Risk estimates for residential handlers from aggregate short-term exposure to simazine and its two chlorinated degradates are based on short-term residential exposure from the dermal and inhalation routes of exposure as well as chronic drinking water exposure. Risk estimates for adults, youths, and toddlers entering treated areas of turfgrass post-application from aggregate short-term exposure are based on short-term residential exposure from the dermal and incidental oral (where applicable) routes of exposure as well as chronic drinking water exposure.

EPA did not aggregate short-term residential exposures with dietary exposure from drinking water for those residential exposure scenarios with risk estimates already above EPA's level of concern. This applies to the MOE calculated for (adult) handlers loading/applying granules via a belly grinder to turfgrass, which is above the Agency's level of concern based on residential exposure only. However, the Agency did aggregate exposures when residential exposure alone was not above EPA's level of concern. No additional risk estimates for residential handlers from aggregate short-term exposure to simazine and its two chlorinated degradates exceed the Agency's level of concern.

Risk estimates for adults and youths entering treated areas of turfgrass post-application from aggregate short-term exposure also do not exceed the Agency's level of concern. However, risk estimates for toddlers entering treated areas of turfgrass post-application are of concern to the Agency when drinking water exposure is aggregated with short-term residential exposure.

The MOE calculated for toddlers entering treated areas of turfgrass post-application does not exceed the Agency's level of concern (i.e., is not below 300) based on short-term residential exposure only; however, modeled concentrations of simazine plus its two chlorinated degradates exceed the Agency's level of concern for toddlers in those scenarios noted above. Aggregating the two exposures, therefore, yields risk estimates above the Agency's level of concern.

Risk estimates for aggregate intermediate-term and chronic exposure are based on chronic dietary exposure from drinking water only as there is no residential exposure for these exposure durations. Risk estimates are of concern to infants, toddlers, and the general U.S. population for those scenarios previously noted.

6. Occupational Exposure and Risk

As with residential exposure, occupational risk is expressed as an MOE. For simazine, a neuroendocrine endpoint was identified for short-term exposure based on an adverse effect of delayed preputial separation observed in a pubertal study on male rats exposed to atrazine. A neuroendocrine endpoint was also identified for intermediate-term exposure based on adverse effects of estrous cycle alterations and LH surge suppression observed in an LH surge study on female rats exposed to atrazine. Neuroendocrine effects such as these are the primary toxicological effects of regulatory concern for simazine. The NOAEL determined for short-term exposure is 6.25 mg/kg/day and the NOAEL determined for intermediate-term exposure is 1.8 mg/kg/day. The MOE level of concern includes an uncertainty factor of 100X which includes 10X each for intraspecies variability (i.e., differences among humans) and interspecies extrapolation (i.e., uncertainty in extrapolating from animal data to humans). In the case of simazine, a short-term or intermediate-term MOE of 100 or greater from dermal and inhalation routes of exposure is not of concern to the Agency.

Occupational exposure and risk are estimated for handlers (mixers/loaders, applicators, flaggers, and mixer/loader/applicators) and re-entry workers who could be exposed when entering a treated area post-application to perform crop-production tasks. For simazine, occupational exposure may be shortor intermediate-term, but it is not expected to be long-term. Occupational exposure is expected to include the parent compound (simazine) alone. Dermal and inhalation absorption rates of 6% and 100%, respectively, as well as maximum application rates and the number of acres that can be reasonably treated in a day, were assumed for each scenario assessed. Based on a common endpoint of toxicity, dermal and inhalation exposure were combined in the calculation of risk.

a. Handler Exposure and Risk

Estimates of exposure for occupational handlers are based on the activity, the formulation type, the application method, and the clothing worn, and are normalized by the amount of pesticide handled for the particular activity. The MOEs for occupational handlers are also calculated at different levels of risk mitigation. Typically, the Agency uses a tiered approach with the lowest tier designated as baseline exposure. Baseline assumes the occupational handler is wearing a long-sleeve shirt, long pants, socks, and shoes but no personal protective equipment (PPE), such as gloves or a respirator. If risks are of concern at baseline, then increasing levels of

PPE (e.g., double layer clothing such as coveralls, gloves, respirators) are evaluated. If risks remain of concern with maximum PPE, then engineering controls (e.g., water-soluble packaging, closed mixing/loading systems, enclosed cabs or cockpits) are evaluated. For simazine the following occupational handler scenarios were assessed at various levels of risk mitigation:

Mixer/Loaders:

- o (1a) Liquids for Aerial Applications
- o (1b) Liquids for Chemigation Applications
- o (1c) Liquids for Groundboom Applications
- o (1d) Liquids for Rights-of-way Applications
- o (1e) Liquids to Support Lawn Care Operator Handgun Applications
- o (2a) Wettable Powder for Aerial Applications
- o (2b) Wettable Powder for Groundboom Applications
- o (2c) Wettable Powder for Chemigation Applications
- o (2d) Wettable Powder for Rights-of-way Applications
- o (2e) Wettable Powder to Support Lawn Care Operator Handgun Applications
- o (3a) Dry Flowables for Aerial Applications
- o (3b) Dry Flowables for Chemigation Applications
- o (3c) Dry Flowables for Groundboom Applications
- o (4a) Granulars for Aerial Applications
- o (4b) Granulars for Tractor Drawn Spreader Applications

• Applicators:

- o (5) Aerial Spray Applications
- o (6) Aerial Granular Applications
- o (7) Groundboom Spray Applications
- o (8) Tractor Drawn Granular Applications
- o (9) Handgun Applications (Lawn Care Operator)
- o (10) Rights-of-way Spray Applications

• Flaggers:

- o (11) Flagging for Aerial Spray Applications
- o (12) Flagging for Aerial Granular Applications

• Mixer/Loader/Applicators:

- o (13) Liquid: Low Pressure Handward Sprayer
- o (14) Liquid: Handgun Sprayer
- o (15) Wettable Powder: Low Pressure Handwand
- o (16) Wettable Powder: Handgun Sprayer
- o (17) Granulars: Pumpfeed Backpack Applicator
- o (18) Granulars: Gravity-feed Backpack Applicator
- o (19) Granulars: Push Type Spreader
- o (20) Granulars: Belly Grinder
- o (21) Dry Flowable: Handgun Sprayer

For the 32 occupational handler scenarios assessed, most short-term MOEs are not of concern to the Agency when some level of risk mitigation is considered. However, for 6 scenarios, short-term MOEs are of concern to the Agency even with maximum feasible risk mitigation included. For 18 scenarios, intermediate-term MOEs are of concern to the Agency, even with maximum feasible risk mitigation included. Potential risks of concern exist particularly for those scenarios with relatively high acres treated (e.g., use on corn) or relatively high maximum application rates (e.g., use on rights-of-way, representing use as nonselective weed control on non-crop land).

Tables 4 and 5 below present those scenarios for which MOEs remain below 100 with maximum risk mitigation feasible for those scenarios taken into account. The maximum MOEs attainable for each scenario are bolded.

Table 4. Occupational handler scenarios with short-term MOEs less than 100

Exposure Scenario	Application	n Area Combined MOEs (Dermal + Inhalation)						
	Rate ^a	Treated Daily (acres)	Baseline	Gloves, single layer (no respirator)	Gloves, double layer (no respirator)	Gloves, single layer + PF 5 Respirator	Gloves, double layer + PF 5	Engineering Control (no respirator)
Mixing/Loading Dry Flowables to Support Aerial Applications (3a)	16	350	16	16	22	19	Respirator 26	93
Applying Granulars via Aerial Equipment (6)	40	350	No Data	No Data	No Data	No Data	No Data	22
Mixing/Loading/	16	5	No Data	3.4	3.7	7.4	9.2	Not Feasible
Applying Wettable	4	5	No Data	14	15	30	37	Not Feasible
Powders with Low	3	5	No Data	18	20	40	49	Not Feasible
Pressure Handwand (15)	2	5	No Data	27	30	59	74	Not Feasible
Loading/Applying	40	10	No Data	17	No Data	18	No Data	Not Feasible
Granulars via Pumpfeed Backpack Applicator (17)	8	10	No Data	86	No Data	90	No Data	Not Feasible
Loading/Applying Granulars via Gravity-feed Backpack Applicator (18)	40	10	No Data	14	No Data	24	No Data	Not Feasible
Loading/Applying Granulars via Belly Grinder (20)	40	1	17	18	27	19	31	Not Feasible

^a Pounds active ingredient per acre (lbs ai/A)

Table 5. Occupational handler scenarios with intermediate-term MOEs less than 100

Exposure Scenario	Application	Area Combined MOEs (Dermal + Inhalation)						
	Rate ^a	Treated Daily (acres)	Baseline	Gloves, single layer (no respirator)	Gloves, double layer (no respirator)	Gloves, single layer + PF 5 Respirator	Gloves, double layer + PF 5 Respirator	Engineering Control (no respirator)
Mixing/Loading	16	350	0.11	7.5	8.7	12	15	32
Liquid Concentrates								
to Support Aerial Applications (1a)	4	1200	0.13	8.7	10	14	18	38
Mixing/Loading Wettable Powders to	4	1200	0.085	0.42	0.44	1.2	1.4	27
Support Aerial Applications (2a)	4	350	0.29	1.5	1.5	4.1	4.7	92
Mixing/Loading Wettable Powders to Support Chemigation Applications (2c)	4	350	0.29	1.5	1.5	4.1	4.7	92
Mixing/Loading Dry	16	350	4.1	4.1	5.4	4.7	6.5	23
Flowables to Support	4	1200	4.8	4.8	6.3	5.5	7.6	28
Aerial Applications (3a)	4	350	16	16	22	19	26	92
Mixing/Loading Dry Flowables to Support Chemigation Applications (3b)	4	350	16	16	22	19	26	92
Applying Sprays via	16	350	No Data	No Data	No Data	No Data	No Data	52
Aerial Equipment (5)	4	1200	No Data	No Data	No Data	No Data	No Data	61
Applying Granulars	40	350	No Data	No Data	No Data	No Data	No Data	6
via Aerial Equipment	4	350	No Data	No Data	No Data	No Data	No Data	55
(6)	3	350	No Data	No Data	No Data	No Data	No Data	73
Applying Granulars via Tractor Drawn Spreader (8)	40	80	19	21	23	50	69	96
Applying Sprays with Rights-of-Way Equipment (10)	3	40	11	33	42	37	50	Not Feasible
Mixing/Loading/ Applying Liquid Concentrates with Low Pressure Handwand (13)	16	5	0.22	24	26	42	48	Not Feasible
Mixing/Loading/ Applying Liquid Concentrates with a Handgun Sprayer (14)	16	5	No Data	47	80	49	88	Not Feasible
Mixing/Loading/	16	5	No Data	0.83	0.92	1.8	2.3	Not Feasible
Applying Wettable	4	5	No Data	3.3	3.7	7.3	9.1	Not Feasible
Powders with Low	3	5	No Data	4.5	4.9	9.8	12	Not Feasible
Pressure Handwand	2	5	No Data	6.7	7.3	15	18	Not Feasible
(15)	1	5	No Data	13	15	29	36	Not Feasible

Exposure Scenario	Application	Area		Comb	oined MOEs	(Dermal + In	halation)	
	Rate ^a	Treated Daily (acres)	Baseline	Gloves, single layer (no respirator)	Gloves, double layer (no respirator)	Gloves, single layer + PF 5 Respirator	Gloves, double layer + PF 5 Respirator	Engineering Control (no respirator)
Mixing/Loading/ Applying Wettable Powders with a Handgun Sprayer (16)	16	5	No Data	12	15	22	35	Not Feasible
Loading/Applying	40	10	No Data	4.2	No Data	4.5	No Data	Not Feasible
Granulars via	8	10	No Data	21	No Data	22	No Data	Not Feasible
Pumpfeed Backpack	4	10	No Data	42	No Data	45	No Data	Not Feasible
Applicator (17)	3	10	No Data	56	No Data	59	No Data	Not Feasible
Loading/Applying	40	10	No Data	3.4	No Data	6	No Data	Not Feasible
Granulars via	8	10	No Data	17	No Data	30	No Data	Not Feasible
Gravity-feed	4	10	No Data	34	No Data	60	No Data	Not Feasible
Backpack Applicator (18)	3	10	No Data	45	No Data	81	No Data	Not Feasible
Loading/Applying Granulars via Push Type Spreader (19)	40	5	19	26	39	37	67	Not Feasible
Loading/Applying	40	1	4.1	4.4	6.7	4.7	7.6	Not Feasible
Granulars via Belly	8	1	20	22	33	24	38	Not Feasible
Grinder (20)	4	1	41	44	67	47	76	Not Feasible
Mixing/Loading/ Applying Dry Flowables Concentrates with a Handgun Sprayer (21)	16	5	No Data	24	32	34	56	Not Feasible

^a Pounds active ingredient per acre (lbs ai/A)

b. Post-Application Exposure and Risk

For re-entry workers, exposure estimates are based on the types of tasks and activities that individuals are likely to be doing in areas recently treated with a pesticide. Estimates of exposure are calculated using transfer coefficients, a standard measure of contact with treated foliage or other surfaces an individual would have while doing a specific task, and chemical-specific calculations of dislodgeable foliar residue, or the amount of pesticide available on the leaf surface that can potentially be transferred to the skin of an individual in contact with the treated surface. Increasing levels of PPE is not considered a viable approach for mitigating post-application risks so PPE is not used when calculating MOEs for re-entry workers; instead, the MOE is calculated for various intervals (by increasing the number of hours or days) after application.

For post-application exposure, risks from simazine applied at a rate of 4 pounds active ingredient per acre (lbs ai/A) are not of concern approximately 12 hours after application for those scenarios assessed that have relatively low transfer coefficients. However, for activities with relatively high transfer coefficients, MOEs exceed the Agency's level of concern for dermal

exposure until 2 days, or 48 hours, after application. These activities include pruning, training, topping, or staking Christmas trees; and harvesting, transplanting, and weeding turfgrass (unless the product is watered in).

7. Human Incident Summary

Databases consulted for the incident report for simazine include the OPP Incident Data System (IDS), Poison Control Centers, California Department of Pesticide Regulation, and National Pesticide Telecommunications Network (NPTN). The Agency concludes that simazine can be a skin or eye irritant from direct exposures based on the following incidents.

A total of 21 incidents were reported in the OPP IDS. Many of these incidents involved irritant effects to the eyes, skin and respiratory passages and several involved general central nervous system effects (e.g., nausea, dizziness, headache, restlessness). Poison Control Incident data (1993-2001) indicated that simazine appears to be much less acutely toxic than other pesticides. The overwhelming majority of symptoms reported due to simazine exposure were eye, dermal, and throat irritation. 74 cases involving simazine were reported to the California Pesticide Illness Surveillance Program from 1982-1999. Nine of these cases either involved the use of simazine alone or were cases in which simazine was judged to be primarily responsible for the health effects. Given simazine's widespread use in California, relatively few cases of simazine illness were reported.

B. Ecological Risk Assessment

To estimate potential ecological risks to non-target organisms, EPA integrates the results of exposure and ecotoxicity studies using the deterministic risk quotient method. Risk quotients (RQs) are calculated by dividing estimated exposure concentrations (EECs) by acute and chronic ecotoxicity values for species identified as representative of a broad taxonomic group of aquatic or terrestrial organisms. EECs are generally based on maximum application rates for the pesticide and can be determined through monitoring studies or modeling. Ecotoxicity values are determined from registrant-submitted studies or studies available in open literature. Acute ecotoxicity values reflect the doses or concentrations that, in an acute toxicity study, are lethal to 50% of the test animals in the group, or cause other similarly severe effects (e.g., immobilization). On an acute basis, simazine is non-toxic to estuarine/marine fish and invertebrates at the limits of its water solubility; practically non-toxic to birds, mammals, and honeybees; moderately toxic to freshwater fish; and highly toxic to freshwater invertebrates. Chronic ecotoxicity values reflect the doses or concentrations that, in an early-life or full-life stage study involving fish and aquatic invertebrates or a reproductive study involving birds and mammals, are representative of the highest "no observed adverse effect concentration" or NOAEC. For simazine, the chronic effects in birds are based on reproductive endpoints (a decrease in the number of eggs laid); in mammals, chronic effects are based reduced body weight gain.

Calculated RQs are compared to the Agency's levels of concern (LOCs), which are standard threshold values across all pesticides. There is potential risk if the RQ value exceeds an LOC, and in general the higher the RQ, the greater the potential risk. Risk characterization

provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, the nature of the effects observed in studies, as well as the existence of reported incidents to non-target organisms as a potential result of use of the pesticide. Risk characterization for simazine has included all but an examination of the spatial and temporal distributions of the communities and species potentially at risk. Table 6 below lists the LOCs that the Agency used to determine ecological risk from pesticide use.

The ecological assessment considers exposure to the parent compound (simazine) only. Available effects data on the degradates of simazine for mammals and non-vascular plants indicate they have a toxicity equal to or less than the parent compound, but effects data are not available for other taxonomic groups. Available laboratory and monitoring data indicate that the three degradates of simazine that are commonly seen in the laboratory studies, DIA, DACT, and hydroxy-simazine, will not be formed in the environment at levels that could significantly impact aquatic and terrestrial organisms.

Simazine's use in ornamental ponds and aquariums is not considered as part of the ecological risk assessment because, as of 1996, labels on end-use products containing simazine prohibit direct discharge into ponds or aquariums larger than 1,000 gallons, as well as application or discharge into lakes, flowing water, or ponds with outflow.

The Agency estimated ecological risks from both non-granular and granular formulations of simazine for non-target aquatic and terrestrial organisms, including freshwater fish and invertebrates, estuarine/marine fish and invertebrates, vascular and non-vascular aquatic plants, birds, mammals, and monocot and dicot terrestrial plants. A preliminary assessment was also completed for Federally Listed Threatened and Endangered Species (Listed Species). Based on the mobility and persistence of simazine, simazine's mode of action, and the potential dietary exposure to simazine of aquatic and terrestrial organisms, the risk hypothesis of the ecological risk assessment presumes that simazine has the potential to cause reduced survival, and reproductive and growth impairment for both aquatic and terrestrial animal and plant species.

Table 6. Risk presumptions and levels of concern for simazine

Risk Presumption Level of Concern (LOC)				
Fish and Invertebrates				
Acute Risk ^a	0.5			
Acute Endangered Species ^b	0.05			
Chronic Risk ^c	1.0			
Birds and Mammals				
Acute Risk	0.5			
Acute Endangered Species	0.1			
Chronic Risk	1.0			
Aquatic and Terrestrial Plants				
Acute Risk	1.0			
Acute Endangered Species	1.0			

^a The potential for acute risk exists; regulatory action may be warranted in addition to restricted use classification.

^b The potential for acute risk to threatened and endangered species exists; regulatory action may be warranted.

^c The potential for chronic risk exists, regulatory action may be warranted.

1. Environmental Fate and Transport

Simazine is moderately soluble (solubility of 3.5 mg/L) in water at 20°C or 68°F. However, simazine's solubility may increase with temperature, reaching 17 mg/L at 50°C or 122°F. Laboratory studies indicate that simazine is persistent, able to persist for months in the environment (half-life of 91 days) and possibly years in oxygen-deprived aquatic systems (half-life of 664 days) as it is not easily degraded by soil microbial organisms. If simazine is released at the soil surface and under direct sunlight, it undergoes relatively faster degradation (half-life of 22 days). Simazine is also quite resistant to aqueous abiotic reactions (e.g., hydrolysis and photolysis), increasing its likelihood to be present in stormwater runoff and to contaminate surface water. Aquatic field studies indicate variable persistence ranging from 12 days to 700 days. The limited number of terrestrial field studies available indicate that simazine could persist in the field for over one month to several years depending on soil texture and soil temperature.

