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September 27, 2007

Reregistration Eligibility Decision for 4-aminopyridine

Reregistration Eligibility Decision (RED) for 4-aminopyridine

List A

Case No. 0015

Approved by: _____

Steven Bradbury, Ph.D.
Director, Special Review and Reregistration Division

Date: 9/27/07

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Glossary of Terms and Abbreviations

ae	Acid Equivalent
ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
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
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)

LC_{50} Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.

LD_{50} Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.

LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MRID Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MUP	Manufacturing-Use Product
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
ppb	Parts per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for 4-aminopyridine (4-AP). The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for 4-AP and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket at http://www.regulations.gov under docket number EPA-HQ-OPP-2007-0400.

II. Chemical Overview

A. Regulatory History

4-Aminopyridine (4-AP) was originally registered in the United States in January 1972. A Registration Standard Guidance Document was issued in September 1980, which summarized the regulatory conclusions based on available data, and specified the additional data required for reregistration purposes. At the time of the Registration Standard, 4-AP was used on food crops as well as nesting and feeding areas to control nuisance birds. Several ecological toxicity, mammalian, environmental fate, and residue chemistry studies were required in a September 1980 data call-in.

In February 1991, a data call-in was issued for ecological fate and effect data, mammalian toxicity data, and crop field trial data. In October 1995 through the agricultural re-entry data call-in, dermal and inhalation passive dosimetry exposure studies and a foliar residue dissipation study were called in.

On October 27, 2004, a Federal Register Notice was published that cancelled 4-AP products with food uses (69 FR 62666) (FRL-7683-7) based on a request from the registrant. A Federal Register Notice published September 21, 2005 announced the revocation of all 4-AP tolerances. The effective date for these revocations was January 15, 2006.

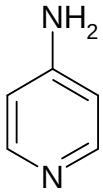
Subsequent to the revocation of 4-AP tolerances, the registrant requested a waiver for the outstanding data requirements based on low volume and minor use classification of the subject active ingredient and its use pattern. Based on the low potential for workers reentering the treated area to experience dermal contact with the residues of 4-AP, the Agency granted the waiver request.

In 2007 the 4-AP registrant requested voluntary cancellation of all labels for products formulated as powder. Additionally, the registrant has requested voluntary cancellation for the only two 4-AP registrations remaining with uses around growing crops, and the only 4-AP registration with gull species as target pests. Thus, only the 4-AP labels for products formulated as bait have been considered for reregistration. Additionally, the previously required residue chemistry, environmental fate, and toxicity studies are no longer required based on the limited use pattern for the remaining 4-AP products.

B. Chemical Identification

4-AP is registered with the EPA as an avicide. It is a member of the pyridine family. 4-AP is a nervous system toxicant and is highly toxic to most vertebrates. Chemical information and the structure for 4-AP is presented in Table 1.

Table 1. Physical-Chemical Properties of 4-Aminopyridine	
PC Code	069201
Chemical Name	4-aminopyridine

Table 1. Physical-Chemical Properties of 4-Aminopyridine	
Structure	
CAS Number	504-24-5
Empirical Formula	$C_5H_6N_2$
Chemical Class	Pyridine
Molecular Weight	94.1
Vapor pressure (20 ºC)	2.09×10^{-4} mm Hg
Water Solubility (20 ºC)	112 g/L

C. Use Profile

Type of Pesticide: Avicide

Target Pests: Pigeons; house sparrows; crows; grackles; cowbirds; starlings; red-winged, yellow-headed, rusty, and Brewers blackbirds; gulls. Note: Registrant has requested voluntarily cancellation for EPA Reg. # 11649-11, the only label that identified gulls as a target pest.

Mode of Action: 4-AP blocks potassium ion channels in nerve fibers.

Use Sites: Registered for use in nesting, feeding, loafing and roosting sites on or in the area of structures, feedlots, landfills, and airports.

Use Classification: Restricted Use Pesticide due to acute avian toxicity.

Formulation Types: Impregnated bait: whole corn, chopped corn, and mixed grains. Powder: powder mix and concentrate; the registrant has requested voluntary cancellation for all powder uses.

Application Methods: Bait: Birds are conditioned over a period of time by the applicator to accept untreated bait. This conditioning is called "prebaiting." Once birds have been conditioned to accept the untreated bait, the applicator will mix 4-AP-treated bait with untreated bait of the same composition in a 1:2 to 1:29 treated bait to untreated bait ratio. The applicator will distribute the mix in the same way as the untreated bait. On some labels applicators are required to use gloves and scoops during application. The bait is sometimes placed in bait trays.

Application Rates: Application rates are dependent on the size of the flock treated. Application rates are estimated to range from 0.0001 pound of active ingredient per acre (lb ai/A) to 0.002 lb ai/A.

Application Timing: Labels recommend that the best time to treat birds is early in the morning when birds have their heaviest feeding.

Registrants: At this time, the sole registrant for 4-AP avicide products is Avitrol Corporation.

D. Estimated Usage of Pesticide

The majority of 4-AP is applied in urban areas to control nuisance pigeons and sparrows, with smaller usage in cattle feedlots for sparrows. Based on usage information provided by the registrant, total annual domestic usage of 4-AP is under 250 pounds. Pigeons are the most frequently targeted species, followed in frequency by starlings, crows, grackles, blackbirds, and sparrows.

Uses Submitted for Voluntary Cancellation

In letters dated May 30, 2007 and September 25, 2007, the 4-AP registrant requested voluntary cancellation of all remaining powder formulations, outlined below in Table 2. Additionally, the registrant has requested voluntary cancellation for the only two labels with uses around growing crops, CA780131 and CA 780132, and the only label with gulls as a target pest, Reg. No. 11649-10.

Table 2. 4-Aminopyridine Registrations Submitted for Voluntary Cancellation.