Laboratory absorption data show low water/soil partitioning for simazine, or ability to be absorbed into the soil. These data indicate that simazine is highly mobile and has a strong potential to leach into ground water systems, especially in soils low in organic matters such sandy soils. Volatilization losses of simazine from soil and water systems are expected to be insignificant compared to dissipation by chemical degradation and metabolism. Simazine also has a low potential to bioaccumulate in fish.

The persistence and mobility of simazine, as demonstrated by the laboratory data, suggest that the chemical could reach surface water via transport from soil surfaces during runoff events and ground water via leaching, or vertical movement through soil. The greatest contribution to EECs in water is runoff, particularly in states where precipitation is a major factor in runoff such as in the Southeast (e.g., Florida) and the Midwest (e.g., Illinois, Missouri). However, spray drift plays a greater role in exposure in the Pacific coastal region (e.g., California, Oregon). Simazine's chlorinated degradates DIA and DACT are shown in studies to be more mobile than simazine, and therefore more likely to leach to ground water than the parent compound. Hydroxy-atrazine, on the other hand, is less mobile than simazine, and has less leaching potential than the parent compound. Based on data from the registrant-supported drinking water monitoring programs VMP and AMP, and the concentration of simazine's chlorinated degradates in CWS where both simazine and atrazine are detected compared to those with only atrazine detections, the Agency is confident that DIA and DACT derived from simazine have the potential to reach surface water, but not at levels that could significantly impact non-target organisms.

2. Aquatic Organism Exposure and Risk

While several sources of monitoring data, including the VMP/AMP database, were used to understand the potential concentrations of simazine in surface water, EECs were estimated for aquatic organism risk calculations using the predictive model PRZM/EXAMS. Most of the monitoring data available were not designed to specifically target areas of intense simazine use and since the sampling designs (e.g., frequency of monitoring) were not intended to capture peak pesticide concentrations, there is high likelihood they may have been missed. The modeled EECs are considered protective upper bound estimates for the aquatic organism risk calculations, as were modeled concentrations in drinking water for dietary human health risk, while the monitoring data provide lower bound estimates.

In order to characterize potential ecological risk to aquatic organisms, ten crops were selected to represent the primary uses of simazine. These crops include turf (representing use as nonselective weed control on non-crop land), citrus, apples, caneberries, corn, pine trees (Christmas trees), grapes, nuts, corn, fruit (peaches and nectarines), and lettuce (as a surrogate for strawberries). A variety of different scenarios were simulated across the selection of crops in order to account for different geographical locations both specified by the labels and based on agricultural practices, with locations concentrated in areas with intense simazine use. Crop scenarios also included variable spray drift assumptions of 0% to 5% to gauge the contribution of drift to runoff and consequently EECs.

Acute RQs calculated for freshwater fish and invertebrates do not exceed the LOC of 0.5 for acute risk. However, there is a high degree of uncertainty associated with the acute freshwater data set because exposure concentrations were not verified in the available acute toxicity tests. Additionally, the results of future studies on atrazine's potential sublethal effects to amphibians, specifically impacts on gonadal development in frogs, may be applicable to simazine because the two chemicals share a similar neuroendocrine mechanism of toxicity, a similar mechanism of herbicidal action, and the same degradates. However, ecotoxicity data on the sublethal effects of simazine to amphibians, a taxonomic group for which freshwater fish data generally substitutes, are currently not available. Acute RQs were not calculated for estuarine/marine fish and invertebrates because acute toxicity data shows that simazine is not likely to be acutely toxic to either estuarine/marine fish or invertebrates at the limits of its water solubility.

Potential chronic effects for both freshwater and marine/estuarine fish and invertebrates are unknown because chronic toxicity data on the technical grade active ingredient for these taxonomic groups are also not available. A freshwater fish early life-cycle test with fathead minnow and a freshwater aquatic invertebrate life-cycle test were submitted for a simazine formulation of 80% active ingredient that indicate the formulation is unlikely to exceed the Agency's LOC of 1.0 for chronic risk. However, acute toxicity data indicate that the technical grade active ingredient may be more toxic to fish than the 80% formulation.

Many of the calculated acute RQs for vascular and non-vascular aquatic plants exceed the LOC of 1.0 for acute risk, and indicate that there is the potential for direct adverse acute effects from both non-granular and granular formulations, especially for non-vascular plants (e.g., a variety of blue green algae, *A. flosaquae*). RQs for vascular aquatic plants range from below the LOC to 2.4. RQs for non-vascular aquatic plants range from below the LOC to 9.33. The Agency does not currently assess chronic risks to plants.

Two important considerations relative to simazine's potential to affect plants are recovery and potential resistance of some species. Recovery is possible following removal of simazine from the site of action, although there is uncertainty associated with the approximate length of time it takes for recovery to occur, given a certain level of exposure. While there is no major evidence that a clearly herbicide-resistant or tolerant community exists, available data suggest that periphytic blue-green algae, unlike the *A. flosaquae* variety which is sensitive to simazine, may be resistant at higher application rates. Periphytic blue-green algae's relative abundance when simazine is used at higher application rates suggests an important ecological shift that may potentially impact the aquatic community structure.

Table 7 presents acute RQs calculated for aquatic organisms with those RQs bolded that exceed the Agency's LOC of 1.0 for acute ecological risk to vascular and non-vascular aquatic plants.

Table 7. Acute RQs for aquatic vascular plants and aquatic non-vascular plants

Crop (Location – formulation, application method)	Vascular Aquatic	Non-vascular Aquatic
Application Rate ^a (# of applications)	Plants ^b	Plants ^b
Turf (FL – granular, ground; 0% drift);	2.4	9.33
40.0 (1)		
Turf (PA – granular, ground; 0% drift);	1.64	6.36
40.0 (1)		
Citrus (FL non-granular, aerial; 5% drift)	1.76	6.86
9.6 (1)		
Citrus (FL non-granular, aerial; 0% drift)	1.52	5.92
9.6 (1)		
Citrus (FL non-granular, ground; 1% drift)	1.63	6.33
9.6 (1)		
Citrus (CA non-granular, aerial; 5% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
4.0 (1)		
Citrus (CA non-granular, aerial; 0% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
4.0 (1)		
Citrus (CA non-granular, ground; 1% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
4.0 (1)		
Apples (NC non-granular, granular)	<loc< td=""><td>3</td></loc<>	3
8.0 (1)		
Apples (PA non-granular, granular)	<loc< td=""><td>1.67</td></loc<>	1.67
8.0 (1)		
Apples (OR non-granular, granular)	<loc< td=""><td>1.03</td></loc<>	1.03
8.0 (1)		
Berries (OR non-granular, granular)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
4.0 (1)		
Pine trees (OR non-granular, aerial; 5% drift)	<loc< td=""><td>1.28</td></loc<>	1.28
5.94 (1)		

Crop (Location – formulation, application method) Application Rate ^a (# of applications)	Vascular Aquatic Plants ^b	Non-vascular Aquatic Plants ^b
Pine trees (OR non-granular, aerial, 0% drift) 5.94 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Pine trees (OR non-granular, ground, 1% drift) 5.94 (1	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Grapes (CA non-granular, aerial; 5% drift) 4.8 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Grapes (CA non-granular, aerial; 0% drift) 4.8 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Grapes (CA non-granular, ground; 1 % drift) 4.8 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Nuts/Pecans (GA non-granular, aerial; 5% drift) 4.0 (1)	1.01	3.94
Nuts/Pecans (GA non-granular, aerial; 0% drift) 4.0 (1)	<loc< td=""><td>3.53</td></loc<>	3.53
Nuts/Pecans (GA non-granular, ground; 1% drift) 4.0 (1)	<loc< td=""><td>3.75</td></loc<>	3.75
Nuts (OR non-granular, aerial; 5% drift) 4.0 (1)	<loc< td=""><td>1.72</td></loc<>	1.72
Nuts (OR non-granular, aerial; 0% drift) 4.0 (1)	<loc< td=""><td>1.11</td></loc<>	1.11
Nuts (OR non-granular, ground; 1% drift) 4.0 (1)	<loc< td=""><td>1.27</td></loc<>	1.27
Nuts (CA non-granular, aerial; 5% drift) 4.0 (1)	<loc< td=""><td>1.64</td></loc<>	1.64
Nuts (CA non-granular, aerial, 0% drift) 4.0 (1)	<loc< td=""><td>1.06</td></loc<>	1.06
Nuts (CA non-granular, ground, 1% drift) 4.0 (1)	<loc< td=""><td>1.22</td></loc<>	1.22
Almonds (CA ground banded, 1% drift) 2.0 banded, equal to 0.89 assuming application to a band 2 feet on each side of the tree row (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Corn (MS non-granular, aerial; 5% drift) 3.0 (1)	<loc< td=""><td>2.67</td></loc<>	2.67
Corn (MS non-granular, aerial; 0% drift) 3.0 (1)	<loc< td=""><td>2.33</td></loc<>	2.33
Corn (MS non-granular, ground; 1% drift) 3.0 (1)	<loc< td=""><td>2.5</td></loc<>	2.5
Corn (IL non-granular, aerial; 5% drift) 3.0 (1)	<loc< td=""><td>2.67</td></loc<>	2.67
Corn (IL non-granular, aerial; 0% drift) 3.0 (1)	<loc< td=""><td>2.19</td></loc<>	2.19
Corn (IL non-granular, ground; 1% drift) 3.0 (1)	<loc< td=""><td>2.38</td></loc<>	2.38
Corn (CA non-granular, aerial; 5% drift) 3.0 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Corn (CA non-granular, aerial; 0% drift) 3.0 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Corn (CA non-granular, ground; 1% drift) 3.0 (1)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
Peach (GA non-granular, aerial; 5% drift) 4.0 (1)	<loc< td=""><td>1.58</td></loc<>	1.58

Crop (Location – formulation, application method) Application Rate ^a (# of applications)	Vascular Aquatic Plants ^b	Non-vascular Aquatic Plants ^b
Peach (GA non-granular, aerial, 0% drift)	<loc< td=""><td>1.06</td></loc<>	1.06
4.0 (1)		
Peach (GA; non-granular, ground, 1% drift)	<loc< td=""><td>1.19</td></loc<>	1.19
4.0 (1)		
Fruit (CA non-granular, ground banded, 1% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
2.0 banded, equal to 0.89 assuming application to a		
band 2 feet on each side of the tree row (1)		
Lettuce (CA non-granular, aerial; 5% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
1.0(1)		
Lettuce (CA non-granular, aerial; 0% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
1.0(1)		
Lettuce (CA non-granular, ground; 1% drift)	<loc< td=""><td><loc< td=""></loc<></td></loc<>	<loc< td=""></loc<>
1.0 (1)		

^a Pounds active ingredient per acre (lbs ai/A)

3. Terrestrial Organism Exposure and Risk

EECs were estimated for terrestrial organism risk calculations by estimating pesticide residue on food items for birds and mammals, as well as estimating the loading of pesticide in granular formulations per unit of treated area using labeled application rates and intervals between applications. For spray applications of non-granular formulations, EECs were derived through modeling for seven crop scenarios including citrus, pine trees, grapes, nuts, corn, almonds/fruit, and strawberries. For granular formulations, EECs were estimated for mammals and birds based on an assumption that all of the granules are unincorporated in the soil, and therefore available for consumption, and based on two possible routes of exposure, both directly through oral consumption of granules, and indirectly through consumption of terrestrial invertebrates that have bioaccumulated pesticide residues. EECs for terrestrial plants were based on standard runoff and spray drift scenarios with inputs such as a pesticide's water solubility, and are modeled for granular formulations assuming that granules are incorporated and unincorporated. Default spray drift assumptions are 1% for application on the ground and 5% for aerial application. That is 1% and 5% of the pesticide reaches a non-target area adjacent to a treated area based on respective ground and aerial applications.

For terrestrial animals, potential ecological risks were characterized for the seven crop scenarios by comparing the EECs to ecotoxicity data. For terrestrial plants, potential ecological risks were determined using RQ estimates for dry and wetland areas adjacent to a treated site, as well as for areas impacted by spray drift.

No acute RQs were generated for birds or mammals because definitive ecotoxicity values were not available. Instead EECs were compared to the dose or concentration at which little or no mortality was observed. None of the EECs exceed or approach this dose for birds; therefore, avian mortality is unlikely from acute exposure to simazine. However, acute sublethal effects (e.g., reduced reaction to external stimuli, wing drop, depression) are possible from non-granular formulations. None of the EECs for mammals exceed or approach the dose at which mortality occurred; therefore, there is also a low likelihood of mortality to mammals from acute exposure to simazine.

^b Does not include Listed Species; Listed Species RQs were calculated separately.

There is the potential for direct adverse chronic effects for both birds and mammals. A number of chronic RQs calculated for birds, based on a reproductive effect (reduction in the number of eggs laid), exceed the LOC of 1.0 for chronic risk from non-granular formulations. The same is true for mammals, based on reduced body weight gain, for both non-granular and granular formulations. Chronic RQs calculated for birds reach a maximum of 23. For non-granular formulations, chronic RQs calculated for mammals reach a maximum of 230 and exceed 50 in five of the seven crop scenarios modeled. For granular formulations, chronic RQs calculated for mammals associated with ingestion of earthworms that have bioaccumulated simazine range from 2 to 36. Table 8 below presents chronic RQs based on non-granular formulations calculated for birds and mammals with those RQs bolded that exceed the Agency's LOC of 1.0 for chronic risk

As with aquatic plants, many of the calculated acute RQs for monocot and dicot terrestrial plants exceed the LOC of 1.0 for acute risk, and indicate that there is the potential for direct adverse acute effects from both non-granular and granular formulations, with greater risk to emerging seedlings than emerged plants exposed via foliar spray. The Agency does not currently assess chronic risks to plants. Table 9 presents acute RQs calculated for monocot and dicot terrestrial plants with those RQs bolded that exceed the Agency's LOC of 1.0 for acute risk.

Table 8. Chronic RQs based on non-granular formulations for birds and mammals

Crop	Food Items	Birds	Mammals
Application Rate ^a (# of applications)			
Citrus	Short grass	23	230
9.6 (1)	Tall grass	10.6	106
	Broadleaf plants/small insects	13	130
	Fruits/pods/seeds/large insects	1.4	14
Pine trees	Short grass	14.3	143
5.94 (1)	Tall grass	6.53	65
	Broadleaf plants/small insects	8.02	80
	Fruits/pods/seeds/large insects	<loc< td=""><td>9</td></loc<>	9
Grapes	Short grass	11.5	115
4.8 (1)	Tall grass	5.28	53
	Broadleaf plants/small insects	6.48	65
	Fruits/pods/seeds/large insects	<loc< td=""><td>7</td></loc<>	7
Nuts	Short grass	9.6	96
4.0(1)	Tall grass	4.4	44
	Broadleaf plants/small insects	5.4	54
	Fruits/pods/seeds/large insects	<loc< td=""><td>6</td></loc<>	6
Corn	Short grass	7.2	72
3.0(1)	Tall grass	3.3	33
	Broadleaf plants/small insects	4.05	41
	Fruits/pods/seeds/large insects	<loc< td=""><td>5</td></loc<>	5
CA almonds and fruit	Short grass	4.8	48
2.0(1)	Tall grass	2.2	22
	Broadleaf plants/small insects	2.7	27
	Fruits/pods/seeds/large insects	<loc< td=""><td>3</td></loc<>	3
Strawberries	Short grass	2.4	24
1.0(1)	Tall grass	1.1	11
	Broadleaf plants/small insects	1.35	14
	Fruits/pods/seeds/large insects	<loc< td=""><td>1.5</td></loc<>	1.5

^a Pounds active ingredient per acre (lbs ai/A)

Table 9. Acute ROs for monocot and dicot terrestrial plants

Application Rate ^a (formulation,	Dry Adja	acent Area	Wetland Adjacent Area		Area Impacted by Drift	
application method)	Monocotb	Dicot ^b	Monocot ^b	Dicotb	Monocot ^b	Dicot ^b
9.6 (non-granular, ground)	9.6	21	53	117	2.9	2.9
4.0 (non-granular, ground)	4	9	22	49	1.2	1.2
1.0 (non-granular, ground)	1	2.2	5.5	12.2	0.3	0.3
9.6 (non-granular, aerial/chemigation)	27	60	53	117	15	15
4.0 (non-granular, aerial/chemigation)	11	25	22	49	6.1	6.1
1.0 (non-granular, aerial/chemigation)	2.8	6.2	5.5	12.2	1.5	1.5
40 (granular unincorporated, ground)	20	44	200	444	N/A	N/A
8.0 (granular unincorporated, ground)	4	9	40	89	N/A	N/A
4.0 (granular unincorporated, ground)	2	4.4	20	44	N/A	N/A
40 (granular incorporated, ground)	20	44	20	44	N/A	N/A
8.0 (granular incorporated, ground)	4	9	4	9	N/A	N/A
4.0 (granular incorporated, ground)	2	4.4	2	4.4	N/A	N/A

^a Pounds active ingredient per acre (lbs ai/A)
^b Does not include Listed Species; Listed Species RQs were calculated separately.

4. Risk to Endangered Species

For purposes of the RED for simazine, the Agency completed a preliminary or screening-level assessment for Listed Species. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on Listed Species and to implement mitigation measures to address these impacts.

The Agency acknowledges that pesticides have the potential to exert not only direct effects but indirect effects as well upon the Listed Species by, for example, perturbing forage or prey available, altering the extent of nesting habitat, etc. Acute and chronic RQs, which represent direct effects, for each taxonomic group are used to make inferences concerning the potential for indirect effects upon Listed Species that rely upon non-threatened and -endangered organisms in these taxonomic groups as resources critical to their life cycle. The greater the RQs for a taxonomic group, the greater concern for potential indirect effects for Listed Species dependent on that taxonomic group. Potential effects of pesticides on designated critical habitats for Listed Species are also included and considered as potential indirect effects. Focus is given to the physical and biological features (constituent elements) of a critical habitat identified by the U.S. Fish and Wildlife and National Marine Fisheries Services as essential to the conservation of a Listed Species and which may require special management consideration or protections.

The Agency's preliminary assessment indicates that the LOC for Listed Species is exceeded for the following combination of taxonomic groups and uses:

- Freshwater fish granular application for nonselective weed control on turf and other non-crop land;
- Freshwater invertebrates non-granular application on citrus, pine trees, nuts, peaches, and corn; granular application for nonselective weed control on turf and other non-crop land as well as apples;
- Vascular aquatic plants non-granular application on citrus, nuts, peaches, and corn; granular application for nonselective weed control on turf and other non-crop land as well as apples;
- Birds non-granular application for all uses;
- Mammals non-granular and granular application for all uses; and
- Monocot and dicot terrestrial plants non-granular and granular application for all uses.