Formulation	EPA reg. #	% ai	Target pest	Use Site
Avitrol Concentrate	11649-10	25	Starlings	In, or in the vicinity of feedlots.
Avitrol Powder Mix	11649-11	50	Gulls	In, on, or in the vicinity of landfills, airports, and structures where gulls feed, nest, loaf or roost.
Avitrol Mixed Grains – Special Local Need	CA780131	0.5	House finch, horned larks, and crowned sparrows in addition to the birds already listed on label 11649-4: pigeon, house sparrows, red-winged, yellow-headed, Brewers, and rusty blackbirds, grackles, cowbirds, and starlings	Sprouting crops
Avitrol Mixed Grains – Special Local Need	CA780132	0.5	House finch in addition to the birds already listed on label 11649-4:	Grape vineyards

Table 2. 4-Aminopyridine Registrations Submitted for Voluntary Cancellation.				
Formulation	EPA reg. #	% ai	Target pest	Use Site
			pigeon, house sparrows, red-winged, yellow-headed, Brewers, and rusty blackbirds, grackles, cowbirds, and starlings	
Avitrol Powder Mix – Special Local Need	PR020001	50	Greater Antillean grackle	Around hotels and industrial facilities

Uses Considered for Reregistration

Table 3 lists the labels and uses considered for reregistration.

Table 3. 4-Aminopyridine Formulations and Registered Uses.				
Formulation	EPA reg. #	% ai	Target pest	Use Site
Avitrol Mixed Grains (CA. only)	11649-4	0.5	Pigeons, house sparrows, red-winged, yellow-headed, Brewers, and rusty blackbirds, grackles, cowbirds, and starlings	In, on, or in the area of structures used for nesting, feeding, loafing, and roosting sites.
Avitrol Double Strength Corn Chops	11649-5	1.0	Red-winged, yellow-headed, rusty and Brewers blackbirds, grackles, cowbirds, and starlings	Feedlots, and structures used for nesting, roosting, and feeding sites.
Avitrol Corn Chops	11649-6	0.5	House sparrows, red-winged, yellow-headed, rusty and Brewers blackbirds, grackles, cowbirds, and starlings	On or in the area of structures used for feeding, nesting, and roosting sites.
Avitrol Whole Corn	11649-7	0.5	Feral pigeons	Structures used for feeding, nesting, loafing, and roosting sites.
Avitrol Double Strength Whole Corn	11649-8	1.0	Crows	In, on, or in the area of structures used for feeding, nesting, and roosting sites.

Yellow-headed, red-winged, rusty, and Brewer's blackbirds, grackles, cowbirds, and crows are protected species under the Migratory Bird Treaty Act (MBTA). The MBTA established a Federal Prohibition, unless permitted by regulations, to "pursue, hunt, take, capture, kill, attempt to take, capture, or kill…any migratory bird" (16 U.S.C. 703). 50 CFR 21.43 established a depredation order under MBTA for blackbirds, cowbirds, grackles, and crows that states, "a Federal permit shall not be required to control yellow-headed, red-winged, rusty, and Brewer's blackbirds, cowbirds, and all grackles, crows, and magpies, when found

committing or about to commit depredations upon ornamental or shade trees, agricultural crops, livestock, or wildlife, or when concentrated in such numbers and manner as to constitute a health hazard or other nuisance…" Thus, red-winged, yellow-headed, Brewer's and rusty blackbirds, cowbirds, grackles, and crows may be listed as target pests on 4-aminopyridine product labels. The pesticide user must determine whether target birds are committing or about to commit depredation, or constitute a health hazard or other nuisance.

III. Summary of 4-Aminopyridine Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessments and supporting documents referenced in Appendix C were used to formulate the regulatory decision for the pesticidal use of 4-AP.

While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket, docket number EPA-HQ-OPP-2007-0400, and may be accessed through http://www.regulations.gov/. Hard copies of these documents may also be found in the OPP public docket under this same docket number.

4-Aminopyridine: HED Chapter of the Reregistration Eligibility Decision Document (RED). Dated August 6, 2007.
4-Aminopyridine: Re-registration Ecological Risk Assessment for 4-Aminopyridine Products. Dated February 27, 2007.

A. Human Health Risk Assessment

The human health risk assessment addressed potential exposure risks from all registered sources. Because 4-AP is no longer registered on any food commodities, nor is exposure expected from drinking water sources, the Agency only assessed potential exposures in occupational and residential settings. For the complete human health risk assessment, refer to *4-Aminopyridine: HED Chapter of the Reregistration Eligibility Decision Document (RED), Dated August 6, 2007,* which is available in the public docket.

1. Toxicity of 4-Aminopyridine

The human health risk assessment utilized both animal and human toxicity studies to estimate risk to humans exposed to 4-AP. When considered together, the animal and human toxicological data are sufficient for selecting toxicity endpoints for risk assessment. The Agency's use of human studies for 4-AP risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

a. Toxicity Profile

4-AP has high acute toxicity to mammals via the oral route of exposure (Category I) and the dermal and inhalation routes of exposure (Category II). The acute and subchronic toxicological effects of 4-AP are manifested as hyperexcitability, hyperirritability, salivation, tremors, and muscular incoordination. 4-AP acts by blocking potassium ion channels in nerve fibers. Adverse effects in humans ingesting low levels of 4-AP (5-30 mg/day) were nervousness, giddiness or dizziness, memory alteration, cramps, arterial vasospasm and peripheral paraesthesia. Higher doses in an accidental poisoning case (one-time estimated dose of 60 mg) produced additional effects including weakness, intense diaphoresis, feeling of

impending doom, dyspnea, agitation and combative behavior, and profound thirst. Human studies demonstrated that 4-AP is eliminated quickly from the body and effects did not accumulate with continuous exposure. Table 4 describes the acute toxicity profile of 4-AP.

Table 4. Acute Toxicity Profile of 4-Aminopyridine				
Guideline Number	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral – rat	NCI 2006	LD_{50} =20 mg/kg	I
870.1200	Acute dermal - rabbit	NCI 2006	LD_{50} = 327 mg/kg	II
870.1300	Acute inhalation	00096481	0.53mg/L	II

Animal Studies

4-AP animal studies conducted in 1968 were reviewed for use in risk assessment (oral subchonic rat studies, MRIDs 00004026 and 00131328, and oral subchronic dog studies MRIDs 00004027 and 00131329). Both sets of studies are deemed unacceptable/non-guideline and do not meet the current guideline requirements for 90-day studies in rodents and non-rodents due to deficiencies regarding the test substance characterization. While the endpoints found in these studies were not used in the 4-AP human health risk assessment, these studies were used to provide qualitative information regarding the toxic effects of 4-AP in experimental animals.

Human Studies

There are several clinical human studies that investigated the efficacy and safety of 4-aminopyridine in spinal cord injury or multiple sclerosis patients. Three such studies were presented to the HSRB on June 28, 2007 for ethical and scientific evaluation. The HSRB concluded that these studies were ethically sound but had reservations on the adequacy of reporting of the adverse effects findings in these studies. The studies emphasized the therapeutic effects of 4-aminopyridine and tended to minimize the adverse effects in these select patients. Nevertheless, HSRB left it to the discretion of EPA whether or not to use these studies in the risk assessment of 4-aminopyridine.

EPA determined that the three studies provided the best information available to the Agency for human health risk assessment. The three studies used in human health risk assessment are listed below:

MRID 47093602. Safety and efficacy of 4-AP in humans with cord injury (SCI): a long-term, controlled trial. Segal *et al*, 1999.
MRID 47093601. Efficacy and Safety of 4-AP in patients with long-term spinal cord injury (SCI): a randomized, double-blind, placebo-controlled trial. Grijalva *et al*, 2003.
MRID 47093603. 4-Aminopyridine in patients with multiple sclerosis: dosage and serum level related to efficacy and safety. Van Diemen *et al*, 1993.

For more information on these studies, refer to the 4-AP human health risk assessment available in the 4-AP public docket.

No human or animal data for assessing the carcinogenic potential of 4-AP were available. Based on the lack of this data and the weight of evidence, the Integrated Risk Information System (IRIS) (1993) classified the carcinogenic potential of 4-AP as "not classifiable to human carcinogenicity." 4-AP was found to be negative in reverse mutation assays.

b. Endpoint Selection

A point of departure (POD) is the data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. The Lowest Observed Adverse Effects Level (LOAEL) of 5 mg daily dose (0.07 mg/kg/day) is selected as a minimal LOAEL for a POD based on the human clinical studies conducted with 4-AP listed above. The LOAEL is used to measure incidental oral, dermal, and inhalation risk. To account for individual variability (intraspecies) in the human population, a 10X uncertainty factor (UF) is applied. An additional uncertainty factor of 3X is applied to account for the use of POD based on a minimal LOAEL. The level of concern MOE is 30. A summary of the toxicity endpoints used in the 4-AP human health risk assessment is listed in Table 5.

Table 5. Summary of Toxicological Doses and Endpoints for 4-aminopyridine for Use in Occupational and Residential Risk Assessment

Exposure/ Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental oral, dermal, and inhalation. Short-Term (1-30 days)	LOAEL= 0.07 mg/kg/day	UF_A= 1x UF_H=10x UF_L = 3x	LOC for MOE = 30	Segal *et al* 1999 (MRID 00004026), Van Diemen *et al* 1993 (MRID 47093603), and Grijalva *et al 2003* (MRID 47093601) clinical human studies. LOAEL = 0.07 mg/kg/day based on mild adverse effects of paresthesias/dysethesthesias, dizziness/light-headedness, gait instability, nausea/vomiting, restlessness/anxiety.
Cancer (oral, dermal, inhalation)	Classification: There is no animal carcinogenicity data or human data to evaluate the carcinogenic potential of 4-AP. For this reason, IRIS maintained a classification of D (not classifiable as to human carcinogenicity) (IRIS, 2006).			

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

c. Dietary Exposure

<u>Drinking Water Exposure</u>

For more detail on the Agency's drinking water determination, refer to the *4-Aminopyridine: HED Chapter of the Reregistration Eligibility Decision Document (RED), Dated August 6, 2007*.

EPA expects 4-AP to be both mobile and persistent in the open environment. The main route of dissipation for 4-AP in the environment is thought to be through aerobic metabolism. The prediction of mobility for 4-AP is based upon high aqueous solubility, a low octanol/water partition coefficient value, and a low modeled soil/water distribution coefficient value. Since 4-AP is thought to be a mobile compound, it may have the potential to reach ground water. On the other hand, there exists the possibility that 4-AP might also be susceptible to aged sorption, which would decrease the possibility that 4-AP could reach ground water. No reports of surface water or ground water monitoring studies that included 4-AP were found in searches of the United States Geological Survey (USGS) online National Water Quality Assessment Data Warehouse (NAWQA) database, the EPA publication, "EPA Pesticides in Ground Water, A Compilation of Monitoring Studies 1971-1991 National Summary", or the Google internet search engine. Abiotic half-life values could not be derived from submitted data, and the assumption of stability has been made for both hydrolysis and photolysis of 4-AP for the purpose of exposure modeling.

Although 4-AP has outdoor use patterns which could lead to potential 4-AP run-off into surface waters, the low amount of 4-AP used (less than 250 lbs/year) in the United States is expected to limit widespread contamination of surface source drinking water. Additionally, while some of the existing labels permit 4-AP to be placed in discrete piles on the bare ground, others indicate that 4-AP be used in areas above ground, such as elevated bait stations. Generally, some 4-AP bait labels recommend that the applicator pick up and remove any remaining product at the end of the dosing period. As a result of reregistration all labels will include this requirement. Additionally, as a result of reregistration, a 25 foot buffer will be required around permanent bodies of water. Therefore, long-term environmental exposure of 4-AP is expected to minimal, and no drinking water exposure is expected.