Although RQs for vascular and non-vascular plants exceed the LOC for Listed Species, there are no endangered species of non-vascular plants. Based on acute and chronic RQs, there are additional potential indirect effects to Listed Species that have the following behaviors:

- Eat fish or amphibians (e.g., fish, mammals, birds, reptiles), or in the case of freshwater mussels, use a fish as a necessary host in their life cycle;
- Rely on freshwater invertebrates (e.g., daphnids) as a primarily food source; rely on aquatic plants for food and/or habitat and shelter;
- Eat birds or require birds as pollinators or seed dispersers;
- Eat mammals or require mammals as pollinators or seed dispersers; and
- Rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependent) for some important aspect of their life cycle.

A total of 977 Listed Species may potentially occur in areas where simazine can be used.

Table 10 lists the taxonomic groups and the direct toxicological effects of simazine on those taxonomic groups whose acute or chronic RQs exceed the Agency's LOC for ecological risk to Listed Species. Those RQs which exceed the Agency's LOC are bolded.

Table 10. Taxonomic groups for which the Listed Species RQs exceed the Agency's LOC

Taxonomic Groups	Direct Effects	RQ Range
Freshwater fish	Acute: mortality	<loc 0.05<="" td="" –=""></loc>
	Chronic: no data	N/A
Freshwater invertebrates	Acute: mortality/immobilization	<loc 0.34<="" td="" –=""></loc>
	Chronic: no data	N/A
Vascular aquatic plants	Acute: reduced frond number	<loc 6.22<="" td="" –=""></loc>
	Chronic: not evaluated	N/A
Non-vascular aquatic plants	Acute: reduced cell density	<loc 62<="" td=""></loc>
	Chronic: not evaluated	N/A
Birds	Acute: potential sublethal effects	Qualitatively evaluated
	Chronic: reduced number of eggs laid	<loc 23<="" td="" –=""></loc>
Mammals	Acute: risks are unlikely	N/A
	Chronic: reduced body weight gain	5 – 230
Monocot terrestrial plants	Acute: shoot height	<loc 2353<="" td="" –=""></loc>
_	Chronic: not evaluated	N/A
Dicot terrestrial plants	Acute: dry weight	<loc 2222<="" td="" –=""></loc>
	Chronic: not evaluated	N/A

Risks to endangered species identified in the ecological risk assessment for simazine are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Rather, this assessment serves as a screen to determine the need for any species specific assessments that will evaluate whether exposure may be at levels that could cause harm to specific Listed Species and their critical habitat. That assessment refines the screening-level assessment to take into account the geographic area of pesticide use in relation to the Listed Species, the habits and habitat requirements of the Listed Species, etc. If the Agency's specific assessments for atrazine result in the need to modify use of the pesticide in specific geographic areas, those changes to the pesticide's registration will take place through the process described in the Agency's Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

5. Ecological Incident Summary

Incident data were reviewed for aquatic and terrestrial organisms. Nine incidents for aquatic animals have been reported, all of which involved fish kills. Six of these incidents were reported with a certainty index of "highly probable" or "probable" in relation to causation by simazine and involved direct application to lakes, ponds, or lagoons. The additional three incidents were categorized as "possible" or unlikely" and involved use of simazine along railroad tracks, on corn, and on an unspecified treatment site. All of the incidents occurred prior to 1996, when label language was clarified to prohibit direct discharge into ornamental ponds or aquariums larger than 1,000 gallons, as well as application or discharge into lakes, flowing water, or ponds with outflow.

Two incidents for terrestrial animals and three incidents for terrestrial plants have been reported. An incident involving two dead quail in Yosemite National Park had a reported certainty index of "unlikely" in relation to causation by simazine, while another incident involving five Canada Geese in Virginia was categorized as "probable." Three incidents involving terrestrial plants have been reported. One incident involved lawn damage from application to a swimming pool, a use that has been cancelled, and the other two involved non-target plant damage following aerial application on corn.

IV. Risk Management and Reregistration 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 (technical grade) data required to support reregistration of products containing simazine as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data would be sufficient to support reregistration of all products containing simazine provided the registrations are amended in a manner consistent with this document.

The Agency has completed its assessment of the dietary (both food and drinking water), residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient simazine. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient simazine, the Agency has sufficient information on the human health and ecological effects of simazine to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing simazine are eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. Specific label changes and language are specified in Section V. Appendix A provides a detailed table of those uses eligible for reregistration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of simazine, and lists the submitted studies the Agency found acceptable. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data or additional data requirements necessary to confirm the decision presented here.

Should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take appropriate regulatory action to address the risk concerns from the use of simazine. The Agency has also concluded that, with these mitigation measures and the mitigation measures in the atrazine IRED, the cumulative risks associated with the chlorinated triazine class of pesticides, including simazine, are below the Agency's level of concern. Therefore, if all changes outlined in this document are incorporated into the product labels, then all current risks for simazine will be adequately addressed for the purposes of this determination

under FIFRA. Once a comprehensive endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section IV.D.5 of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach these regulatory decisions for simazine. During the public comment period on the risk assessments, which closed on September 12, 2005, the Agency received comments from California Department of Pesticide Regulation, American Water Works Association, University of Hawaii, Golf Course Superintendents Association, Triazine Network, Syngenta Crop Protection, Inc. (a technical registrant), and Florida Department of Agriculture & Consumer Services. These comments expressed agreement with some portions of the risk assessments, argued that the risk assessments used unnecessarily conservative assumptions at times, discussed the need for the availability of specific application rates and methods for particular uses of simazine, provided simazine usage statistics and described target weeds which simazine is used to control, and listed potential mitigation measures.

These comments were reviewed and taken into consideration when the revised risk assessments and their supporting documents, in addition to this simazine RED, were completed. The comments are available in their entirety in the public docket EPA-HQ-OPP-2005-0151 located on-line in FDMS http://www.regulations.gov. The Agency's responses to substantive comments are available in memoranda in the public docket and the revised assessments available in the public docket reflect these responses.

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 simazine. The Agency has concluded that, with the risk mitigation measures outlined in this document, the aggregate exposure to the pesticide simazine and its two chlorinated degradates (from food, drinking water, and residential sources) is within the "risk cup." The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children.

FQPA also requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the neuroendocrine mechanism of toxicity shared by the structurally-related chlorinated triazines atrazine, simazine, propazine, and their three chlorinated degradates. The Agency has completed its cumulative risk assessment for the chlorinated triazine class of pesticides and has concluded that with the mitigation measures in this document and in the 2003 IRED for atrazine the cumulative risks associated with these pesticides are below the Agency's level of concern.

The Agency has determined that tolerances for simazine meet the FQPA safety standards and are now considered reassessed.

b. Determination of Safety to U.S. Population (Including Infants and Children)

The Agency has determined that the established tolerances for simazine, with label amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to Section 408(b)(2)(C) and 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers, from the use of simazine. The safety determination considers factors such as the toxicity, use practices and exposure scenarios, and environmental behavior of simazine.

In determining whether or not infants and children are particularly susceptible to toxic effects from simazine residues, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The Agency determined it was unnecessary to retain a safety factor in the acute dietary assessment to account for hazard-based uncertainty because open literature data demonstrate that any neuroendocrine effect, the primary toxicological effects of regulatory concern, that could result from a single dose would only occur at a very high dose. However, when available water monitoring data were used to estimate drinking water exposure, a 3X FQPA safety factor was retained to account for exposure-based uncertainty due to limitations in the monitoring database. The full 10X FQPA safety factor was retained and applied to the chronic dietary assessment to account for both exposure-based uncertainty in the water monitoring data and because of residual uncertainty regarding the effects of the neuroendocrine mechanism of action on the developing child. When drinking water concentration values were estimated using modeling, which the Agency believes is conservative and protective, the 3X for exposure-based uncertainty was unnecessary for inclusion in the chronic dietary assessment. The total FQPA safety factor applied to the residential assessment for simazine was reduced from the default 10X FQPA safety factor to 3X. The Agency determined that it was unnecessary to retain a 3X FQPA safety factor in the residential assessment to account for exposure-based uncertainty because the assessment is based on EPA's Standard Operating Procedures using high-end default values and assumptions that would be protective of infants and children. A 3X FQPA safety factor was retained to account for hazard-based uncertainty.

c. 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 for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

There is direct evidence that simazine is associated with neuroendocrine disruption. Direct measurements of serum hormones such as certain steroid hormones and luteinizing hormone, as well as changes in estrus cycling and histomorphic changes in hormone responsive tissues, indicate neuroendocrine disruption. EPA has responded, in part, to simazine's known neuroendocrine disrupting capacity by regulating on endpoints based on neuroendocrine disruptor effects and requiring risk mitigation measures, label amendments, and additional confirmatory data to reduce potential risks to below the Agency's levels of concern. The Agency has determined that, with label amendments and changes as specified in this document, there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers, from the use of simazine. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, simazine may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

FQPA stipulates that when determining the safety of a pesticide chemical EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to 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 mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

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 OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

EPA evaluated simazine along with two other structurally-related chlorinated triazines, atrazine and propazine, and their three chlorinated degradates, as sharing a neuroendocrine mechanism of toxicity. After subchronic and chronic exposure to these compounds, a variety of species were shown to exhibit neuroendocrine effects resulting in both reproductive and developmental consequences that are considered relevant to humans. These compounds disrupt the hypothalamic-pituitary-gonadal (HPG) axis, part of the central nervous system, and cause

cascading changes to hormone levels and developmental delays. The Agency has completed its cumulative risk assessment for the chlorinated triazine class of pesticides and has concluded that with the mitigation measures in this document and in the 2003 IRED for atrazine the cumulative risks associated with these pesticides are below the Agency's level of concern. The Agency has determined that, with label amendments and changes as specified in this document and the 2003 IRED for atrazine, there is a reasonable certainty that no harm will result to the general U.S. population, infants, children, or other major identifiable subgroups of consumers, from the use of simazine, atrazine, and propazine. The cumulative risk assessment and supporting documents are available in the public docket EPA-HQ-OPP-2005-0481 located on-line in FDMS, http://www.regulations.gov.

2. Tolerance Summary

A tolerance summary and tolerance reassessment decision is presented for simazine in Table 11 below. Currently there are 62 tolerances listed in 40 CFR 180.213 for simazine on agricultural crops and animal commodities. With the exception of tolerances set for bananas and fish, tolerances for simazine residues are currently expressed in terms of the parent compound only. The Agency has determined that residues of concern in/on raw agricultural commodities are simazine and its two chlorinated degradates, DIA and DACT. The Agency will propose changing the tolerance expression for all commodities to reflect combined residues of the parent compound, simazine (2-chloro-4,6-bis(ethylamino)-s-triazine), plus its two chlorinated degradates (2-amino-4-chloro-6-ethylamino-s-triazine and 2,4-diamino-6-chloro-s-triazine), the total residue to be measured in/on raw agricultural commodities for tolerance enforcement.

The crop and animal commodity tolerances which the Agency will propose to revoke because the registrants are not supporting related uses include alfalfa, alfalfa (forage and hay), Bermuda grass, Bermuda grass (forage and hay), fish, grass, grass (forage and hay), and sugarcane (molasses). The Agency intends to propose to revoke the tolerance for bananas as well because the registrants are not supporting use; however, available residue data may be appropriate to support a tolerance of 0.2 ppm if use is supported in the future. The Agency will also propose to revoke the following tolerances because there is no reasonable expectation of finding residues at quantifiable levels (40 CFR 180.6(a)(3)): cattle (fat), goat (fat), hog (fat, meat, and meat byproducts), horse (fat), poultry (fat, meat, and meat byproducts), and sheep (fat).

Available residue data support lowering tolerances for avocado, blackberry, blueberry, corn (forage and grain), filbert (i.e., hazelnut), grape, loganberry, peach, plum, olive, and raspberry. Available residue data also support lowering tolerances for apples, provided a pre-harvest interval is added to labels. The Agency will propose that tolerances for boysenberry and dewberry be reassigned (no longer listed as separate tolerances) because they are covered by the blackberry tolerance. Available residue data support increasing tolerances for pecan, cattle (meat and meat byproducts), goat (meat and meat byproducts), horse (meat and meat byproducts), milk, sheep (meat and meat byproducts), and egg. Available residue data supports maintaining the tolerance for corn (stover). Additional confirmatory residue data are necessary to support tolerances for almond, almond (hulls), cherry, corn (sweet), cranberry, currant, grapefruit, lemon, macadamia nut, orange, pear, strawberry, and walnut. However, there are no dietary (from food

or drinking water) risk concerns associated with these 13 tolerances, and the Agency considers them reassessed at the current tolerance level. Tolerances will be proposed, and additional data are necessary, for citrus oil and rotational crops.

No maximum residue limits (MRLs) for simazine have been established or proposed by Codex for any agricultural commodity. Canada does not currently have MRLs for simazine.

Table 11. Tolerance reassessment summary for simazine

Current Commodity	Current	Tolerance	Comments		
	Tolerance (ppm)	Reassessment	[Correct Commodity Definition]		
		Decision (ppm)			
Tolerances Listed Under 40 CFR 180.213(a)(1)					
Alfalfa	15	Revoke	Use is not being supported.		
Alfalfa, forage	15	Revoke	Use is not being supported.		
Alfalfa, hay	15	Revoke	Use is not being supported.		
Almond	0.25	TBD ^a	Additional confirmatory residue data are required.		
Almond, hulls	0.25	TBD ^a	Additional confirmatory residue data are required.		
Apple	0.25	0.2	Available residue data support lowering tolerance provided a pre-harvest interval is added to labels.		
Avocado	0.25	0.2	Available residue data supports lowering tolerance.		
Bermuda grass	15	Revoke	Food/feed use is not being supported.		
	15	Revoke	Food/feed use is not being supported. Food/feed use is not being supported.		
Bermuda grass, forage					
Bermuda grass, hay	15 0.25	Revoke 0.2	Food/feed use is not being supported.		
Blackberry			Available residue data support lowering tolerance.		
Blueberry	0.25	0.2	Available residue data support lowering tolerance.		
Boysenberry	0.25	Reassign	Boysenberry is covered by the Blackberry tolerance.		
Cattle, fat	0.02 (N) ^b	Revoke	There is no reasonable expectation of finding quantifiable		
G at a t a	0.02.01)	0.02	residues (40 CFR 180.6(a)(3)).		
Cattle, meat byproducts	0.02 (N)	0.03	Tolerance should be increased to accommodate total		
G at	0.02.00	0.02	residue of parent compound plus degradates.		
Cattle, meat	0.02 (N)	0.03	Tolerance should be increased to accommodate total		
CI	0.25	TDD ²	residue of parent compound plus degradates.		
Cherry	0.25	TBD^{a}	Additional confirmatory residue data are required.		
C f	0.25	0.2	[Cherry, tart and Cherry, sweet].		
Corn, forage	0.25	0.2	Available residue data support lowering tolerance.		
G 6 1 ()	0.25	TDD ³	[Corn, field, forage and Corn, sweet, forage]		
Corn, fresh (inc. sweet,	0.25	TBD^{a}	Additional confirmatory residue data are required.		
kernel plus cob with husks removed)			[Corn, sweet, kernel pus cob with husks removed]		
Corn, grain	0.25	0.2	Available residue data support lowering tolerance.		
Corn, gram	0.23	0.2	[Corn, field, grain and Corn, pop, grain]		
Corn, stover	0.25	0.25			
Corn, stover	0.23	0.23	[Corn, field, stover and Corn, pop, stover and Corn,		
Cranharry	0.25	TBD ^a	sweet, stover]		
Cranberry Currant	0.25	TBD ^a	Additional confirmatory residue data are required. Additional confirmatory residue data are required.		
Dewberry	0.25	Reassign	Dewberry is covered by the Blackberry tolerance.		
	0.23 0.02 (N)	0.03	Tolerance should be increased to accommodate total		
Egg	0.02 (11)	0.03	residue of parent compound plus degradates.		
Filbert	0.25	0.2	Available residue data support lowering tolerance.		
Goat, fat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable		
,			residues (40 CFR 180.6(a)(3)).		
Goat, meat byproducts	0.02 (N)	0.03	Tolerance should be increased to accommodate total		
, , , , , , , , , , , , , , , , , , ,			residue of parent compound plus degradates.		

Current Commodity	Current	Tolerance	Comments
Current Commounty	Tolerance (ppm)	Reassessment	[Correct Commodity Definition]
	Tolerance (ppin)	Decision (ppm)	[correct commonly 20jimmon]
Goat, meat	0.02 (N)	0.03	Tolerance should be increased to accommodate total
Joan, mout	0.02 (1.)	0.00	residue of parent compound plus degradates.
Grapefruit	0.25	TBD ^a	Additional confirmatory residue data are required.
Grape	0.25	0.2	Available residue data support lowering tolerance.
Grass	15	Revoke	Food/feed use is not being supported.
Grass, forage	15	Revoke	Food/feed use is not being supported.
Grass, hay	15	Revoke	Food/feed use is not being supported.
Hog, fat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Hog, meat byproducts	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Hog, meat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Horse, fat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Horse, meat byproducts	0.02 (N)	0.03	Tolerance should be increased to accommodate total residue of parent compound plus degradates.
Horse, meat	0.02 (N)	0.03	Tolerance should be increased to accommodate total residue of parent compound plus degradates.
Lemon	0.25	TBD^{a}	Additional confirmatory residue data are required.
Loganberry	0.25	0.2	Available residue data supports lowering tolerance.
Milk	0.02 (N)	0.03	Tolerance should be increased to accommodate total residue of parent compound plus degradates
Nut, macadamia	0.25	TBD^{a}	Additional confirmatory residue data are required.
Olive	0.25	0.2	Available residue data support lowering tolerance.
Orange, sweet	0.25	TBD^b	Additional confirmatory residue data are required. [Orange]
Peach	0.25	0.2	Available residue data support lowering tolerance.
Pear	0.25	TBD^{a}	Additional confirmatory residue data are required.
Pecan	0.1 (N)	0.02	Available residue data support increasing tolerance.
Plum	0.25	0.2	Available residue data support lowering tolerance.
Poultry, fat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Poultry, meat byproducts	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Poultry, meat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Raspberry	0.25	0.2	Available residue data supports lowering tolerance.
Sheep, fat	0.02 (N)	Revoke	There is no reasonable expectation of finding quantifiable residues (40 CFR 180.6(a)(3)).
Sheep, meat byproducts	0.02 (N)	0.03	Tolerance should be increased to accommodate total residue of parent compound plus degradates.
Sheep, meat	0.02 (N)	0.03	Tolerance should be increased to accommodate total residue of parent compound plus degradates.
Strawberry	0.25	TBD^{a}	Additional confirmatory residue data are required.
Sugarcane, molasses	1	Revoke	Use is not being supported.
Walnut	0.2	TBD^{a}	Additional confirmatory residue data are required.
	Tolerance	to be Proposed unde	·
Citrus, oil	None	$\overline{\mathrm{TBD}^{\mathrm{c}}}$	Additional residue data are required. However, the existing orange processing study indicates that a tolerance of at least 0.3 ppm is necessary.

Current Commodity	Current	Tolerance	Comments
	Tolerance (ppm)	Reassessment	[Correct Commodity Definition]
Decision (ppm)			
Rotational Crops	None	TBD^{c}	Field trials are required.
Tolerances Listed Under 40 CFR 180.213(a)(2)			
Banana	Banana 0.2 Revoke Use is not being supported. However, available resid		Use is not being supported. However, available residue
	data may be appropriate to support a tolerance of 0.2 p		data may be appropriate to support a tolerance of 0.2 ppm
	if use is supported in the future.		
Fish	12	Revoke	Food/feed use is not being supported.

^a The Agency has no dietary (from food or drinking water) risk concerns associated with these tolerances and considers them reassessed at the current tolerance level. The TBD or "to be determined" designation is used, however, to convey that the Agency expects that the data required in the DCI that will be issued as a result of this RED will confirm that conclusion.

^b (N) designation indicates negligible residues and EPA will propose to remo ve the "N" designation from all entries to conform to current Agency administrative practice.

D. Regulatory Rationale

The Agency has determined that simazine is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. The following is a summary of the risk mitigation measures and EPA's rationale for the decision for managing risks associated with the use of simazine. Where labeling revisions are warranted, label changes and language are presented in Section V.

1. Human Health Risk Management and Mitigation

a. Dietary Risk Mitigation (Food and Drinking Water)

As discussed in Sections III.A.2 and 3, acute dietary risks (from food and drinking water) do not exceed the Agency's level of concern. Additionally, chronic risks from food alone do not exceed the Agency's level of concern. There are potential chronic risks of concern to infants and children less than 1 year old, however, from drinking water from one surface water CWS in the Midwest where simazine is primarily used on corn. The following uses of simazine also present potential chronic risks of concern to infants and children (from less than 1 year old to 6 years old) from drinking water exposure: use on nuts (mainly in California and Hawaii) when applied at a non-banded rate of 4 pounds active ingredient per acre (lbs ai/A); use on fruit trees (apples, cherries, nectarines, peaches, pears, and plums) in states other than California when applied at a non-banded rate of 4 lbs ai/A or higher; and use on citrus in Florida when applied at a rate of 9.6 lbs ai/A. An additional use that potentially results in concentrations that exceed the level of concern for the general U.S. population is "non-selective weed control on non-crop land."

To reduce human exposure to simazine and its two chlorinated degradates from drinking water and to address subsequent risks of concern, the following mitigation measures are necessary:

- prohibit use as "non-selective weed control on non-crop land" on product labels;
- prohibit aerial application and add a statement to product labels indicating this prohibition; and
- reduce maximum application rates to typical rates (as specified in Section V, Table 13) and harmonize application rates on simazine product labels.

^c To be determined when additional data are submitted to the Agency.

Additionally, the Agency has discussed with the registrants the addition to simazine product labels of setbacks from wells and waterways in addition to restrictions for use in tile-outletted terraced fields containing standpipes. These setbacks and use restrictions were previously instituted for atrazine to reduce water contamination, and will do the same for simazine plus have an overall effect of reducing drinking water exposure to simazine and its chlorinated degradates. As further detailed in Section V, Table 13, the following setbacks and use prohibitions will be added to simazine product labels for uses under the Worker Protection Standard for Agricultural Pesticides (WPS) and non-WPS commercial uses (as further detailed in Section V, Table 13):

- prohibit use, mixing, and loading within 50 feet of all wells, including abandoned wells, drainage wells, and sink holes;
- prohibit mixing and loading with 50 feet of intermittent streams and rivers, natural or impounded lakes and reservoirs;
- prohibit application within 66 feet of points where field surface water runoff enters perennial or intermittent streams and rivers (if applied to highly erodible land, the buffer must be planted to the crop or seeded with grass or other suitable crop);
- prohibit application within 200 feet of natural or impounded lakes and reservoirs;
 and
- prohibit application to tile-outletted terraced fields containing standpipes within 66 feet of standpipes unless either immediately incorporated to a depth of 2-3 inches in the entire field or applied under a no-till practice when a high crop residue management practice is practiced (high crop residue management is described as a crop management practice where little or no crop residue is removed from the field during or after crop harvest).

The Agency also has received requests from the simazine technical registrants to amend the terms and conditions of registration for their manufacturing-use products (MUPs) to require a surface water CWS monitoring program with mitigation measure triggers. EPA intends to grant these amendments and to require the monitoring program as part of the confirmatory data to be called-in for simazine. The monitoring program will involve frequent monitoring at any CWS with a surface water source for which there is monitoring data indicating the concentration of simazine plus its two chlorinated degradates exceeds, or is predicted to exceed, the chronic DWLOC for infants and children, 12.5 ppb total. Six CWS, listed below, have been identified for immediate inclusion in the monitoring program, and additional CWS may be identified in the future for inclusion based on SDWA data or other reliable monitoring data. CWS with a ground water source will not be a part of this monitoring requirement at this time because, as discussed in Section III.A.3, no ground water CWS were identified with concentrations indicating risks of concern.

If concentrations of simazine plus its two chlorinated degradates at any surface water CWS meet or exceed the Agency's level of concern or performance standard, then additional mitigation measures will be required at the associated watershed(s). Further details of the program are explained below, and a copy of the letter technical registrants completed and submitted to amend the terms and conditions of registration for their MUPs is included as Appendix J.

As with atrazine, exceedances do not appear to be linked to nation-wide use practices that can be amended on the label but rather to watershed characteristics and local conditions. Based on simazine monitoring data, the Agency has determined that drinking water risks from simazine use are localized problems and, as such, lend themselves to a localized mitigation plan. This localized mitigation program will ensure that mitigation actions taken in watersheds of concern are providing results in raw drinking water and will prevent any exceedances from occurring or going undetected in the future. In addition, this localized approach is consistent with both the conclusions from a February 2000 FIFRA Scientific Advisory Panel meeting (Partial Report May 25, 2000. Report Number 2000-01) as well as with the intent of the Agency's January 2003 Water Quality Trading Policy. This policy encourages solutions within watersheds, provides incentives and encourages actions, and provides flexibility to meet local challenges and accountability to ensure improvements.

The localized drinking water mitigation program allows the Agency to make a safety finding because any future exceedances in raw water will trigger localized use prohibitions in the watershed of concern. Since this exceedance is in raw, not finished, water, treatment of water by CWS operators to meet the MCL may prevent actual exposure above the Agency's level of concern. In addition, the Agency does not expect future exceedances to occur because of the responsible use programs being implemented and coordinated for atrazine by the simazine technical registrants, all of whom are also technical registrants for atrazine. Simazine usage data available to the Agency indicates that a majority of simazine used in the Midwest is tank mixed with atrazine, and, therefore, these responsible use programs would consequently impact the use of simazine as well. The Agency feels that the risk of localized use prohibitions is a strong incentive for simazine users and registrants to prevent exceedances. The performance standard approach makes the prevention of simazine water contamination the responsibility of the user, but compliance is assured through EPA oversight of the intensive monitoring program.

i. Simazine Surface Water CWS Monitoring Program

For the surface water CWS monitoring program, the Agency used the 12.5 ppb chronic DWLOC for infants and children less than 1 year old, the most sensitive subpopulation, to identify specific CWS of concern to the Agency. As discussed in Section III.A.3, one CWS, Hillsboro CWS (IL1350300) of Illinois, was identified with a 90-day average concentration in 1994 of simazine plus its two chlorinated degradates exceeding 12.5 ppb. Hillsboro CWS is currently being monitored for atrazine and its three chlorinated degradates as part of the atrazine surface water CWS monitoring program. While mitigation measures may be triggered for this CWS through the mechanisms in the monitoring program, and thus may be required in the future, the Agency has determined that no risk mitigation, aside from that being required for all simazine products as described above, is necessary at this CWS at this time. Simazine usage data available to the Agency indicates that a majority of simazine used in the Midwest is tank mixed with atrazine, and therefore use restrictions (e.g., setbacks from waterways, restrictions for use in tile-outletted terraced fields containing standpipes, rate reductions), which have been added to atrazine labels in the years following 1994, have consequently restricted the use of simazine as well. Additionally, concentrations of simazine plus its two chlorinated degradates in this CWS have remained well below the DWLOC of 12.5 ppb level for the past eleven years.

The Agency has also considered available data from SDWA compliance monitoring, which typically consists of samples taken quarterly at a CWS. The Agency has determined that the existence of an annual average concentration in a CWS at or above 2.6 ppb total simazine plus its chlorinated degradates, based on this data, is an appropriate early predictor that the 12.5 ppb DWLOC could be exceeded. Based on SDWA compliance data from 1997 to 2004, five additional CWS have been identified as having concentrations that predict high-end seasonal exposure. These CWS include Johnston County Water System CWS (NC0351070) in North Carolina; Patoka CWS (IL1210400), Farina CWS (IL0510150), and Flora CWS (IL0252100) in Illinois; and Stucker Fork Water Utility CWS (IN5272002) in Indiana. The latter three CWS are currently being monitored for atrazine and its three chlorinated degradates as part of the atrazine surface water CWS monitoring program.

CWS in the program will be subject to an intensive monitoring schedule that will include weekly monitoring for simazine and its two chlorinated degradates in raw water at the water intake during the simazine use season and biweekly monitoring for simazine and its two chlorinated degradates in raw water during the remainder of the year. Appendix J includes a list of the use season for simazine by state, and subsequently the monitoring schedule, for the states in which CWS currently in the monitoring program are located. The regression equation discussed in Section III.A.3 was initially used to identify CWS to put into the simazine surface water monitoring program based on monitoring data for the parent compound only, and it was used to determine the total concentration of parent compound (atrazine) plus its three chlorinated degradates for CWS in the atrazine surface water monitoring program. However, the Agency understands that technology is now available which allows for the collection of measured values for all chlorinated degradates as well as the triazine parent compound s. Thus, the terms of the simazine surface water monitoring program require that the registrant s directly measure both the parent compound (simazine) plus its two chlorinated degradates for any CWS undergoing the intensive simazine monitoring program.

In addition to the six CWS initially in the simazine monitoring program, if the concentration of simazine plus its two chlorinated degradates reaches 2.6 ppb as an annual average in finished water, or 12.5 ppb as a 90-day rolling average in raw water at the drinking water intake, based on SDWA data or other reliable monitoring data, for any surface water CWS not already in the monitoring program, then the CWS will be subject to the intensive monitoring program involving weekly (during the use season) and biweekly (during the remainder of the year) monitoring. One exception is that if a CWS has an annual average concentration of 2.6 ppb or greater based on only one quarterly sample from SDWA data, and that annual average also does not exceed EPA's MCL of 4.0 ppb for simazine alone, as established under SDWA, then the technical registrants have the option of either: 1) putting the CWS into the intensive monitoring program the year following the measurement or 2) taking four quarterly samples the year following the measurement to determine if the 2.6 ppb trigger is met or exceeded based on the four samples, and if so, putting the CWS into the monitoring program. If a CWS has an annual average concentration of 2.6 ppb or greater based only on one quarterly sample that exceeds 4.0 ppb for simazine alone, the CWS must be put into the intensive monitoring program the year following the measurement. Should the CWS to be added to the monitoring program be in a state or states not listed in Appendix J, EPA will determine the corresponding simazine use season in the state(s) to identify the appropriate monitoring schedule for the CWS.

The technical registrants must identify, by April 1 of the subsequent year, any surface water CWS with a concentration of 2.6 ppb or greater simazine plus its two chlorinated degradates based on SDWA compliance data, which includes measurements of the parent compound only in finished water, and use of the regression equation developed for simazine. The deadline for identification of CWS from 2005 SDWA compliance data is May 30, 2006, rather than April 1, to allow sufficient time for analysis of 2005 SDWA compliance data after completion of this RED. After five years of consecutive monitoring under the simazine surface water CWS monitoring program, the technical registrants may petition the Agency to remove or modify this requirement to review and report on SDWA data.

As part of the simazine surface water CWS monitoring program, technical registrants must establish a Simazine Watershed Information Center (SWIC) to provide detailed information on what watershed areas have become subject to a use prohibition for simazine. The circumstances that may lead to a use prohibition through this monitoring program are explained below. The SWIC must be accessible to the public daily, including weekends and holidays, through a toll-free number available 24 hours a day and seven days a week, a World Wide Web site, and a regular mailing address. Based on changes that will be required on MUP labels (see Table 13 below), all simazine products, except those labeled only for use by homeowners on turfgrass or labeled only for use as an algaecide, will be required to bear labels containing the following statements, as specified in Section V, Table 13:

"ANY USE OF THIS PRODUCT IN AN AREA WHERE USE IS PROHIBITED IS A VIOLATION OF FEDERAL LAW [this sentence must be in all capital letters]. Before using this product, you must consult the Simazine Watershed Information Center (SWIC) to determine whether the use of this product is prohibited in your watershed. SWIC can be accessed through [website address] or [toll-free phone number] or [mailing address]. If the SWIC indicates that use of this product is prohibited in your watershed, you may return this product to your point of purchase or contact [insert name of Registrant] for a refund."

This intensive monitoring program will determine the maximum 90-day average concentration of simazine plus its two chlorinated degradates with sufficient accuracy to allow removal of the 3X FQPA safety factor included in the calculation of the DWLOC to account for exposure-based concerns for inadequate monitoring data. As such, the Agency is establishing 37.5 ppb, rather than 12.5 ppb, simazine plus its two chlorinated degradates in raw water at the CWS intake as a 90-day average as the Agency's level of concern and performance standard that must be met in any CWS that is being intensively monitored in this program. Once CWS are in the intensive monitoring program, mitigation measures, as detailed below, will be required based on this performance standard of 37.5 ppb. However, as described above, CWS will continue to enter into the intensive monitoring program based on SDWA data or other reliable monitoring data when compared to a trigger of 2.6 ppb as an annual average in finished water, or 12.5 ppb as a 90-day rolling average in raw water at the drinking water intake.

Under the terms of the monitoring program, the technical registrants are required to submit annual reports to the Agency that include all the results of the year's analysis by January 30 of the following year. Simazine technical registrants must also notify EPA in writing of any

90-day rolling average of 37.5 ppb simazine plus its two chlorinated degradates or higher in raw water at the CWS intake within 30 days of the date of the last water sample in that result. For any CWS in the monitoring program, monitoring will occur for at least five years and may only cease if no 90-day rolling average meets or exceeds the performance standard of 37.5 ppb during the five-year period.

If this concentration is met or exceeded once in any CWS undergoing intensive monitoring, the technical registrants must submit to the EPA, and begin implementing within 90 days of the exceedance, a written mitigation plan including mitigation measures to be implemented within the watershed area containing the CWS where the exceedance occurred. This mitigation plan will include mitigation measures to be implemented within the watershed area containing the CWS and will include consideration of Best Management Practices such as buffer strips, grass waterways, changes in tillage practices, changes in application timing, and use rate reductions. The mitigation plan will also include information on how these measures will be communicated to growers. The technical registrants must submit semi-annual progress reports to EPA describing the mitigation measures taken during that period until notified by EPA that these reports may cease.

If this concentration of 37.5 ppb simazine plus its two chlorinated degradates is met or exceeded in two separate years in any CWS undergoing intensive monitoring, further use of products containing simazine, except those labeled only for use as an algaecide, will be prohibited in the watershed area containing the CWS. The boundaries of the watershed area will be determined by the Agency after consulting with the technical registrants. Products labeled only for algaecides are not included in this use prohibition because, as of 1996, labels confine their use to enclosed ornamental ponds or aquariums of 1,000 gallors or less and prohibit application or discharge into lakes, flowing water, or ponds with outflow. The SWIC must be updated within 5 business days of receiving EPA's determination, or changes to this determination, of the boundaries of the watershed area subject to the use prohibition so as to describe this watershed area. In addition, all simazine products labeled only for use by homeowners on turfgrass need to be removed from the shelves of any retailer located within all counties containing any portion of any watershed area listed in the SWIC. Corresponding label language is specified in Section V, Table 13.

If a CWS is reported to EPA to be in violation of the simazine MCL, the technical registrants must consult with the State Drinking Water Administrator of the state where the CWS is located to develop a written mitigation plan, including mitigation measures to be implemented within the watershed area containing the CWS where the MCL violation occurred, and a schedule for the mitigation plan's implementation. Technical registrants will submit the written mitigation plan to the EPA within 90 days of the exceedance. If EPA in consultation with the states, determines that the mitigation plan is not reasonably likely to reduce simazine concentrations in the CWS' water supply, or that the implementation schedule is not met, then the use of the products containing simazine, except those labeled only for use as an algaecide, would be prohibited in the watershed area containing the CWS, and the watershed area would be added to the SWIC.

ii. Revised Model Concentrations and Additional Confirmatory Data Needs

For those scenarios in which the concentration of simazine was modeled, the document "Drinking Water Estimated Concentrations for Simazine and its degradates – Addendum to Memorandum '080807 D307018 DWA revised/ May 27, 2005'," dated January 6, 2006, provides new estimates of simazine plus its two chlorinated degradates in drinking water based on the mitigation measures. While the predictive model PRZM/EXAMS suggests that the chronic DWLOC or the Agency's level of concern is exceeded in some cases, the Agency believes that these estimates are upper bound and are driven by conservative assumptions used in the model, such as maximum application rates, high spray drift, and high runoff. Additionally, the equation used to calculate the amount of the parent compound (simazine) plus its two chlorinated degradates is conservative and likely overestimates the total concentration due to the equation's derivation from data collected on degradates which can result from both simazine and atrazine. Further, the data used to derive the equation were collected in areas with a history of atrazine use and much higher atrazine concentrations than simazine concentrations. Based on all of this information, EPA believes that actual concentrations of simazine plus its two chlorinated degradates in drinking water will be below the Agency's level of concern. For those crops for which modeled scenarios exceed the chronic DWLOC, the Agency also intends to require representative confirmatory data in the form of a drinking water monitoring study at CWS determined by the Agency to be the most vulnerable to simazine contamination

The Agency also intends to require as confirmatory data a prospective ground water monitoring study to be completed in Florida. While modeled concentrations of the parent compound (simazine) alone for ground water do not exceed the DWLOC, the Agency needs confirmation that the total concentration of simazine plus its two chlorinated degradates will not meet or exceed the DWLOC of 37.5 ppb for infants and children less than 1 year old in ground water in areas of Florida where simazine can be applied at a high rate and where there is high leaching ability due to the sandy soil type, low water table, and high rainfall amount. The lack of sufficient monitoring data on rural wells, and the identification of one sample with a simazine concentration of 11 ppb, substantiate this confirmatory data need. While a well-vulnerability study is being completed for atrazine as required in the 2004 DCI for atrazine, this study is targeted for areas of atrazine use, not simazine use, and does not cover citrus-producing areas in Florida. The Agency intends to place a rural well monitoring study in reserve so these data may be required at a later date if necessary as determined by the results of the prospective ground water monitoring study.

b. Residential Risk Mitigation

As discussed in Section III.A.4, there are potential short-term risks of concern from homeowner exposure to simazine when loading/applying granules via a belly grinder to turfgrass, but post-application risks to toddlers, youths, and adults do not exceed the Agency's level of concern.

To reduce homeowner handler exposure to simazine, the use of simazine by homeowners using hand-held devices (e.g., belly grinders or handheld rotary applicators) must be restricted to

spot treatment only and a statement must be added to end-use product labels indicating this restriction. EPA has determined that this mitigation measure will reduce risks to homeowner handlers below the Agency's level of concern.

c. Aggregate Risk Mitigation

As discussed in Section III.A.5., there are potential aggregate risks of concern from the combination of dietary exposure from drinking water and residential exposure for those scenarios where either exposure alone exceeds the Agency's level of concern. Also there are potential aggregate risks of concerns to toddlers entering treated areas of turfgrass post-application, due to risks of concern for this subpopulation from drinking water exposure alone.