Other Dietary Exposure

4-AP is not registered for any food uses in the US. Additionally, the only two 4-AP labels (CA780131 and CA780132) that permit use around agricultural areas (sprouting plants and grape vineyards, respectively) have been submitted for voluntary cancellation by the registrant. Because drinking water exposure to 4-AP is not expected, and there are no 4-AP food uses registered in the U.S., no dietary exposure assessment was conducted for 4-AP.

2. Residential (Non-Occupational) Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure, other than exposure due to residues in food and drinking water. For non-occupational exposure, EPA calculates a margin of exposure (MOE), which is then compared to a LOC to estimate potential risk. The UF for 4-AP is 30X, to account for individual variability (intraspecies) in the human population (10X), and 3X to account for a minimal LOAEL in the

human toxicity studies from which the short-term endpoint for 4-AP is selected. For 4-AP, estimated MOEs greater than the target MOE of 30 would not pose risks of concern.

a. Residential Handler Exposure Assessment

4-AP can be applied to residential settings by certified applicators. Since all 4-AP products are restricted use products, no residential handler exposure scenario is expected.

b. Residential Post-application Exposure Assessment

Post-application residential exposures to 4-AP may result from application in residential settings. 4-AP can be used in and around residential structures such as high rise apartment buildings and condominium complexes. Some 4-AP labels instruct applicators to place treated bait in areas that are inaccessible to the public. This statement will be required in all post reregistration labels. It is unlikely that adults will be exposed to the bait through dermal exposure, inhalation exposure, or through incidental oral exposure. However, to ensure that children are adequately protected from accidental ingestion, an episodic incidental oral ingestion exposure scenario was assessed.

Granule Ingestion Assessment

EPA does not believe that children will be routinely exposed to 4-AP. However, it is possible that small children or toddlers could accidentally ingest treated granules when 4-AP is applied in residential or public areas. EPA's review of the Poison Control Center data base found incidents of accidental ingestion by children 6 years old and younger during the years 1993 through 2004. Toddlers in a number of states were reported as having been exposed. The majority of the reported incidents occurred in the child's own residence.

In order to characterize the potential for harm to children, EPA conducted a granule ingestion exposure assessment. This assessment found that a small child accidentally consuming 1-2 treated corn seeds could experience mild adverse effects such as dizziness and nausea. The assumptions used in this assessment can be found in the HED risk assessment.

Based on the assessment and incident information EPA believes that additional measures and labeling is warranted to reduce the likelihood of accidental ingestion by children. These measures are discussed in Section IV of this document.

3. Aggregate Exposure and Risk

With the exception of potential granule ingestion exposure, no residential exposures are expected. Also, dietary exposures from food and drinking water are not expected. Therefore, no aggregate risk assessment is needed.

4. Occupational Exposure Assessment

Workers can be exposed when loading and applying baits treated with 4-AP. Based on the 4-AP use pattern, post-application exposure to workers is not expected. The Agency assessed risk to occupational handlers and workers by using the MOE approach. The target MOE of 30 reflects the ratio of the estimated exposure divided by the LOAEL. MOEs greater than 30 are not of concern to the Agency.

a. Occupational Handler/Applicator Assessment

The Agency has determined that there is potential for exposure to occupational handlers and applicators of products containing 4-AP. To assess the handler risks, the Agency used surrogate unit exposure data from the Pesticide Handler Exposure Database (PHED) to address seed treatment scenarios. In this PHED exposure scenario, the individual who opens the container of treated product, loads the product into bait stations or otherwise dispenses the treated product is considered a "handler." There are currently no registered manufacturing use products of 4-AP; all baits come pre-treated. Thus, the handler will only "load" (combine the treated bait with untreated bait to achieve the desired application rate) and "apply" (place the treated bait in the desired location) 4-AP products. No mixing of 4-AP active ingredient with bait material occurs at the time of application.

The registrant has requested voluntary cancellation of the 4-AP powder end-use products and associated special local need registrations (SLNs) (registration numbers 11649-10, 11649-11, CA78131, CA78132, and PR020001). Thus, no occupational risk assessment was completed for the 4-AP powder products.

To assess occupational handler and applicator exposures, the Agency used exposure data based on seed treatment scenarios. Seed treatment exposure scenarios are protective of occupational exposures to 4-AP treated baits because of the high quantity of product treated. Two seed treatment scenarios were used to assess handler exposures for bait products: 1) load/apply, and 2) multiple activities. The following assumptions were used to estimate risks to occupational handlers exposed to 4-AP:

- The body weight of an adult handler is 70 kg.
- The exposure duration was short-term only.
- The worker will handle 100 pounds of product a day, with a maximum exposure of 1 pound ai per day. This is a highly conservative assumption, considering that less than 250 pounds ai of 4-AP are used a year. Additionally, this assessment assumes that the entire amount of product used in a season is handled in one day, which is a high-end exposure.
- Unit exposures are from ExpoSAC Policy Number 14.

Based on the assessed occupational exposure scenarios, all of the MOEs are greater than the LOC of 30 with baseline personal protective equipment (PPE) plus gloves. Thus, these exposures do not pose any risks of concern to the Agency. A summary of the MOEs is shown in Table 6.

Table 6: Summary of 4-Aminopyridine Occupational Handler Risks

Exposure Scenario	Source	Formulation concentration	Amount handled (lbs seed/ season)	Amount handled (lb ai/ season)	PPE	MOE
Loading and Applying Flowable Concentrate (used liquid scenario)	Commercial Seed treatment	1%	100	1	Baseline (long-sleeved shirt, long pants, shoes, and socks), gloves	210
Multiple Activities Flowable Concentrate (used liquid scenario)	Commercial Seed treatment	1%	100	1	Baseline (long-sleeved shirt, long pants, shoes, and socks), gloves	120

b. Occupational Post-application Exposures

No post-application occupational exposures are expected based on the 4-AP use pattern.

5. Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) *"may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, 4-AP may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

B. Environmental Risk Assessment

Available 4-AP ecotoxicity and fate data were insufficient for a standard, quantitative deterministic assessment of ecological risk. Instead, a risk description was developed by applying quantitative methods to label information, use patterns, fate and ecotoxicity data, models and other information to assist in framing the potential risk. The full assessment, *Re-Registration Ecological Risk Assessment for 4-Aminopyridine End-Use Products, February 27, 2007* is available on the internet and in the public docket at www.regulations.gov (EPA-HQ-OPP-2007-0400).

1. Environmental Fate and Transport

EPA expects 4-AP to be both mobile and persistent in the open environment. The main route of dissipation for 4-AP in the environment is thought to be through aerobic metabolism. The prediction of mobility for 4-AP is based upon high aqueous solubility, a low octanol/water partition coefficient value, and a low soil/water distribution coefficient value estimated with structure activity relationship (SAR) modeling. 4-AP is likely a mobile compound and has the potential to reach ground water. However, 4-AP may also be susceptible to aged sorption, which would decrease its mobility. No surface water or ground water monitoring data were found in searches of the United States Geological Survey (USGS) online National Water Quality Assessment Data Warehouse (NAWQA) database, the EPA monitoring publication, "EPA Pesticides in Ground Water, A Compilation of Monitoring Studies 1971-1991 National Summary", or the Google internet search engine.

Abiotic half-life values could not be derived from submitted data, and the assumption of stability has been made for both hydrolysis and photolysis of 4-AP for purposes of exposure modeling. 4-AP has been shown to be stable under anaerobic conditions. Under aerobic conditions, half-life values ranged between 3 and 32 months. These biotic half-lives are consistent with model predictions. The EPI Suite level III fugacity model half-life predicts an aerobic metabolism half-life of 75 days, and an anaerobic metabolism half-life of about one year for 4-AP.

Model calculations for volatility predict 4-AP partitioning into the air and sediment would be slightly greater than 0.1% for both environmental compartments combined. This is consistent with available data. Both the vapor pressure and the Henry's Law Constant are relatively high for this pesticide, and aqueous solubility is unusually high at the grams per liter range. This high aqueous solubility along with the low octanol/water partition coefficient suggests that 4-AP has a low potential to bioaccumulate in the fatty tissues of fish.

Except for carbon dioxide, no data concerning the quantity, the identity or the environmental fate properties of any potential degradation products of 4-aminopyridine are available.

2. Ecological Exposure and Risk

The pesticide use profile, exposure data, and toxicity information were used to determine risk estimates to non-target aquatic and terrestrial organisms. Because a maximum application rate could not be calculated from the label at the time the ecological risk assessment was completed, and the lack of some ecotoxicity information for 4-AP, a qualitative ecological risk assessment was completed.

As applicable, acute and chronic terrestrial toxicity studies are required to establish the potential toxicity (hazard) of 4-AP to non-target species. Estimated Environmental Concentrations (EECs) are estimates of potential residue concentrations, derived from the maximum or typical application rate of 4-AP, to which an organism may be exposed. A risk quotient (RQ) is the ratio of the EECs to the organism's toxicity endpoint, which would yield

the deterministic risk estimates. The RQ is then compared to the level of concern (LOC) to determine if that particular exposure scenario would pose a risk to the non-target organism.

Table 7 outlines the Agency's LOCs and the corresponding risk presumptions.

Table 7. Agency's LOCs and Risk Presumptions			
Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Species – there is potential for endangered species risk	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

Terrestrial Organisms

Exposure

4-AP treated and/or untreated bait is manually placed either directly on the ground or onto protected and/or elevated structural sites, with, or without, the use of bait trays. Pre-baiting with the carrier matrix is always recommended to ensure efficacy by teaching birds to associate effects of the avicide with the location rather than with the bait, and to assist in restricting exposure of non-target species to 4-AP. After feeding patterns have been established through pre-baiting, treated bait is mixed with untreated bait in ratios ranging from 1:2 to 1:29 parts treated bait to parts untreated bait. Labels do not specify the number of times the treated bait can be replaced at any one use site, which might result in locally higher concentrations of 4-AP. Birds that consume the treated bait will normally react by flapping their wings erratically and issuing audible distress calls which are supposed to frighten away the remainder of the flock. Reactions of individual birds are expected to vary. In most cases, the labels advise the user to dispose of any dead birds that are found. Bait used at any location should be replaced after being exposed to a rainfall event, but the labels do not specify the number of times the treated bait can be replaced at any one use site.

Terrestrial animals (birds, mammals, reptiles, and terrestrial-phase amphibians) may come in contact with baits treated with 4-AP. Although 4-AP is generally used around heavily managed and/or densely populated areas and there are labeling instructions and precautions designed to minimize exposure to non-target species, the ecological risk assessment and the incidence data, described below, indicate acute risk to local non-target terrestrial animal populations (including secondary poisoning to predatory species), as well as acute risk to migrating species if they come in contact with the baits. Incident data from the Ecological Incident Information System (EIIS) indicate that many birds can potentially be killed from a single exposure event. Terrestrial animals may also be exposed to 4-AP if they come in contact with water contaminated with 4-AP. 4-AP has a high aqueous solubility, it is possible that flooded bait trays could contain contaminated water, which local animals may utilize as drinking water.

Gross estimates of the oral dose of bait needed to reach the LD_{50} for the most sensitive bird and mammal were calculated by utilizing the percent active ingredient per weight of the bait, the recommended dilution rates of treated bait with untreated bait, the reported LD_{50}s for birds and mammals and the assumed mean body weights for each of the surrogate species. Adjusted LD_{50}s for different sized animals was not possible with the current models. The results were expressed as weight in milligrams of bait that can be consumed per surrogate bird or surrogate mammal. The amount of active ingredient per seed was also estimated for canary and rape seed, wheat, sorghum, chopped corn and whole corn. Since the chopped corn formulation does not contain complete kernels, the amounts were based on the weight of an individual piece of corn chop (20 mg). With the mg a.i./seed values, the number of seeds that can be consumed to reach the LD_{50} for each surrogate species was estimated. These estimations are explained in detail in the Risk Description Section for terrestrial animals.

1. Avian and Mammalian Assessment

Toxicity to Birds

A variety of acute oral toxicity studies are available on birds with acute LD_{50} values ranging from 2.4 mg/kg for red winged blackbirds and black- and yellowbilled magpies to 15.0 mg/kg for bobwhite quail.

Acute and subchronic dietary studies are available for a variety of birds with the number of exposure days ranging from 7 to 40 days. In general, LC_{50}s and in many cases, NOAECs and LOAECs were reported for these studies. The LC_{50} value for an 8 day study with mallard ducks is 681 ppm. Sublethal effects included decreases in body weight gain and food consumption and depression and lower limb weakness prior to death. The NOAEC for sublethal effects (decreased body weight gain and food consumption) was < 464 ppm, the lowest concentration tested. The LC_{50}s for other dietary studies with additional species and varying exposure periods ranged from 316 to 479 ppm.

In two separate studies, 4-aminopyridine was administered to coturnix quail (*Coturnix coturnix*) via the diet to determine potential reproductive effects (MRID 05003186). The first test was conducted to determine the effects of chronic dietary exposure on reproduction in breeding pairs and the second test was conducted to determine the effects of chronic exposure to the parents on reproduction in the F_1 generation. The overall NOAEC for both studies is 31.6 ppm and the LOAEC is 100 ppm based on reduced body weight gain in males at 100 ppm and above. There were reduced food consumption and clinical signs of toxicity at 316 ppm and above. No reproductive parameters were affected; however, not all guideline parameters were measured. Single mortalities were observed at 31.6 and 100 ppm; however, it is uncertain as to whether or not this was related to treatment since a single mortality was observed in the control group in the second dietary study. Table 8 summarizes the results of the avian toxicology studies.

Table 8. Acute, Short-Term Dietary, and Chronic Toxicity of 4-AP to Birds

Test Organism	Test Substance	Test Type	Endpoint	Value mg/kg or ppm	MRID Classification
Acute endpoint					

Table 8. Acute, Short-Term Dietary, and Chronic Toxicity of 4-AP to Birds					
Test Organism	Test Substance	Test Type	Endpoint	Value mg/kg or ppm	MRID Classification
Red Winged blackbird *Agelaius phoeniceus*	4-aminopyridene	Acute oral	LD_{50}	2.4 mg/kg	05003191 Supplemental
Blackbilled and Yellowbilled magpies *Pica pica* and *Pica nuttalli*	4-aminopyridine	Acute oral	LD_{50} NOAEL	2.4 mg/kg (95% CI could not be calculated) 1.8 mg/kg	00004001
Short-term dietary endpoint					
Mallard duck *Anas platyrhynchos*	4-aminopyridene	8-Day Dietary	LC_{50} NOAEC	681 (95% C.I.: 517-896) ppm < 464 ppm	00147985
Chronic endpoint					
Coturnix quail *Coturnix coturnix*	4-aminopyridene		NOAEC LOAEC	31.6 ppm 100 ppm for sublethal effects	05003186

Toxicity to Mammals

An acute oral toxicity study with rats reports an LD_{50} of 28.7 mg/kg with a high increase in mortality over a short dosing range. 4-AP is even more toxic to dogs when administered by capsule, with an LD_{50} of 3.7 mg/kg reported. Clinical signs were observed, starting at the lowest dose administered (2.0 mg/kg). Table 9 below summarizes the results of the studies.

No chronic toxicity studies were available for mammals.

Table 9. Acute Toxicity of 4-AP to Mammals					
Test Organism	Test Substance	Test Type	Endpoint	Value (mg/kg)	MRID
Rat *Rattus norvegicus*	Compound 1861 Hydrochloride (purity not reported)	Acute oral Gavage	LD_{50}	28.7	00004024
Dog Mongrel	Compound 1861 Hydrochloride (purity not reported)	Acute oral Capsule	LD_{50}	3.7 ± 0.2. Range of doses: 2.0 – 6.8 mg/kg. Clinical signs (ataxia, hyperactivity) observed at two lowest dose levels (2.0 and 3.0), beginning ½ hour following dosing and persisting to 8 hours post-dosing. Normal by 24 hours. More severe clinical signs at higher dose levels. No gross pathologic lesions.	00004024

Acute Risk to Birds and Mammals

At the time the ecological risk assessment for 4-AP was completed it was not possible to determine accurate potential dietary exposure from the labels, which were very general. For risk description purposes, rough estimates of the oral dose of bait needed to reach the LD_{50} for the most sensitive bird (blackbird), small mammal (rat) and large mammal (dog) were calculated. Potential dietary exposure for terrestrial species was calculated, based on the percent active ingredient per weight of the bait and the recommended dilution rates. The reported LD_{50}s for blackbirds, rats and dogs are 2.4, 28.7 and 3.7 mg/kg body weight, respectively. The assumed mean body weights for blackbirds, rats and dogs are 0.07, 0.40 and 10 kg, respectively. Therefore, the estimated amount of 4-aminopyridine that can be consumed by these three species to reach the respective LD_{50}s are 0.168 mg/blackbird, 11.5 mg/rat and 37 mg/dog. Table 10 summarizes the various available baits, the percentages of 4-AP per weight of medium in each bait and the estimated quantity that must be eaten to reach the LD_{50} for the most sensitive bird (blackbird), small mammal (rat) and large mammal (dog). The table shows that based on the reported LD_{50}s it takes very few seeds to reach the LD_{50} level for birds. For small and large mammals significantly more seeds need to be ingested. However, when expressed as total grams of bait, the amounts are within the capability for mammals to consume in a short period of time.