Because these risks of concern are all driven by scenarios noted above for which mitigation measures are being required, no additional risk mitigation is necessary to specifically address aggregate risk. The Agency believes that with the required risk mitigation, aggregate risks will be below the Agency's levels of concern for all subpopulations, including infants and children less than 1 year old.

d. Occupational Risk Mitigation

As discussed in Section III.A.6, there are potential shortand intermediate-term risks of concern to occupational handlers for multiple scenarios involving mixing/loading, applying, and mixing/loading/applying products containing simazine.

To reduce exposure to simazine for occupational handlers and to address subsequent risks of concern, the following mitigation measures are necessary:

- prohibit use as "non-selective weed control on non-crop land" on product labels;
- prohibit formulation of simazine into wettable powder formulations;
- prohibit formulation of simazine into granular formulations for occupational use, which includes uses covered under the WPS and non-WPS commercial uses;
- prohibit aerial application and add a statement to product labels indicating this prohibition; and
- reduce application rate on corn to a maximum of 2 pounds active ingredient per acre (lbs ai/A) per application and a maximum of 2.5 lbs ai/A per year.

Additional rate reductions to typical rates (as specified in Section V, Table 13) and harmonization of application rates on simazine product labels will further reduce occupational handler exposure to simazine for various scenarios. In order to eliminate the need to use engineering controls with dry flowables formulations to reduce occupational handler risks below the Agency's level of concern, the registrants agreed to reduce the application rate on grapes to a maximum of 4 lbs ai/A per application and per calendar year. As discussed in the document "Review of Simazine Dry Flowable Exposure Scenario for Applications to Corn, Grapes, and Florida Oranges, D307039," dated January 30, 2006, the Agency has also determined that intermediate-term exposure will not occur when occupational handlers are mixing/loading dry flowable and liquid formulations for chemigation application, so PPE or engineering controls to address these scenarios are unnecessary.

The recalculated MOEs, based on the mitigation measures and additional reduced rates, are available in the document "Simazine: Addendum to HED Risk Assessment (11/30/05, D320052) Chapter of the Reregistration Eligibility Decision (RED). DP Barcode: 325685," dated January 31, 2006. For many of simazine's use scenarios, the PPE necessary to reduce occupational handler risks below the Agency's level of concern is chemical-resistant gloves (as specified in Section V, Table 13). In addition to gloves, mixer/loaders of dry flowable formulations supporting groundboom applications need to wear coveralls over their long-sleeve shirts and pants, chemical-resistant footwear, and PF 5 NIOSH-approved respirators with a dust/mist filter in order to reduce exposure risks below the Agency's level of concern. In other words, with this PPE no MOEs exceed the Agency's level of concern.

The Worker Protection Standard for Agricultural Pesticides requires a restricted-entry interval (REI) of at least 12 hours for all uses and this REI must appear on all product labels. There are two uses for which potential risks of concern exist after 12 hours for re-entry workers – Christmas trees and turfgrass on sod farms when applied at a rate of 4 lbs ai/A. To reduce post-application exposure and to address subsequent risks of concern the following mitigation measures are necessary:

- specify an REI for Christmas trees of 48 hours on product labels; and
- require watering-in of products that can be used on turfgrass on sod farms when the rate is greater than 2 lbs ai/A through a statement on products labels.

2. Ecological Risk Management and Mitigation

As discussed in Sections III.B.2, and 3, there are potential acute risks of concern, or direct adverse acute effects, to non-target aquatic and terrestrial organisms in the following taxonomic groups from exposure to the parent compound (simazine) only: vascular aquatic plants, non-vascular aquatic plants, monocot terrestrial plants, and dicot terrestrial plants. The Agency also estimates that although avian mortality is unlikely from acute simazine exposure there is a potential for acute sublethal effects to birds (e.g., reduced reaction to external stimuli, wing drop, depression).

The Agency estimates that there are potential chronic risks of concern, or direct adverse chronic effects, to non-target terrestrial organisms in the following taxonomic groups: birds and mammals. Potential chronic effects for both freshwater and marine/estuarine fish and invertebrates are unknown for the technical grade active ingredient although available data on a formulation of 80% active ingredient indicate that the use of simazine is unlikely to result in chronic risk to fish and invertebrates.

To reduce aquatic and terrestrial organism exposure to simazine and to address subsequent risks of concern, the following mitigation measures are necessary:

- prohibit use as "non-selective weed control on non-crop land" on product labels;
- prohibit formulation of simazine into granular formulations for agricultural use; and
- reduce maximum application rates to typical rates (as specified in Section V, Table 13), further restrict use on corn in areas with highly erodible soils (similar

to rate reductions for use of atrazine on corn), and harmonize application rates on simazine product labels.

Chronic RQs for these organisms were recalculated based on the mitigation measures in the document "Revised Simazine RQs for Terrestrial Animals and Plants Based on Proposed Harmonized Labels," dated December 8, 2005. While the Agency's acute and chronic level of concern is still exceeded for some taxonomic groups, most notably for birds and mammals, the Agency believes that these estimates are conservative since they consider 100% of the organism's diet is from areas treated with simazine. Additionally, the prohibition of aerial application of simazine, a risk mitigation measure necessary to reduce drinking water and occupational exposure and subsequent risks of concern, plus the addition of pesticide-specific label language describing the environmental hazards of simazine use and restricting spray drift (as further detailed in Section V, Table 13), will have an overall effect of reducing aquatic and terrestrial organism exposure to simazine.

The Agency intends to require confirmatory acute toxicity data on freshwater fish and invertebrates; confirmatory chronic toxicity data on freshwater and estuarine/marine fish and invertebrates; confirmatory acute oral toxicity data on birds for sublethal effects; and confirmatory ecotoxicity data on simazine's two chlorinated degradates for all taxonomic groups except mammals, birds, and plants. The Agency will also take into consideration the results of laboratory and field studies now underway on atrazine's potential sublethal effects to amphibians, specifically impacts on gonadal development in frogs, and intends to place in reserve a similar study for simazine in the DCI so that these data may be required at a later date if necessary.

3. Other Labeling Requirements

In order to be eligible for reregistration, simazine use and user safety information also needs to be included in the labeling of all end-use products containing simazine. For the specific label statements and a list of additional data requirements necessary to confirm this decision, refer to Section V of this RED document.

4. Threatened and Endangered Species Considerations

For Listed Species, the Agency's level of concern for direct effects was exceeded for the following taxonomic groups: freshwater fish, freshwater invertebrates, vascular aquatic plants, birds, mammals, monocot terrestrial plants, and dicot terrestrial plants. There also may be the potential for indirect adverse effects for some Listed Species that are dependent on these taxonomic groups.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on threatened and endangered species and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize Listed Species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for

REDs and then considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will take into consideration any risk mitigation measures that are being implemented as a result of this RED.

Following this future species-specific analysis, a determination that there is a likelihood of potential effects to a Listed Species may result in limitations on use of simazine, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries as appropriate. If the Agency determines use of simazine "may effect" Listed Species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until a 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 simazine at levels of concern. EPA is not requiring specific simazine label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of Listed Species, the Agency will implement them through the Endangered Species Program

V. What Registrants Need to Do

The Agency has determined that simazine is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. The Agency intends to issue DCIs for generic (technical grade) data and product-specific data. Generally, registrants will have 90 days from receipt of a generic DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. Table 12 below presents the additional generic data the Agency intends to require for simazine to confirm the decision that simazine is eligible for reregistration. For product-specific DCIs, registrants will have eight months to submit data and amend labels. In order for simazine to be eligible for reregistration, all product labels must be amended to incorporate the specific changes and language presented in Table 13 below. Table 13 also describes how the required language should be incorporated.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of simazine has been reviewed and determined to be substantially complete. However, EPA is requiring the following additional data to confirm the decisions presented in this RED. The Agency intends to issue a generic DCI for this data.

Table 12. Data requirements for the reregistration of simazine

Data Requirement Data Requirement	New OPPTS	Old OPP
1	Guideline	Guideline
	Number (GLN)	Number
Terrestrial Field Dissipation	835.6100	164-1
Prospective Ground Water Monitoring Study	835.7100	166-1
Spray Droplet Size Spectrum	840.1100	201-1
Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids	850.1010	72-2a
Acute toxicity tests on freshwater invertebrates based on mean-measured		
concentrations of simazine's technical grade active ingredient (TGAI) plus		
ecotoxicity data on the chlorinated degradates (DIA and DACT).		
Mysid Acute Toxicity Test	850.1035	72-3c
Acute toxicity tests on estuarine/marine invertebrates based on mean-		
measured concentrations of simazine's TGAI plus ecotoxicity data on the		
chlorinated degradates (DIA and DACT).		
Fish Acute Toxicity Test, Freshwater	850.1075	72-1a and c
Acute toxicity tests on freshwater fish (warm and cold water) based on		
mean-measured concentrations of simazine's TGAIplus ecotoxicity data		
on the chlorinated degradates (DIA and DACT).		
<u>Daphnid Chronic Toxicity Test</u>	850.1300	72-4b
Chronic toxicity studies for freshwater invertebrates using the TGAI of		
simazine.		
Mysid Chronic Toxicity Test	850.1350	72-4b
Chronic toxicity studies for estuarine/marine invertebrates using the TGAI		
of simazine.		
Fish Early-Life Stage Toxicity Test	850.1400	72-4a
Chronic toxicity studies for freshwater and estuarine/marine fish using the		
TGAI of simazine.		
Fish Life Cycle Toxicity (in reserve)	850.1500	72-5
Pending results of Fish Early-Life Stage Toxicity Test (850.1400).		
Avian Acute Oral Toxicity Test	850.2100	71-1a
The mallard duck acute oral LD ₅₀ study is classified as supplemental		
because it deviates from the guideline protocol in that the birds were 14		
days old rather than 14 to 16 weeks. Given the observed sublethal effects		
and the potential influence of age on the results of the study, a study is		
needed on avian acute oral toxicity.		
Residue Analytical Methods	860.1340	171-4c and d
Enforcement methods capable of measuring simazine and its two		
chlorinated degradates for plant commodities and for livestock		
commodities. Independent laboratory validations of existing data-		
gathering methods are sufficient to meet this requirement.	0.60.1200	171 4
Storage Stability Data	860.1380	171-4e
Storage stability data for up to three years to support existing field trials on		
orange crops.	0.50 1.500	151 41
Magnitude of the Residue in Crops	860.1500	171-4k
Field trials for pear, cherry, cranberry, currant, strawberry, grapefruit,		
lemon, orange, almond, macadamia nut, walnut, and sweet corn crops.	0.00 1.500	151 41
Magnitude of the Residue in Processed Food/Feed	860.1520	171-41
Additional processing studies to depict the potential for concentration of		
simazine residues in processed commodities of apple, corn grain, grape,		
olive, and orange crops.	0.00 1000	165.0
Field Accumulation in Rotational Crops	860.1900	165-2
Limited field trials on representative rotational crops, corn and strawberry,		
are required.		

Amphibian Endocrinology and Development Study (in reserve)	Special study	N/A
Pending results of similar atrazine study (Special study).		
Surface Water CWS Monitoring Program	Special study	N/A
Drinking Water Monitoring Study	Special study	N/A
Rural Well Monitoring Study (in reserve)	Special study	N/A
Surface and Ground Water Monitoring for Simazine	Special study	N/A

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, labeling for all MUPs should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the specific language presented in Table 13 below.

B. End-Use Products

1. Additional Product-Specific Data Requirements

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

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. The specific changes and language are presented in Table 13 below. 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.

Table 13. Summary of required labeling changes for simazine products

	Manufacturing-Use Products				
Description	Amended Labeling Language	Placement on Label			
For all Manufacturing- Use Products	"Only for formulation into an herbicide/algaecide for the following use(s) [fill blank only with those uses that are being supported by MUP Registrant]." The use of simazine as nonselective weed control on non-cropland (including industrial sites; highway medians and shoulders; railroad rights-of-way; lumberyards; petroleum tank farms; noncrop areas on farms such as around buildings, equipment, and fuel storage areas; and along fences, road-sides, and lanes) is cancelled. Uses and use-patterns on alfalfa, Bermuda grass, and other grasses are also cancelled except when these grasses are a component of turfgrass. Manufacturing-use and end-use product labels must be revised to delete all references to and use directions for these cancelled use products. "Not for formulation into wettable powder end-use product formulations." "Not for formulation into granular end-use product formulations intended for occupational use."	Directions for Use			
One of these statements may be added to a label to allow reformulation of the product for a specific use or use-pattern or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use			
Text required as part of terms and conditions of registration	"This product may not be reformulated or repackaged into another product unless the registration of the reformulated or repackaged product was granted or amended so as to be consistent with the Surface Water CWS Monitoring Program set forth in the Simazine Reregistration Eligibility Decision (RED)."	Directions for Use			

Text required as part of	"No product other than a product labeled only for use by homeowners on	Directions for Use
erms and conditions of	turfgrass or labeled only for use as an algaecide may be formulated or	
registration	repackaged from this product unless the formulated or repackaged product bears a	
	label including all of the following statements prominently displayed in the	
	"Directions for Use" section: "ANY USE OF THIS PRODUCT IN AN AREA	
	WHERE USE IS PROHIBITED IS A VIOLATION OF FEDERAL LAW [this	
	sentence must be in all capital letters]. Before using this product, you must consult	
	the Simazine Watershed Information Center (SWIC) to determine whether the use	
	of this product is prohibited in your watershed. SWIC can be accessed through	
	www.simazine-watershed.info or 1-888-365-2874. If the SWIC indicates that use	
	of this product is prohibited in your watershed, you may return this product to your	
	point of purchase or contact [insert name of Registrant] for a refund."	
	"No products labeled only for use by homeowners on turfgrass may be	
	reformulated or repackaged from this product unless the registration of the	
	resulting product is subject to the following terms and conditions of registration,	
	which shall require that the Registrant:	
	1) Immediately cease all sale and distribution to any retailer or any entity	
	distributing or selling such product to any retailer located within all counties	
	containing any portion of the watershed area listed in the SWIC;	
	2) Ensure the removal of any such Simazine product from the shelves of any	
	retailer located within all counties in containing any portion of any watershed area	
	listed in the SWIC; and	
	3) Repurchase any such Simazine product from any of the purchasers described	
	above.	
	4) In addition, such Registrant shall consult with the State(s) in which such	
	counties are located to determine whether additional territory shall be included in	
	the area to which these requirements will apply. If the States(s) determine that a larger area is warranted, the Registrant shall within 10 days of such determination	
	notify the Director of EPA's Special Review and Reregistration Division (SRRD)	
	(7508P), Office of Pesticide Programs, of the State(s) determination. EPA will	
	then notify such Registrant of the specific boundaries within which the stop sale,	
	removal, and repurchase shall take place."	

Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to aquatic invertebrate. 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
	End-Use Products Intended for WPS and/or Occupational Use	
PPE Requirements Established by the RED ^a For Liquid Formulations	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [Registrant inserts correct chemical-resistant material]. If you want more options, follow the instructions for category [Registrant inserts A, B, C, D, E, F, G, or H] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: - Long-sleeve shirts and long pants, - Shoes plus socks, and - Chemical-resistant gloves."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED ^a for Dry Flowable Formulations	Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are [Registrant inserts correct chemical-resistant material]. If you want more options, follow the instructions for category [Registrant inserts A, B, C, D, E, F, G, or H] on an EPA chemical-resistance category selection chart."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

PPE Requirements Established by the RED ^a for Dry Flowable Formulations (cont.)	"Mixers and loaders supporting groundboom applications must wear: - Coveralls over long-sleeve shirt and long pants, - Chemical-resistant footwear plus socks, - Chemical-resistant gloves, - Chemical-resistant apron, and - a NIOSH-approved respirator with a dust/mist filter (with MSHA/NIOSH approval number prefix TC-21C or with any N, R, P, or HE filter)." If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped. "All other mixers, loaders, applicators, and other handlers must wear: - Long-sleeve shirts and long pants, - Shoes plus socks, and - Chemical-resistant gloves."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Wettable Powder Formulations will not be eligible for reregistration and are no longer permitted for end-use products containing simazine.		
Granular Formulations will not be eligible for reregistration and are no longer permitted for enduse products containing simazine that are intended for occupational use.		
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product=s concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Engineering Controls for Liquid Formulations	"Engineering Controls When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240 (d)(4, 5)), the handler PPE requirements may be reduced or modified as specified in WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Engineering Controls for Dry Flowable Formulations	"Engineering Controls When handlers use enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240 (d)(4, 5)), the handler PPE requirements may be reduced or modified as specified in WPS."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards for products with directions for aquatic use in aquariums or ornamental ponds only	"Environmental Hazards Do not apply to or allow discharge to lakes, flowing water, or ponds with outflow. Do not contaminate domestic livestock or irrigation water supplies."	Precautionary Statements immediately following the User Safety Recommendations

Environmental Hazards for products with directions for aquatic use in aquariums or ornamental ponds in addition to terrestrial uses	"Environmental Hazards Simazine can travel (seep or leach) through soil and can enter ground water which may be used as drinking water. Simazine has been found in ground water. Users are advised not to apply simazine to sand and loamy sand soils where the water table (ground water) is close to the surface and where these soils are very permeable; i.e., well-drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water." "This pesticide is toxic to aquatic invertebrates. Except when following the Directions for Use for applications to aquariums and outdoor ponds when permitted on the label, do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff and drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water." For aquatic use in aquariums or ornamental ponds: "Do not apply to or allow discharge to lakes, flowing water, or ponds with outflow. Do not contaminate domestic livestock or irrigation water supplies."	Precautionary Statements immediately following the User Safety Recommendations
Environmental Hazards for products with directions for terrestrial (nonaquatic) uses only	"Environmental Hazards Simazine can travel (seep or leach) through soil and can enter ground water which may be used as drinking water. Simazine has been found in ground water. Users are advised not to apply simazine to sand and loamy sand soils where the water table (ground water) is close to the surface and where these soils are very permeable; i.e., well-drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water." "This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff and drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water."	Precautionary Statements immediately following the User Safety Recommendations

Environmental Hazards for products with directions for terrestrial uses (in addition to statements specified above) "Product must not be mixed or loaded within 50 feet of intermittent streams and rivers, natural or impounded lakes and reservoirs. Product must not be applied within 66 feet of points where field surface water runoff enters perennial or intermittent streams and rivers or within 200 feet of natural or impounded lakes and reservoirs. If this product is applied to highly erodible land, the 66 foot buffer or setback from runoff entry points must be planted to crop, or seeded with grass or other suitable crop."

Precautionary Statements immediately following the environmental hazard statements specified above

"Product must not be mixed or loaded, or used within 50 feet of all wells, including abandoned wells, drainage wells, and sink holes. Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 ft. of any well are prohibited, unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or wash water, and rain water that may fall on the pad. Surface water shall not be allowed to either flow over or form the pad which means the pad must be self-contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above-specified minimum containment capacities do not apply to vehicles when delivering pesticide to the mixing/loading sites."

"Additional State imposed requirements regarding well-head setbacks and operational area containment must be observed."

Environmental Hazards for products with directions for terrestrial uses (in addition to statements specified above) (cont.)	"One of the following restrictions must be used in applying simazine to tile- outletted terraced fields containing standpipes: Do not apply within 66 feet of standpipes in tile-outletted terraced fields. Apply this product to the entire tile-outletted terraced field and immediately incorporate it to a depth of 2-3 inches in the entire field. Apply this product to the entire tile-outletted terraced field under a no-till practice only when a high crop residue management practice is practiced. High crop residue management is described as a crop management practice where little or no crop residue is removed from the field during and after crop harvest."	Precautionary Statements immediately following the environmental hazard statements specified above
Restricted-Entry Interval for products with directions for uses and use-patterns within the scope of WPS	"For Christmas trees, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 48 hours. For all other crops and use-patterns, do not enter or allow worker entry into treated areas during the REI of 12 hours."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for uses and use-patterns within the scope of WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: - Coveralls, - Shoes plus socks, and - Chemical-resistant gloves made of any waterproof material"	Direction for Use Agricultural Use Requirements box
Entry Restrictions for products with Occupational uses and use-patterns (non-WPS) that are applied by spray	"Do not enter or allow others (including children or pets) to enter until sprays have dried."	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.

Text required as terms and conditions of registration for products with directions for terrestrial (nonaquatic) use	"ANY USE OF THIS PRODUCT IN AN AREA WHERE USE IS PROHIBITED IS A VIOLATION OF FEDERAL LAW [this sentence must be in all capital letters]. Before using this product, you must consult the Simazine Watershed Information Center (SWIC) to determine whether the use of this product is prohibited in your watershed. SWIC can be accessed through www.simazine-watershed.info or 1-888-365-2874. If the SWIC indicates that use of this product is prohibited in your watershed, you may return this product to your point of purchase or contact [insert name of Registrant] for a refund."	Directions for Use
General Application Restrictions for all formulations	"Aerial application is prohibited."	Near the beginning of the Directions for Use in bold type and red lettering.
Use-specific Application Restrictions (The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.)	"When tank-mixing or sequentially applying simazine or products containing simazine, the total pounds of simazine applied must not exceed the specific maximum rate per calendar year as noted in the use directions." Delete all references to and use directions for the following uses and use-patterns: – nonselective weed control on non-cropland (including industrial sites; highway medians and shoulders; railroad rights-of-way; lumberyards; petroleum tank farms; noncrop areas on farms such as around buildings, equipment, and fuel storage areas; and along fences, road-sides, and lanes) – alfalfa, and – Bermuda grass and other grasses (except when these grasses are a component of turfgrass)	Directions for Use

Use-specific Application Restrictions (The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.) (cont.) For products with the following uses and use-patterns please amend labels to include specified language or reflect the following application rates, application timing, and application directions.

Corn (field and sweet)

"Apply a maximum of 2.0 lbs ai/acre as a single preemergence application on soils that are not highly erodible or on highly erodible soils, as defined by the Natural Resources Conservation Service, if at least 30% of the soil is covered with plant residues. If a second treatment is required following an earlier herbicide application, the total simazine applied may not exceed 2.5 lbs ai/acre per calendar year."

"Apply a maximum of 1.6 lbs ai/acre as a single preemergence application on highly erodible soils if <30% of the soil is covered with plant residues."

Pre-grazing/pre-harvest interval for field corn: 60 days. Pre-grazing/pre-harvest interval for sweet corn: 45 days.

Citrus (Grapefruit, Lemons, and Oranges)

AZ (Lemons and Oranges only)

Do not apply more than 3.2 lbs ai/acre per calendar year.

Do not apply more than 1.6 lbs ai/acre per application.

Can be applied once during the fall and once during the spring.

CA

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than twice per calendar year.

Directions for Use

Use-specific Application Restrictions (The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.) (cont.)

Citrus (Grapefruit, Lemons, and Oranges) (cont.)

FL (Grapefruit and Oranges only)

Do not apply more than 8 lbs ai/acre per calendar year.

Do not apply more than 4 lbs ai/acre per application.

Can be applied once during the fall and once during the spring.

For control of difficult species a maximum of 8 lbs ai per treated acre may be applied in a single application in the spring as a 50% band: "Apply no more than 8 lbs ai of [Registrant inserts end-use product name] per treated acre as a single application in the spring using a 50% band application. The amount of [Registrant inserts end-use product name] applied per acre of field should not exceed 4 lbs ai. Apply in the spring growing season between January and April. Do not make a fall application if this treatment was used in the spring."

Directions for Use

TX (Grapefruit and Oranges only)

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than twice per calendar year.

Apples

Do not apply more than 4 lbs ai/acre per calendar year.

Delete specific rates for dormant use above 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Pre-harvest interval: 150 days

Cherries (tart and sweet)

Do not apply more than 4 lbs ai/acre per calendar year.

Delete specific rates for dormant use above 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Pears

Do not apply more than 4 lbs ai/acre per calendar year.

Delete specific rates for dormant use above 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Plums

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Use-specific Application Restrictions (The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.) (cont.)

Peaches

Do not apply more than 2 lbs ai per treated acre per calendar year in CA.

Must be applied in a 2-4 ft band on each side of tree rows in CA.

Do not apply more than 4 lbs ai/acre per calendar year in other states.

Delete specific rates for dormant use above 2 lbs ai/acre per calendar year in CA and 4 lbs ai/acre per calendar year in other states.

Do not apply more than once per calendar year.

Nectarines

Apply only in CA.

Do not apply more than 2 lbs ai per treated acre per calendar year.

Must be applied in a 2-4 ft band on each side of tree rows.

Do not apply more than once per calendar year.

Almonds

Apply only in CA.

Do not apply more than 2 lbs ai per treated acre per calendar year.

Must be applied in a 2-4 ft band on each side of tree rows.

Do not apply more than once per calendar year.

Filberts or Hazelnuts

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than twice per calendar year.

Macadamia Nuts

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Pecans

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Walnuts

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Directions for Use

Use-specific Application Restrictions (The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.) (cont.)

Strawberries

Apply only in OR and WA.

Do not apply more than 1 lb ai/acre per calendar year.

Do not apply more than once per calendar year.

Blueberries and Caneberries (Blackberries, Boysenberries, Loganberries, and Raspberries)

Directions for Use

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than twice per calendar year.

Avocados

Apply only in CA and FL.

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Cranberries

Do not apply more than 4 lbs ai/acre per calendar year in MA.

Do not apply more than 2 lbs ai/acre per calendar year in all other states.

Do not apply more than once per calendar year.

Grapes

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Olives

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Nurseries (Woody Ornamentals, Deciduous Trees, and Conifers)

Do not apply more than 3 lbs ai/acre per calendar year.

Do not apply more than once per calendar year.

Christmas Tree Plantings

Do not apply more than 4 lbs ai/acre per calendar year.

Do not apply more than twice per calendar year.

Use-specific Application Restrictions (The product label must list the specified application rates in pounds or gallons of formulated products in place of pounds of active ingredient.) (cont.)	Shelterbelt Plantings (Woody Ornamentals, Deciduous Trees, and Conifers) Do not apply more than 4 lbs ai/acre per calendar year. Do not apply more than twice per calendar year. Tree Plantations for Timber (Black Walnut, Slash Pine, White Pine, and Loblolly Pine only) Do not apply more than 4 lbs ai/acre per calendar year. Do not apply more than once per calendar year. Turfgrass on Sod farms in FL "This product must be watered in immediately after application if applied at a rate greater than 2 lbs ai/acre."	Directions for Use
Spray Drift	"SPRAY DRIFT MANAGEMENT: A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, chemigation) can influence pesticide drift. The applicator and grower must evaluate all factors and make appropriate adjustments when applying this product." Wind Speed "Do not apply at wind speeds greater than 10 mph." Droplet Size "Apply as a coarse or coarser spray (ASAE standard 572)." Release Height "For groundboom applications apply with a nozzle height no more than 4 feet above the ground or crop canopy."	Directions for Use
	End-Use Products Intended for Homeowner Use	
Environmental Hazards for products with directions for aquatic use in aquariums or ornamental ponds only	"Environmental Hazards Do not apply to or allow discharge to lakes, flowing water, or ponds with outflow. Do not contaminate domestic livestock or irrigation water supplies."	Precautionary Statements immediately following the environmental hazard statements specified above

Environmental Hazards for products with directions for aquatic use in aquariums or ornamental ponds in addition to terrestrial uses	"Environmental Hazards Simazine can travel (seep or leach) through soil and can enter ground water which may be used as drinking water. Simazine has been found in ground water. Users are advised not to apply simazine to sand and loamy sand soils where the water table (ground water) is close to the surface and where these soils are very permeable; i.e., well-drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water." "This pesticide is toxic to aquatic invertebrates. Except when following the Directions for Use for applications to aquariums and outdoor ponds when permitted on the label, do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff and drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water." For aquatic use in aquariums or ornamental ponds: "Do not apply to or allow discharge to lakes, flowing water, or ponds with	Precautionary Statements immediately following the User Safety Recommendations
Environmental Hazards for products with directions for terrestrial (nonaquatic) uses only	outflow. Do not contaminate domestic livestock or irrigation water supplies." "Environmental Hazards Simazine can travel (seep or leach) through soil and can enter ground water which may be used as drinking water. Simazine has been found in ground water. Users are advised not to apply simazine to sand and loamy sand soils where the water table (ground water) is close to the surface and where these soils are very permeable; i.e., well-drained. Your local agricultural agencies can provide further information on the type of soil in your area and the location of ground water." "This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff and drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water."	Precautionary Statements immediately following the environmental hazard statements specified above

Application Restrictions for all products intended for Homeowner use	"Do not apply this product in a way that will contact other persons or pets either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions for products with directions for use on lawns	"Do not allow people or pets to enter the treated area until dusts have settled. In addition, if directions for use require watering-in, do not allow people (except those involved in the watering-in) or pets to enter the treated area until the watering-in process is complete and the area has dried."	Directions for use under General Precautions and Restrictions
Precautionary Statements for Granular Formulations	"Broadcast applications must NOT be made using hand-held devices, such as a belly grinder or handheld rotary applicator. Such equipment may only be used for spot treatments."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

^a 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. Appendices

Appendix A. Simazine Uses and Use-Patterns Eligible for Reregistration

Site	Max. Single Application Rate (lbs ai/A except where noted)	Max. Number of Applications per Calendar Year	Max. Total Pounds per Calendar Year (lbs ai/A)	Pre-grazing or Pre- harvest Interval	Use Limitations
Alfalfa (grown for seed) (Special Local Need WA only)	0.6	1	0.6	N/A	Special Local Need (Section 24(c) of FIFRA) registration for WA only. Do not use harvested seed for sprouting. Do not graze or feed screenings from treated fields. Crop cannot be used for human consumption.
Almond (CA only)	2 lbs ai/treated acre	1	2 lbs ai/treated acre	NS ^a	Use is restricted to CA. Must be applied in a 2-4 foot band on each side of tree rows.
Apple	4	1	4	Pre-harvest interval: 150 days	
Avocado (CA and FL only)	4	1	4	NS	Use is restricted to CA and FL.
Blueberry	4 or (2+2)	1 or (2)	4	NS	Apply one application in spring or a split application in spring and fall. Do not apply when fruit is present.
Cabbage (grown for seed) (Special Local Need WA only)	0.8	2	1.6	N/A	Special Local Need (Section 24(c) of FIFRA) registration for WA only. Do not use on crop, crop residue, or seed screenings for food or feed.
Caneberry (Blackberry, Boysenberry, Loganberry, and Raspberry)	4 or (2+2)	1 or (2)	4	NS	Apply one application in spring or a split application in spring and fall. Do not apply when fruit is present.
Cherry (tart and sweet)	4	1	4	NS	
Christmas Tree Plantings	4 or (2+2)	1 or (2)	4	N/A	Apply one application or a split application.
Citrus Fruit in AZ (Lemon and Orange)	1.6	2	3.2	NS	Apply in spring and/or fall.

Citrus Fruit in CA (Grapefruit, Lemon, and Orange)	4 or (2+2)	1 or (2)	4	NS	Apply one application or a split application in spring and fall.
Citrus Fruit in FL	4	2	8	NS	Apply in spring and/or fall.
(Grapefruit and Orange)	4 equivalent to 8 lbs ai/treated acre	1	4	NS	Rate for control of difficult species. Must be applied as a 50% band application in the spring if used at this rate as specified in the Table 13. Summary of required label changes for simazine products.
Citrus Fruit in TX (Grapefruit and Orange)	4 or (2+2)	1 or (2)	4	NS	Apply one application or a split application in spring and fall.
Corn (field and sweet)	1.6	1	1.6	Pre-grazing and Pre- harvest intervals: Field corn – 60 days Sweet corn – 45 days	Rate for use on highly erodible soils if less than 30% of the soil is covered with plant residues as specified in the Table 13. Summary of required label changes for simazine products. Do not graze treated areas.
	2	2	2.5	Pre-grazing and Pre- harvest intervals: Field corn – 60 days Sweet corn – 45 days	Rate for use only on soils that are not highly erodible or highly erodible soils if at least 30% of the soil is covered with plant residues as specified in the Table 13. Summary of required label changes for simazine products. Do not graze treated areas.
Cranberry	2	1	2	NS	
	4	1	4	NS	Use is restricted to MA.
Filbert or Hazelnut	4 or (2+2)	1 or (2)	4	NS	Apply one application in fall or a split application in spring and fall. Do not apply when nuts are on the ground during the harvest period.
Grape	4	1	4	NS	

Macadamia Nut	4	1	4	NS	Apply in 50 gallons of water/acre. Do not apply when nuts are on the ground during harvest period.
Nectarine (CA only)	2 lbs ai/treated acre	1	2 lbs ai/treated acre	NS	Use is restricted to CA. Must be applied in a 2-4 foot band on each side of tree rows.
Nurseries (Woody Ornamentals, Deciduous Trees, and Conifers)	3	1	3	N/A	
Olive	4	1		NS	
Ornamental Ponds and Aquariums	0.00067 lbs ai/100 gallons	NS	NS	N/A	
Peach	2 lbs ai/treated acre	1	2 lbs ai/treated acre	NS	Use is restricted to CA. Must be applied in a 2-4 foot band on each side of tree rows.
	4	1	4	NS	
Pear	4	1	4	NS	
Pecan	4	1	4	NS	Do not apply when nuts are on the ground. Do not allow animals to graze treated areas.
Plum	4	1	4	NS	-
Seedbeds of Woody Ornamentals, Deciduous Trees, and Conifers (Special Local Need IN only)	0.9	1	0.9	N/A	Special Local Need (Section 24(c) of FIFRA) registration for IN only.
Shelterbelt Plantings (Woody Ornamentals, Deciduous Trees, and Conifers)	4 or (2+2)	1 or (2)	4	N/A	Apply one application or a split application.
Strawberry (OR and WA only)	1	1	1	NS	Use is restricted to OR and WA.
Tree Plantations for Timber (Black Walnut, Slash Pine, White Pine, and Loblolly Pine only)	4	1	4	N/A	
Turfgrass on Golf courses (Fairways)	2	2	3	N/A	Do not graze or feed turf clippings to animals.

Turfgrass for	0.1 lbs ai/ 2,500 sq.	NS	NS	N/A	Rate for homeowner use.
Ornamental Lawns and	ft.				
Turf	2	2	3	N/A	Do not graze or feed turf clippings to animals.
Turfgrass on Sod farms	2	2	3	N/A	Do not graze or feed turf clippings to animals.
	4	2	6	N/A	Use is restricted to FL.
					Product must be watered-in immediately after
					application if applied at a rate greater than 2
					lbs ai/A.
					Do not graze or feed turf clippings to animals.
Walnut	4	1	4	NS	Do not apply when nuts are on the ground.

^a NS = Not specified

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0070 (simazine) covered by this RED. It contains generic data requirements that apply to simazine 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. <u>Data Requirement</u> (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.
- 2. <u>Use Pattern</u> (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
 - A. Terrestrial food
 - B. Terrestrial feed
 - C. Terrestrial non-food
 - D. Aquatic food
 - E. Aquatic non-food outdoor
 - F. Aquatic non-food industrial
 - G. Aquatic non-food residential
 - H. Greenhouse food
 - I. Greenhouse non-food
 - J. Forestry
 - K. Residential
 - L. Indoor food
 - M. Indoor non-food
 - N. Indoor medical
 - O. Indoor residential
- 3. <u>Bibliographic Citation</u> (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix (Appendix D) for a complete citation of the study.