The mixed grain bait consists of a mixture of sorghum, wheat and corn chops (http://www.Avitrol.com/Product/index.php). The following seed weights were used to estimate the number of seeds needed to reach the LD_{50} for each species:

Canary seed: 58,000 seeds/pound: 8 mg/seed
Rapeseed: 115,000 seeds/pound: 3.9 mg/seed
Wheat and sorghum: 45-90 mg/seed (from 10,000 – 20,000 seeds/pound)
Corn chops: 20 mg/chop
Whole corn: 350 mg/seed (from 1300 seeds/pound)

The amount of 4-AP (mg) per seed was estimated by using the equations below with 10,000 seeds/pound and a 0.5% formulation diluted 1:3 with untreated bait as an example.

1 pound/10,000 seeds x 0.45 kg/pound = 0.000045 kg/seed = 45 mg/seed
10,000 seeds/pound x 1 pound/0.45 kg = 22,222.22 seeds/kg
0.5% formulation = 0.5 g a.i./100 g = 5 g a.i./kg or 5000 mg a.i./kg
5000 mg a.i./kg bait diluted 1:2 with untreated seed = 1700 mg a.i./ kg diluted bait.
1700 mg a.i./kg bait x 1 kg bait/22,222.22 seeds = 0.08 mg a.i./seed
LD_{50} = 0.168 mg a.i./bird
0.168 mg a.i./0.08 mg a.i./seed = 2 seeds

Table 10. Acute Risk to Birds and Mammals. Approximations of Amount of Bait Consumed to Reach LD_{50} Levels for Birds and Small and Large Mammals

Product Name (EPA Reg. No.)	Bait Type	Dilution Ratio with Bait Medium/Estimation of mg 4-AP/kg Bait	Quantity Required to Reach Most Sensitive LD_{50}
Avitrol Mixed Grains (0.5%) (11649-4)	Rape seed/canary seed 1:3 (pre-mixed)	1:2 treated to untreated seed/1700 mg 4-AP/kg bait	Blackbird: 98 mg or 12 seeds Rat: 6.8 g or 800 seeds Dog: 22 g or 2700 seeds
Avitrol Mixed Grains (11649-4)	Mixed grains (pre-mixed): sorghum, wheat and specified corn chops	1:2-1:9 treated to untreated seed/500 – 1700 mg 4-AP/kg bait	Blackbird: 98 – 336 mg or 1-20 seeds Rat: 6.8 – 23 g or 70-115 seeds Dog: 22 – 74 g or 250 – 4000 seeds
Avitrol Corn Chops (0.5%) (11649-6)	Corn chops	1:5 - 1:9 treated to untreated corn chops. 500 – 800 mg 4-AP/kg bait	Blackbird: 210 - 336 mg or 10-20 seeds Rat: 15 – 25 g or 700 – 1400 seeds Dog: 46 - 74 g or 2300 – 3700 seeds
Avitrol Double Strength Corn Chops (1%) (11649-5)	Corn chops	1:4 - 1:9 treated to untreated 1000 – 2000 mg 4-AP/kg bait	Blackbird: 84 – 168 mg or 4 – 8 seeds Rat: 6 – 15 g or 290 – 600 seeds Dog: - 19 - 37 g or 900 – 1800 seeds
Avitrol Whole Corn (0.5%) (11649-7)	Whole corn	Maximum 1:9 treated to untreated 500 mg 4-AP/kg bait	Blackbird: 336 mg or 1 seed Rat: 25 g or 70 seeds Dog: 74 g or 200 seeds
Avitrol Whole Corn (0.5%) (11649-7)	Whole corn	Maximum 1:9 treated to untreated. 500 mg 4-AP/kg bait	Blackbird: 336 mg or 1 seed Rat: 25 g or 70 seeds Dog: 74 g or 200 seeds
Avitrol Mixed Grains (0.5%) (11649-4)	Mixed grains: sorghum, wheat and specified corn chops	1:5 – 1:9 treated to untreated. 500 – 800 mg/kg bait	Blackbird: 210 - 336 mg or 10-20 seeds Rat: 15 – 25 g or 700 – 1400 seeds Dog: 46 – 74 g or 2000 – 4000 seeds
Avitrol Mixed Grains (0.5%) (11649-4)	Mixed grains: sorghum, wheat and specified corn chops	1:5 – 1:9 treated to untreated. 500 – 800 mg/kg bait	Blackbird: 210 – 336 mg or 10-20 seeds Rat: 15 – 25 g or 700 – 1400 seeds Dog: 46 – 74 g or 2000 – 4000 seeds
Avitrol Double Strength Whole Corn (1%) (11649-8)	Whole corn	At least 1:9 treated to untreated At least 1000 mg/kg bait	Blackbird: 168 mg or < 1 seed Rat: 15 g or 35 seeds Dog: 37 g or 100 seeds

Chronic Risk to Birds

In a chronic study with coturnix quail, observed effects were reduced body weight gain, reduced food consumption, clinical signs of toxicity and mortalities. No reproductive parameters were affected (egg production, eggshell thinning, hatchability and chick mortality) up to a concentration level of 316 ppm. At 1000 ppm, all birds died within 3 weeks. The overall NOAEC for both studies is 31.6 ppm and the LOAEC is 100 ppm based on reduced body weight gain in males at 100 ppm and above. There were reduced food consumption and clinical signs of toxicity at 316 ppm and above. Comparing these concentration levels to the estimated amounts in the baits, the baits have 4-AP concentration levels higher than the bird chronic NOAEC and LOAEC. Some types of treated bait have concentration levels higher than 1000 ppm, which resulted in complete mortality in the chronic study after 3 weeks. It is possible that some birds may eat less than the amount that would result in mortality and then come back for multiple days to eat similar amounts if the baits are left in the same place each day. Reproductive effects may not be as significant a risk for these birds as sublethal effects; however, the data are not sufficiently complete for an estimate that would cover all the current

reproductive parameters. The repeated dose studies with birds indicate that 4-AP does not have cumulative effects in birds (MRID 00004083). Therefore, daily feeding may not necessarily result in death of these birds; however, death may occur from reduced feeding and the clinical signs of toxicity would make the birds more vulnerable to predators. It is more likely that the amounts eaten will result in quick mortality, thus providing minimal opportunities for chronic exposure. In addition, this chemical is designed to scare away birds, thus reducing the probability of chronic exposure.