New Guideline	Old Guideline	Requirement	Use Pattern	Bibliographic Citation(s)
Number	Number		• • • • • • • • • • • • • • • • • • • •	
020 4770			duct Chemistry	00000077 00440440 40774004 00774404
830.1550	61-1	Product Identity and Composition	A,B,C,G,J,K	00023955 00143169 42751801 CSF 4/21/93
830.1600	61-2a	Start. Mat. & Mfg. Process	A,B,C,G,J,K	00023955 00143169 40765101
830.1620	61-2b	Description of Production Process	A,B,C,G,J,K	00023955 00143169 40765101
830.1670	61-2b	Discussion of Impurities	A,B,C,G,J,K	00143169
830.1700	62-1	Preliminary Analysis	A,B,C,G,J,K	00143169 40765101 42181501
830.1750	62-2	Certification of limits	A,B,C,G,J,K	00023955 00143169 40765101 42181501 42503701
830.1800	62-3	Analytical Method	A,B,C,G,J,K	00023955 00143169 40765101 42181501 42503701
830.6302	63-2	Color	A,B,C,G,J,K	00023955
830.6303	63-3	Physical State	A,B,C,G,J,K	00023955
830.6304	63-4	Odor	A,B,C,G,J,K	00023955
830.6313	63-13	Stability temp and ions	A,B,C,G,J,K	00023955
830.6314	63-14	Oxidation and Reduction	A,B,C,G,J,K	00143169
830.6315	63-15	Flammability	A,B,C,G,J,K	00143169
830.6316	63-16	Explodability	A,B,C,G,J,K	00143169 Data Gap
830.6317	63.17	Storage stability	A,B,C,G,J,K	00023955
830.6319	63-19	Miscibility	A,B,C,G,J,K	N/A
830.6320	63-20	Corrosion Characteristics	A,B,C,G,J,K	Data Gap
830.7000	63-12	рН	A,B,C,G,J,K	43553700
830.7050	N/A	UV/Visible absorption	A,B,C,G,J,K	Data Gap
830.7100	63-18	Viscosity	A,B,C,G,J,K	N/A
830.7200	63-5	Melting point/melting range	A,B,C,G,J,K	00023955 40765101
830.7220	63-6	Boiling point/range	A,B,C,G,J,K	N/A
830.7300	63-7	Density	A,B,C,G,J,K	00023955
830.7370	63-10	Dissociation Constants in Water	A,B,C,G,J,K	00143169
830.7550	63-11	Partial Coefficient, shake flask	A,B,C,G,J,K	00143169 40765101
		method		
830.7840	63-8	Water Solubility	A,B,C,G,J,K	00023955
830.7950	63-9	Vapor Pressure	A,B,C,G,J,K	00023955 40765101
			ironmental Fate	
835.2120	161-1	Hydrolysis	A,B,C,G,J,K	00027856
835.2240	161-2	Photodegradation Water	A,B,C,G,J,K	00143171 42503708
835.2410	161-3	Photodegradation Soil	A,B,C,G,J,K	40614410 42739101
835.4100	162-1	Aerobic Soil Metabolism	A,B,C,G,J,K	00158638 43004501
835.4200	162-2	Anaerobic Soil Metabolism	A,B,C,G,J,K	00027857

835.4400	162-3	Anaerobic Aquatic Metabolism	A,B,C,G,J,K	40614411
835.4300	162-4	Aerobic Aquatic Metabolism	A,B,C,G,J,K	43004502
835.1240	163-1	Leaching/Adsorption/Desorption	A,B,C,G,J,K	41257902 41257903 41257904 41257906 41442903
835.6100	164-1	Terrestrial Field Dissipation	A,B,C,G,J,K	40614413 40614414 40614415 40614416 40614417 40614418
		_		40634201 40634202 43226402 00027863 Data Gap
835.6200	164-2	Aquatic Field Dissipation	A,B,C,G,J,K	40614420 40614422 00024374
N/A	165-4	Accumulation in Fish	A,B,C,G,J,K	00043668
N/A	165-5	Accumulation Aquatic Non-target	A,B,C,G,J,K	00027984 00025444 00027983 00027985 00034709 00025412
				00025413
840.1100	201-1	Spray Droplet Size Spectrum	A,B,C,G,J,K	Data Gap
		Environmental Fate -	- Drinking Water	r Monitoring Data
835.7100	166-1	Prospective Ground Water	A,B,C,G,J,K,	Data Gap
		Monitoring Study		
N/A	N/A	Special Study – Simazine	A,B,C,G,J,K	43598634 43934413 44152122 44315414 44597601 44711001
		Drinking Water Monitoring Data		44997002 45058704 45253401 45622305 46083001 46083002
		(PLEX, VMP/AMP, and SDWA		45870402 46215003 46484202 44997001 Data Gap
		Compliance Data)		
N/A	N/A	Special Study – Simazine Ground	A,B,C,G,J,K	43934414 44222601 44222602 45399906 45545304 46561032
		Water Monitoring Data (including		Data Gap
		rural well monitoring)		
1			cological Effects	
850.2100	71-1a	Avian Oral LD50 Quail/Duck	A,B,C,G,J,K	00072798 00037750 00037751 Data Gap
850.2200	71-2a	Avian Dietary LC50 Quail	A,B,C,G,J,K	00022923 00139393 00023318
850.2200	71-2b	Avian Dietary LC50 Quail	A,B,C,G,J,K	00022923 00023319
850.2300	71-4a	Avian Reproduction Quail	A,B,C,G,J,K	00163134
850.2300	71-4b	Avian Reproduction Duck	A,B,C,G,J,K	43576901
850.1075	72-1a	Freshwater Fish LC50 Bluegill	A,B,C,G,J,K	00025438 00033309 00023322 00025435 Data Gap
		(warm water)		
850.1075	72-1c	Freshwater Fish LC50 Rainbow	A,B,C,G,J,K	00163135 0043668 40245701 00025435 Data Gap
		trout (cold water)		
850.1010	72-2a	Freshwater Invertebrate LC50	A,B,C,G,J,K	45088221 40098001 Data Gap
		Daphnia magna		
850.1045	72-3a	Estuarine/Marine Fish LC50	A,B,C,G,J,K	42503702 00043677
850.1025	72-3b	Estuarine/Marine Mollusk EC50	A,B,C,G,J,K	42503703 00043677
850.1035	72-3c	Estuarine/Marine Shrimp EC50	A,B,C,G,J,K	Data Gap
850.1400	72-4a	Fish Early Life-Stage (freshwater)	A,B,C,G,J,K	Data Gap
850.1400	72-4a	Fish Early Life-Stage	A,B,C,G,J,K	Data Gap
		(estuarine/marine)		

850.1300	72-4b	Aquatic Invertebrate Life-Cycle (freshwater)	A,B,C,G,J,K	00043676 Data Gap
850.1350	72-4b	Aquatic Invertebrate Life-Cycle (estuarine/marine)	A,B,C,G,J,K	Data Gap
850.1500	72-5	Freshwater Fish Full Life-Cycle	A,B,C,G,J,K	00043676 Data Gap
850.4225	123-1a	Seed Germ./Seedling Emergence (Tier 2)	A,B,C,G,J,K	42634603
850.4250	123-1b	Vegetative Vigor (Tier 2)	A,B,C,G,J,K	42634604
850.4400	122-2	Aquatic Plant Growth (Tier 2)	A,B,C,G,J,K	42503704 42662401 42503705 40228491 42503706 42503707 40228491
850.3020	141-1	Honey Bee Acute Contact LD50	A,B,C,G,J,K	00036935
N/A	N/A	Special Study – Amphibian Endocrinology and Development Study	A,B,C,G,J,K	Data Gap
		Re	sidue Chemistry	
860.1300	171-4a	Nature of Residue in Plants	A,B,C,G,J,K	00023913 00024025 00024026 00026286 00029632 00084431 40614436 40614437 43159001 43336002 43336003 43401801 43401802 43598602
860.1300	171-4b	Nature of Residue in Livestock	A,B,C,G,J,K	40614429 40614431 40614432 40614435 43506801 43598602
860.1340	171-4c	Residue Analytical Method plant	A,B,C,G,J,K	00023328 00023897 00024057 00025457 00027819 00139356 40614440 Data Gap
860.1340	171-4d	Residue Analytical Method livestock	A,B,C,G,J,K	00023897 00025447 40431382 40614439 Data Gap
860.1340	171-4d	Residue Analytical Method water/fish	A,B,C,G,J,K	00025458 00027835 00027986
860.1360	171-4m	Multiple Residue Methods	A,B,C,G,J,K	N/A
860.1380	171-4e	Storage Stability Data	A,B,C,G,J,K	00025458 40614441 40614442 40614443 42739102 Data Gap ^a
860.1400	171-4h	Fish	A,B,C,G,J,K	00023296 00025412 00025444 00034709 40614421 40614422
860.1460	171-4i	Food handling	A,B,C,G,J,K	N/A
860.1480	171-4j	Fat, Mbyp and Meat of Cattle, Goat, Hogs, Horses, Sheep	A,B,C,G,J,K	00026977 00080629 40614456
860.1480	171-4j	Fat, Fat, Mbyp, and Meat of Poultry	A,B,C,G,J,K	40614457
860.1480	171-4j	Egg	A,B,C,G,J,K	40614457
860.1480	171-4j	Milk	A,B,C,G,J,K	00025452 40614456
860.1500	171-4k	Cropfield Residue (grapefruit)	A,B,C,G,J,K	Data Gap
860.1500	171-4k	Cropfield Residue (lemon)	A,B,C,G,J,K	000023329 Data Gap

860.1500	171-4k	Cropfield Residue (orange)	A,B,C,G,J,K	00023329 00024033 00025409 00032571 00033035 00035665
				00087676 00106691 00113821 40614450 Data Gap
860.1500	171-4k	Cropfield Residue (apple)	A,B,C,G,J,K	00012166 00023898 00024059 00106691 00132787 40614451
860.1500	171-4k	Cropfield Residue (pear)	A,B,C,G,J,K	0023920 Data Gap
860.1500	171-4k	Cropfield Residue (cherry)	A,B,C,G,J,K	00023329 00023922 00131376 Data Gap
860.1500	171-4k	Cropfield Residue (peach)	A,B,C,G,J,K	00023908 00131376 40614452
860.1500	171-4k	Cropfield Residue (plum)	A,B,C,G,J,K	00023329 00023910 00023921
860.1500	171-4k	Cropfield Residue (b lackberry,	A,B,C,G,J,K	00023895 00023901 00023902 00023903 00023904 40614455
		boysenberry, dewberry,		
		loganberry, and raspberry)		
860.1500	171-4k	Cropfield Residue (blueberry)	A,B,C,G,J,K	00023900 40614453
860.1500	171-4k	Cropfield Residue (currant)	A,B,C,G,J,K	Data Gap
860.1500	171-4k	Cropfield Residue (almond, nutmeat and hulls)	A,B,C,G,J,K	00023917 00035666 00131377 Data Gap
860.1500	171-4k	Cropfield Residue (filbert)	A,B,C,G,J,K	00023329 00023932 00035666
860.1500	171-4k	Cropfield Residue (macadamia	A,B,C,G,J,K	00023907 Data Gap
		nut)		
860.1500	171-4k	Cropfield Residue (pecan)	A,B,C,G,J,K	00023327 00023329 00131377
860.1500	171-4k	Cropfield Residue (walnut)	A,B,C,G,J,K	00023923 00131377 Data Gap
860.1500	171-4k	Cropfield Residue (corn, grain)	A,B,C,G,J,K	00023336 00023272 00027973 40614449
860.1500	171-4k	Cropfield Residue (corn, fresh (inc. sweet) (K+CWHR))	A,B,C,G,J,K	00023336 00023272 00027973 40614449 Data Gap
860.1500	171-4k	Cropfield Residue (corn, forage and fodder)	A,B,C,G,J,K	00023272 00023336 00027972 00027973
860.1500	171-4k	Cropfield Residue (grasses,	A,B,C,G,J,K	N/A
		Bermuda, forage and hay)		
860.1500	171-4k	Cropfield Residue (alfalfa, forage and hay)	A,B,C,G,J,K	N/A
860.1500	171-4k	Cropfield Residue (artichoke)	A,B,C,G,J,K	00023918 40614444
860.1500	171-4k	Cropfield Residue (asparagus)	A,B,C,G,J,K	00023899 40614445
860.1500	171-4k	Cropfield Residue (avocado)	A,B,C,G,J,K	00092496 40614446
860.1500	171-4k	Cropfield Residue (banana)	A,B,C,G,J,K	00023273 00023274 00023275 00023276 00023277
860.1500	171-4k	Cropfield Residue (cranberry)	A,B,C,G,J,K	00023905 Data Gap
860.1500	171-4k	Cropfield Residue (grape)	A,B,C,G,J,K	00023906 00027967 40614454
860.1500	171-4k	Cropfield Residue (olive)	A,B,C,G,J,K	00023973 40614447
860.1500	171-4k	Cropfield Residue (strawberry)	A,B,C,G,J,K	Data Gap
860.1500	171-4k	Cropfield Residue (sugarcane, cane)	A,B,C,G,J,K	00023911 00084430 40614448

860.1520	171-41	Processed Food/Feed (apple)	A,B,C,G,J,K	40614451 Data Gap
860.1520	171-41	Processed Food/Feed (apple) Processed Food/Feed (corn)	A,B,C,G,J,K	40614449 Data Gap
		` '		
860.1520	171-41	Processed Food/Feed (grape)	A,B,C,G,J,K	40614454 Data Gap
860.1520	171-41	Processed Food/Feed (orange)	A,B,C,G,J,K	40614450 Data Gap
860.1520	171-41	Processed Food/Feed (olive)	A,B,C,G,J,K	40614447 Data Gap
860.1520	171-41	Processed Food/Feed (plum (fresh	A,B,C,G,J,K	N/A
0.50.4.50.0	4=4 41	prunes))		
860.1520	171-41	Processed Food/Feed (sugarcane,	A,B,C,G,J,K	40614448
		molasses)		
860.1850	165-1	Confined rotational crops	A,B,C,G,J,K	43336001
860.1900	165-2	Field rotational crops	A,B,C,G,J,K	Data Gap
			Toxicology	
870.1100	81-1	Acute Oral Toxicity Rat	A,B,C,G,J,K	00148897
870.1200	81-2	Acute Dermal Toxicity Rabbit/Rat	A,B,C,G,J,K	00148898
870.1300	81-3	Acute Inhalation Toxicity Rat	A,B,C,G,J,K	00148899
870.2400	81-4	Primary Eye Irritation Rabbit	A,B,C,G,J,K	00148900
870.2500	81-5	Primary Skin Irritation	A,B,C,G,J,K	00148901
870.2600	81-6	Dermal Sensitization	A,B,C,G,J,K	41184501
870.3100	82-1a	90-Day Feeding Rodent	A,B,C,G,J,K	00143265, 41293501
870.3150	82-1b	13-Day Dietary Dog	A,B,C,G,J,K	00146655
870.3200	82-2	21-Day Dermal Rabbit/Rat	A,B,C,G,J,K	00005767
870.3700a	83-3a	Developmental Toxicity	A,B,C,G,J,K	40614403, 41065202
		(Teratogenicity) Rat		
870.3700b	83-3b	Developmental Toxicity	A,B,C,G,J,K	00161407
		(Teratogenicity) Rabbit		
870.3800	83-4	2-Generation Reproduction Rat	A,B,C,G,J,K	41803601
870.4100a	83-1	Chronic Toxicity Rat		43532001
870.4100b	83-1	Chronic Toxicity Dog	A,B,C,G,J,K	40614402
870.4200	83-2	Carcinogenicity Rat	A,B,C,G,J,K	40614405
870.4300	83-5	Chronic Toxicity/Carcinogenicity	A,B,C,G,J,K	40614404, 43532001
		Mouse and Rat		
870.5100	84-2	Bacterial reverse mutation assay	A,B,C,G,J,K	40722304, 40614406
870.5375	84-2	Invitro Mammalian Cytogenetics	A,B,C,G,J,K	41479401
870.5395	84-2	Invivo Mammalian Cytogenetics:	A,B,C,G,J,K	41442901
		Micronucleus Assay		
870.5550	84-2	Unscheduled DNA Synthesis in	A,B,C,G,J,K	41441902, 40722305, 40888101
		Mammalian Cells		

870.7485	85-1	Metabolism and Pharmacokinetics Rat	A,B,C,G,J,K	00143266
870.7600	85-3	Dermal Absorption Rat and Human	A,B,C,G,J,K	40614409, 44152144
N/A	N/A	Special Study Invivo Endocrine Effects Rat	A,B,C,G,J,K	43598614
N/A	N/A	Special Study LH Surge Rat	A,B,C,G,J,K	45471002, 44152102
		Occupation	onal/Residue Exp	osure
875.1100	231	Dermal Exposure Outdoor	A,B,C,G,J,K	44972201
875.1300	232	Inhalation Exposure Outdoor	A,B,C,G,J,K	44972201
875.2100	132-1	Foliar Dislodgeable Residue Dissipation	A,B,C,G,J,K	44883601 44958701 44958801
875.2400	133-3	Dermal Passive Dosimetry Exposure	A,B,C,G,J,K	45167201
875.2500	133-4	Inhalation Passive Dosimetry Exposure	A,B,C,G,J,K	45167201
N/A	N/A	Special Study – Worker Exposure in Banana Plantation	A,B,C,G,J,K	45250702
N/A	N/A	Special Study – Dermal Transfer Efficiency Hand Press Data	A,B,C,G,J,K	45622310

^a Storage stability data for up to three years is necessary to support existing field trials on orange crops.

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket EPA-HQ-OPP-2005-0151. This docket may be accessed in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov.

The docket initially contained preliminary risk assessments, supporting documents, and technical (or manufacturing-use) registrant error comments for simazine as of July 13, 2005. After a sixty-day public comment period, EPA considered the public comments that were submitted to the docket and revised the risk assessments as necessary. The revised risk assessments, any supporting documents that needed to be revised, and memos describing the Health Effects Division (HED) and the Environmental Fate and Effects Division (EFED) response to public comments will be added to the docket on April 26, 2006.

The Agency documents in the docket include:

- 1. Federal Register Notice: Simazine Risk Assessment and Risk Reduction Options; Notice of Availability
- 2. Reader's Guide to the Simazine EDOCKET OPP-2005-0151
- 3. Overview of the Simazine Risk Assessments
- 4. Request for Additional Information and Risk Management Suggestions for the Reregistration of Simazine
- 5. Simazine Use Closure Memo
- 6. Environmental Fate and Ecological Risk Assessment for Simazine
- 7. Environmental Fate and Ecological Risk Assessment Appendix A Label Use Information
- 8. Environmental Fate and Ecological Risk Assessment Appendix B Environmental Fate Data Review and Discussion
- 9. Environmental Fate and Ecological Risk Assessment Appendix C Aquatic Exposure Assessment PRZM/EXAMS Outputs
- 10. Environmental Fate and Ecological Risk Assessment Appendix D AgDRIFT Modeling Approach and Results
- 11. Environmental Fate and Ecological Risk Assessment Appendix E Submitted Ecological Effects Data

- 12. Environmental Fate and Ecological Risk Assessment Appendix F Open Literature Ecological Effects Data
- 13. Environmental Fate and Ecological Risk Assessment Appendix G The Risk Quotient Method and Levels of Concern
- 14. Environmental Fate and Ecological Risk Assessment Appendix H Detailed Risk Ouotients
- 15. Environmental Fate and Ecological Risk Assessment Appendix I Summary of Endangered/Listed Species
- 16. Environmental Fate and Ecological Risk Assessment Appendix J Environmental Protection Agency Guideline Sequence Bibliography for Simazine
- 17. Environmental Fate and Ecological Risk Assessment Appendix K Ecotoxicity Bibliography
- 18. Environmental Fate and Ecological Risk Assessment Appendix L Data Requirements for Simazine
- 19. Environmental Fate and Ecological Risk Assessment Appendix M Aquatic Monitoring Data
- 20. Environmental Fate and Ecological Risk Assessment Appendix N Aquatic Incidents
- 21. Environmental Fate and Ecological Risk Assessment Appendix O Terrestrial Chronic Exposure Estimates for Granular Application of Simazine
- 22. EFED Responses to Registrant's Error Comments for Simazine
- 23. Simazine: Revised Preliminary HED Chapter of the Reregistration Eligibility Decision Document (RED); Revised for Error Correction.
- 24. Drinking Water Assessment for Simazine
- 25. Simazine: Residue Chemistry Chapter for the RED, Revised for Errors
- 26. Simazine: Product Chemistry Review Chapter in Support of a Reregistration Eligibility Decision
- 27. Simazine: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document
- 28. Review of Simazine Incident Reports
- 29. Simazine: Third Report of the Cancer Assessment Review Committee

- 30. Simazine: Response to Error Only Review of Preliminary Human Health Risk Assessments
- 31. Federal Register Notice: Simazine; Reregistration Eligibility Decision; Notice of Availability
- 32. Additional Reader's Guide to the Simazine Docket EPA-HQ-OPP-2005-0151
- 33. Reregistration Eligibility Decision for Simazine
- 34. Revised Simazine RQs for Terrestrial Animals and Plants Based on Proposed Harmonized Labels
- 35. Drinking Water Estimated Concentrations for Simazine and its degradates Addendum to Memorandum "080807 D207018 DWA revised/ May 27, 2005"
- 36. Revised Environmental Fate and Effects Chapter: Environmental Fate and Ecological Risk Assessment for Simazine
- 37. EFED Responses to Public Comments for Simazine
- 38. Simazine: Addendum to HED Risk Assessment (11/30/05, D320053) Chapter of the Reregistration Eligibility Decision (RED). DP Barcode: 325685
- 39. Review of Simazine Dry Flowable Exposure Scenario for Applications to Corn, Grapes, and Florida Oranges, D307039
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- 42. EFED Responses to Public Comments for Simazine 2
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- 44. Simazine: Response to Public Comments on Revised Human Health Risk Assessments. PC Code: 080807, Case #: 0070, DP Barcode: 322002

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

Guide to Appendix D

- 1. Contents of Bibliography. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
- 2. <u>Units of Entry</u>. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
- 3. <u>Identification of Entry</u>. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
- 4. Form of Entry. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the

- document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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16662	Seim, V. (1974) Compare CGA 24705 6E (GA-2-631) to CGA 24705 8E (GA-2-630) for Grass Control, and Injury in Corn: Test No. NE OH 204 74. (Unpublished study received Mar
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16664	Seim, V. (1975) Eval. Comb. of 18762 + Princep and 24705 Prob. Grass Applied
	Preemergence: Test No. NE OH 205 74. (Unpublished study received Mar 26, 1975 under
	5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094383-Q)
16665	Seim, V. (1974) Evaluate CGA -24705 and CGA -18762 for Weed Control and Corn Inj. Alone
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16666	Seim, V.; Russel, R. (1974) Obtain Large Plot Pre Data CGA 2470518762 Combinations To
10000	Satisfy EPA 0.5 Acre Plots: Test No. NE OH 212 74. (Unpublished study received Mar 26,
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	under Piedmont Conditions: Test No. SE OH 104 74. (Unpublished study received Mar 26,
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16674	Westmoreland, W.G. (1974) To Compare Herbicide Effects on Weeds & Corn of CGA 18762,
	CGA 24704 & CGA 24705 Alone & in Combination with Atrazine: Test No. SE OH 105 74. (Unpublished study received Mar 26, 1975 under 5F1606; submitted by Ciba-Geigy Corp.,
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16695	Higgins, E.R.; Dickerson, H. (1976) Dual + Cycle or Aatrex Prepacks and Tank Mixes for
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16730	Schnappinger, M.G. (1976) To Evaluate Dual 6E with Several Varieties of Corn: Test No. NE
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16740	Alley, M.M. (1976) Label GA -2-758 as a PPI Pre and Post Application for Complete Weed
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16742	Alley, M.M. (1976) Compare Response of Field Corn Varieties to Dual and Lasso: Test No.
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	Greensboro, N.C.; CDL:228118-AL)
16852	Ciba-Geigy Corporation (1975) Dual^(TM)I 6E and Cycle^(TM)I 80W-Corn Large Plot
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16875	Higgins, E.R. (1977) Dual + Aatrex and Cycle as Tank Mix and Prepaks for Pre Control of
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16881	Alley, M.M. (1977) Label GA -2-758 as a PPI Pre and Post Application for Complete Weed
	Control in Corn: Test No. NE OH 209 76. (Unpublished study received Jun 20, 1977 under
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16901	Alley, M.M. (1977) Label GA -2-758 as a PPI, Pre, and Early Post Application for Complete Weed Control in Corn: Test No. NE OH 205 76. (Unpublished study received Jun 20, 1977)
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16970	Threewitt, T. (1977) Evaluate Dual + Cycle or Princep and + Paraquot ?sic for Minimum-Till
	Corn, and Dual+Aatrex+Paraquot ?sic for Label: Test No. MW OH 312 76. (Unpublished
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16976	Schnappinger, M.G. (1977) To Evaluate Dual Combinations for Weed Control in No-Tillage
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17.150	SH 114 76. (Unpublished study received May 23, 1977 under 100-EX-36; submitted by Ciba-
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46770104	the FIFRA 6(a)(2) Data Requirements for Atrazine. Transmittal of 4 Studies.
46770104	Mayer, T. (2006) Simazine: FIFRA Section 6(a)(2) Annual Report for Simazine Monitoring
	Data from the 2005 Atrazine Monitoring Program (AMP) for Selected Community Water
	Systems (CWS) Relying on Surface Water Sources: Final Report. Project Number:
	T000765/06, IL1835120, IL0170100. Unpublished study prepared by Syngenta Crop
	Protection, Inc. 171 p.

Appendix E. Generic Data Call-In (GDCI)

Note that a complete generic DCI, with all pertinent instructions, will be sent to registrants under separate cover.

Appendix F. Product-Specific Data Call-In (PDCI)

Note that a complete product-specific DCI, with all pertinent instructions, will be sent to registrants under separate cover.

Appendix G. EPA's Batching of Simazine Products for Meeting Acute Data Requirements for Reregistration

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an

Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. owever, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

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

Batching Instructions:

Batch 5: EPA Reg. No. 7689-17 may not cite data generated with EPA Reg. No. 7689-16.

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

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

Batch 1	EPA Reg. No.	Percent Active Ingredient
	100-541	97.0
	19713-59	98.0
	19713-386	97.0
	35915-10	97.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	100-603	90.0
	9779-295	90.0
	19713-252	90.0
	34704-686	90.0
	35915-12	90.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	19713-46	80.0
	19713-271	80.0
	34704-685	80.0

Batch 4	EPA Reg. No.	Percent Active Ingredient
	100-526	41.90
	9779-296	41.90
	19713-60	42.10
	19713-273	42.10
	34704-687	42.80
	35915-11	42.80
	51036-127	41.67
Batch 5	EPA Reg. No.	Percent Active Ingredient
	7689-16	3.71
	7689-17	4.38
Batch 6	EPA Reg. No.	Percent Active Ingredient
	72-289	4.0
	5481-285	4.0
	19713-546	4.0
Batch 7	EPA Reg. No.	Percent Active Ingredient
	7689-14	0.6
	9712-8	0.9

Batch 8	EPA Reg. No.	Percent Active Ingredient
	769-978	Simazine: 0.76 Prometone: 5.00 Sodium Chlorate: 39.80 Sodium Metaborate: 40.00
	53883-97	Simazine: 0.76 Prometone: 5.00 Sodium Chlorate: 39.80 Sodium Metaborate: 40.00
	66222-23	Simazine: 0.76 Prometone: 5.00 Sodium Chlorate: 39.80 Sodium Metaborate: 40.00

No Batch	EPA Reg. No.	Percent Active Ingredient
	5481-213	4.00
	7401-192	0.63
	19713-171	Simazine: 21.41 Atrazine: 21.42
	19713-553	Simazine: 45.00 Atrazine: 45.01

Appendix H. List of Registrants Sent this Data Call-In Notice

Miller Chemical and Fertilizer Corporation PO Box 333 Hanover, PA 17331

Syngenta Crop Protection, Inc. PO Box 18300 Greensboro, NC 27419-8300

Value Gardens Supply, LLC PO Box 585 Saint Joseph, MO 64502

Amvac Chemical Corporation 4695 MacArthur Court, Suite 1250 Newport Beach, CA 92660-1706

Voluntary Purchasing Group, Inc. Brazos Associates, Inc. 1806 Auburn Driver Carrollton, TX 75007-1451

The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094

Weco Products, Inc. RegWest Co. 30856 Rocky Road Greeley, CO 80631-9375

Agriliance, LLC PO Box 64089 St. Paul, MN 55164-0089

Drexel Chemical Co. PO Box 13327 Memphis, TN 38113-0327

Loveland Products, Inc. PO Box 1286 Greeley, CO 80632

Oxon Italia S.P.A. Sipcam Agro USA, Inc. 300 Colonial Parkway, Suite 230 Roswell, GA 30076 Micro-Flo Company, LLC 530 Oak Court Drive Memphis, TN 38117

Control Solutions, Inc. 5903 Genoa-Red Bluff Pasadena, TX 77507-1041

Makhteshim-Agan of North America, Inc. 4515 Falls of Neuse Road, Suite 300 Raleigh, NC 27609

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

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

Instructions:

- 1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
- 2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
- 3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the following address for the Document Processing Desk.:

Document Processing Desk (distribution code)* Office of Pesticide Programs (7504P) Environmental Protection Agency 1200 Pennsylvania Ave, NW Washington, DC 20460-0001

* Distribution Codes are as follows:
(APPL) Application for product registration
(AMEND) Amendment to existing registration
(CAN) Voluntary Cancellation
(EUP) Experimental Use Permit
(DIST) Supplemental Distributor Registration
(SLN) Special Local Need
(NEWCO) Request for new company number
(NOTIF) Notification
(PETN) Petition for Tolerance
(XFER) Product Transfer

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at *williams.nicole@epamail.epa.gov*. If you want these forms mailed or faxed to you, please contact Lois White, *white.lois@epa.gov* or Floyd Gayles, *gayles.floyd@epa.gov*.

If you have any questions concerning how to complete these forms, please contact OPP's ombudsperson for conventional pesticide products: Linda Arrington, (703) 305-5446

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

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

Pesticide Registration Kit 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.

- 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)
 - 40 CFR Part 158, Data Requirements for Registration (PDF format)
 - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27,

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

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

National Technical Information Service (NTIS) 5285 Port Royal Road

Springfield, VA 22161

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

- 3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.
- 4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their 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:

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

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

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

Appendix J. Letter to Amend Terms and Conditions of MUP Registrations

I hereby request that the registration for [insert registration numbers for all manufacturing use products; can be listed in an attachment] be amended to include the following terms and conditions of continued registration.

Drinking water mitigation:

- 1) SWIC: [Registrant] shall establish a database of information (referred to hereafter as Simazine Watershed Information Center or SWIC). The SWIC will provide detailed information on what watershed areas have become subject to a prohibition of Simazine use pursuant to paragraph 3)f) below. Only information approved by EPA will be included in the SWIC. The SWIC will be accessible to the public daily, including weekends and holidays, through a toll-free telephone number available 24 hours a day and seven days a week, a World Wide Web site, and a regular mailing address. Information for each means of contact will be included on all Simazine product labels pursuant to paragraph 2) below. The SWIC will be updated a) within 5 business days of receiving EPA's determination of the boundary of any watershed area in which use of Simazine is prohibited due to results of monitoring under paragraph 3) below; and b) within 5 business days of receipt of notification from EPA of a change to the description of any watershed area affected by a use prohibition. This condition of registration may also be satisfied by offering to pay compensation to another registrant that performs the acts required.
- 2) Label changes: the following label changes will be submitted to the Director of EPA's Registration Division (7505C), Office of Pesticide Programs, ATTN: Jim Tompkins, PM Team 25, for approval no later than June 1, 2006.
 - a) The label shall include under "Directions for Use" the following statements:
 - i) "This product may not be reformulated or repackaged into another product unless the registration of the reformulated or repackaged product was granted or amended so as to be consistent with the Surface Water CWS Monitoring Program set forth in the Simazine Reregistration Eligibility Decision (RED)."
 - ii) "No product other than a product labeled only for use by homeowners on turfgrass or labeled only for use as an algaecide may be reformulated or repackaged from this product unless the formulated or repackaged product bears a label including all of the following statements prominently displayed in the "Directions for Use" section: "ANY USE OF THIS PRODUCT IN AN AREA WHERE USE IS PROHIBITED IS A VIOLATION OF FEDERAL LAW [this sentence must be in all capital letters]. Before using this product, you must consult the Simazine Watershed Information Center (SWIC) to determine whether the use of this product is prohibited in your watershed. SWIC can be accessed through [website address] or [toll-free phone number] or [mailing address]. If the SWIC indicates that use of this product is

- prohibited in your watershed, you may return this product to your point of purchase or contact [insert name of Registrant] for a refund."
- iii) "No products **labeled only for use by homeowners on turfgrass** may be reformulated or repackaged from this product unless the registration of the resulting product is subject to the following terms and conditions of registration, which shall require that the Registrant:
 - (1) Immediately cease all sale and distribution to any retailer or any entity distributing or selling such product to any retailer located within all counties containing any portion of any watershed area listed in the SWIC;
 - (2) Ensure the removal of any such Simazine product from the shelves of any retailer located within all counties containing any portion of any watershed area listed in the SWIC; and
 - (3) Repurchase any such Simazine product from any of the purchasers described above.
 - (4) In addition, such Registrant shall consult with the State(s) in which such counties are located to determine whether additional territory shall be included in the area to which these requirements will apply. If the State(s) determine that a larger area is warranted, the Registrant shall within 10 days of such determination notify the Director of EPA's Special Review and Reregistration Division (SRRD) (7508C), Office of Pesticide Programs, of the State(s) determination. EPA will then notify such Registrant of the specific boundaries within which the stop sale, removal and repurchase shall take place."
- b) All manufacturing use product sold or distributed after July 31, 2006 will bear this revised label.
- 3) Surface water monitoring program: [Registrant] will conduct the following water monitoring program as a term and condition of continued registration of the product. This condition of registration may also be satisfied by offering to pay compensation to another registrant that performs the acts required.
 - a) Review of Safe Drinking Water Act (SDWA) data: Beginning with 2005 data, each year, [Registrant] will review all SDWA data for every Community Water System (CWS) that has a surface water source and tests for Simazine. If any such CWS has an annual average concentration of Simazine and its two chlorinated degradates equal to or greater than 2.6 ppb in finished water, that system will be placed into the intensive monitoring program in paragraph 3)c) below. (Except, that if a CWS has an annual average based on a single sample equal to or greater than 2.6 ppb Simazine and its two chlorinated degradates but less than 4.0 ppb Simazine (parent compound only), then [Registrant] has the option of either placing the CWS in the intensive monitoring program the year following these measurements or taking quarterly samples at that CWS during the year following these measurements and averaging the quarterly samples. If the average of the

quarterly samples is greater than 2.6 ppb Simazine and its two chlorinated degradates, then the CWS must be placed in the intensive monitoring program the following year.) [Registrant] will submit a report of this review for the 2005 data by May 30, 2006. For each subsequent year, [Registrant] will submit a report by April 1 of the following year, beginning April 1, 2007.

i) For any CWS where concentrations of only the Simazine parent compound have been measured (<u>i.e.</u> no degradates), the total concentration of Simazine and its two chlorinated degradates will be calculated using the following regression formula:

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\Sigma(Simazine + G28273 + G28279) = 0.364 + 1.378 * (Simazine)
G-28273 = (diaminochlorotriazine or DACT)
G-28279 = (des-isopropyl atrazine or DIA)
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- ii) After 5 years of consecutive monitoring under paragraph 3)c) [Registrant] may request that EPA remove or modify this requirement to review and report on SDWA data.
- b) Systems to be monitored: The following CWS will be intensively monitored for Simazine and its two chlorinated degradates:
 - i) IL1350300 Hillsboro CWS, Illinois IL1210400 Patoka CWS, Illinois IL0510150 Farina CWS, Illinois IL0252100 Flora CWS, Illinois NC0351070 Johnston County Water System CWS, North Carolina IN5272002 Stucker Ford Water Utility CWS, Indiana;
 - ii) Any CWS identified through annual review of SDWA data pursuant to paragraph 3)a) noted above; and
 - iii) Any other CWS that has a surface water source and for which any reliable data indicates an annual concentration of 2.6 ppb or more Simazine and its two chlorinated degradates in finished water or a concentration of 12.5 ppb or more Simazine and its two chlorinated degradates as a 90-day average in raw water.
- c) Intensive monitoring: Beginning no later than April 30, 2006, each CWS identified in paragraph 3)b)i) will be monitored for actual concentrations of Simazine and each of its two chlorinated degradates in raw water at the water intake weekly during peak use seasons based on Simazine usage in the area (listed in Attachment 1) and bi-weekly during the rest of the year. Each CWS identified through paragraphs 3)b)ii) and 3)b)iii) will be monitored for actual concentrations of Simazine and each of its two chlorinated degradates in raw water at the water intake weekly during peak use seasons based on Simazine usage in the area as

determined by EPA upon identification of the CWS, and bi-weekly during the rest of the year. [Registrant] will calculate 90-day rolling average concentrations of the total of Simazine and its two chlorinated degradates. Monitoring at any specific CWS may cease when five consecutive years have passed without any 90-day rolling average concentration of Simazine and its two chlorinated degradates meeting or exceeding 37.5 ppb.

d) Reporting: The results of monitoring will be reported to EPA annually by January 30 of the following year. In addition, if any CWS has a 90-day rolling average total concentration of Simazine and its two chlorinated degradates greater than 37.5 ppb, this will be reported to EPA within 30 days from the last water sample included in that result.

e) Mitigation plans:

- i) If any CWS has a 90-day rolling average total concentration of Simazine and its two chlorinated degradates at or above 37.5 ppb, then [Registrant] will submit to EPA and begin implementing within 90 days of that exceedance a written Mitigation Plan including mitigation measures to be implemented within the watershed area containing that CWS (except as provided in paragraph 3)g) below). Such plan shall include consideration of Best Management Practices such as buffer strips, grass waterways, changes in tillage practices, changes in application timing, and use rate reductions, and how the measures will be communicated to growers. [Registrant] will implement this Mitigation Plan and submit progress reports to EPA semi-annually describing the measures taken during that period, until notified by EPA that semi-annual reports may cease.
- ii) If any CWS is reported to EPA to be in violation of the maximum contaminant level (MCL) for Simazine (as determined by reporting under the Safe Drinking Water Act), then [Registrant] will consult with the State Drinking Water Administrator of the State where such CWS is located to develop a written Mitigation Plan including mitigation measures to be implemented within the watershed area containing that CWS and a schedule for implementation. Such plan shall include consideration of Best Management Practices such as buffer strips, grass waterways, changes in tillage practices, changes in application timing, and use rate reductions, and how the measures will be communicated to growers. [Registrant] will submit the plan to EPA within 90 days of the reported violation and will implement this Mitigation Plan and submit progress reports to EPA semi-annually describing the measures taken during that period, until notified by EPA that semi-annual reports may cease. However, if EPA, in consultation with the State, determines that the Mitigation Plan is not reasonably likely to reduce Simazine concentrations in the CWS's water supply, or that the implementation schedule is not met, then use of products containing Simazine

would be prohibited and the watershed area where the CWS is located would be included in the SWIC pursuant to paragraph 3)f) below.

- f) Prohibition of use through the SWIC: If any CWS has a 90-day rolling average total concentration of Simazine and its two chlorinated degradates at or above 37.5 ppb in two separate years within a five year period, then use of Simazine will be prohibited in the watershed area containing that CWS (except as provided in paragraph 3)g) below and for products labeled only for use as an algaecide). The boundaries of the watershed area will be determined by EPA, after consulting with Registrants of Simazine. The watershed area will be listed in the SWIC, through which users can determine whether use is allowed where they intend to use the product.
- g) Force Majeure: In the event that [Registrant] can demonstrate that any CWS's 90-day rolling average total concentration of Simazine and its two chlorinated degradates meets or exceeds 37.5 ppb due solely to acts of sabotage, non-farm point source incidents such as rail or truck spills, or acts of God (excluding runoff from rainfall), that reading will not count toward either prohibition of use of Simazine under paragraph 3)f) above or submission of a Mitigation Plan under paragraph 3)e) above.
- 4) [Registrant] agrees that failure to comply with any of the terms and conditions in this amendment will be grounds for cancellation under FIFRA § 6(b), and that the only issue for resolution would be whether or not [Registrant] complied with the terms and conditions.

I certify that I am authorized to request this registration amendment on behalf of [Registrant]. Any further communications concerning this registration should be directed to [contact info].

Attachment 1. Peak Use Season and Schedule for Weekly and Biweekly Monitoring

State Where CWS Is Located (Crops)	Use Season/Months for Weekly Sampling	Months for Biweekly Sampling
Illinois (Corn, Apples, Peaches)	April June	January March and July December
Indiana (Corn, Apples)	April June	January March and July December
North Carolina (Corn, Apples, Peaches)	February May	January and June December