Chronic Risk to Mammals

There are no reproduction or developmental toxicity studies conducted with mammals. There are two subchronic toxicity studies conducted with 4-AP hydrochloride with rats (MRID 00004026) and dogs (MRID 00004027) which indicate some neurological symptoms (hyperirritability to noise and touch in rats at 300 ppm (15 mg/kg bw/day)), and salivation and muscular weakness in dogs at 2.0 - 3.25 mg/kg bw/day. There were also some changes in brain weights (increased in rat, decreased in dog) and liver weights (increased in rat). The NOAELs of these two studies were 30 ppm (1.5 mg/kg bw/day) and 1.0 mg/kg bw/day for rats and dogs, respectively. Using the same calculations as in the acute risk section, the estimated amount of 4-AP that can be consumed by rats and dogs to reach the respective NOAEL/LOAELs for the studies are 0.5/5 mg/rat and 10/20 mg/dog. Although the effects observed in these two studies cannot be quantitatively linked to reproduction, growth or survival, these studies represent the only data beyond acute toxicity studies for mammals and they provide some sublethal data. The listed effects are similar to the sublethal effects observed in the acute toxicity studies. Again, it is more likely that sufficient amounts will be eaten such that quick mortality will result, thus providing minimal opportunities for chronic exposure.

2. Terrestrial and Semi-aquatic Plant Assessment

Toxicity to Terrestrial Plants

Terrestrial and semi-aquatic plants around the treated area may be exposed to 4-AP if there are rain events followed by runoff. Terrestrial plant ecotoxicity data are limited. The results of a toxicity test on corn are described in Table 11 below.

Table 11. Toxicity of 4-AP to Terrestrial Plants

Test Organism	Test Substance	Test Type	Endpoint	Value	Affected Endpoint	MRID Classification
Corn (*Zea may*) Pioneer 3956 Hybrid	4-AP purity unspecified	Phytotoxicity to seeds and seedlings	NOAEC	ppm 10 ppm <0.1 ppm following 2 apps.	Germination (no effect up to 1.0 ppm) Fresh weights of seedlings (no effect up to 10 ppm following single application, slight effect at all concentrations (5-12% reduction) following 2 applications up to 100 ppb	00004124 00004037 Supplemental

Risk to Terrestrial Plants

A phytotoxicity study with corn showed that 4-AP had no effect on germination up to 1.0 ppm and no effect on fresh weights of seedlings up to 10 ppm following a single application. Following 2 applications, there was a slight effect at all concentrations (5-12% reduction) up to 100 ppb. This effect (5-12%) falls below the Agency's LOC of 25% effect. A translocation study was conducted with the same variety of corn seeds. The authors of the studies stated that the observations of the phytotoxicity and translocation studies suggest smaller single doses of 4-AP can be assimilated by the plants resulting in little to no adverse affects; furthermore, increasing the number of plants in a unit diminishes adverse effects. As with terrestrial animals, the fact that 4-AP is used in either heavily managed areas and/or areas densely populated by humans and that less than 250 pounds active ingredient were used in 2005, impacts to terrestrial plants are not expected.

b. Aquatic Organisms

Aquatic ecosystems potentially at risk include water bodies adjacent to 4-AP bait stations. Since 4-AP has the potential to be used in coastal areas, adjacent marine water bodies are also potentially at risk. Risks will be discussed for aquatic animals (fish, invertebrates, amphibians) and plants, which are assumed to occur in small, static ponds that receive runoff from areas adjacent to the baits. Additionally, the proposed labels do not specify the number of times the treated bait can be replaced at any one use site, which might result in locally higher concentrations of 4-AP.

The estimated environmental concentrations (EECs) for surface water could not be calculated for 4-AP in the absence of both fully acceptable environmental fate data and an application rate in terms of pounds per acre. The open literature, SAR modeling, and conservative assumptions were used to supplement the sparse environmental fate data. The Tier 1 surface water model, GENEEC2, was used to estimate the application rate for 4-AP, in terms of pounds per acre, which could be applied without exceeding levels of concern for representative species. Normally, the Agency assesses risk by integrating both EECs and toxicity endpoints from the most sensitive species and estimating the likelihood of adverse ecological effects to non-target species. This approach utilizes the ratio of the exposure estimate divided by a single point estimate of toxicity to calculate an RQ. The RQ is then compared to the respective LOCs, which serve as criteria for categorizing potential risk to non-target organisms. For 4-AP, the fate and environmental effects data are insufficient to determine RQ values with reasonable associated uncertainties. Therefore, for risk description purposes, the reported toxicity values for fish, amphibians and aquatic invertebrates were utilized to determine EECs and associated application rates which may potentially approach LOCs for aquatic species.

1. Fish and Invertebrates

<u>Freshwater and Marine/Estuarine Fish and Invertebrates</u>

Similar to RQs calculated for terrestrial organisms, aquatic acute RQs are derived by dividing the peak EECs by the LC_{50} to estimate acute hazard. Chronic RQs for freshwater invertebrates are derived by dividing the 21-day EECs by the NOAEC values. However, for 4-AP, the EECs for surface water could not be precisely calculated in the absence of both fully acceptable environmental fate data and an application rate in terms of pounds per acre at the time of the ecological risk assessment.

The endangered fish and aquatic invertebrate species LOC is 0.05. For endangered freshwater fish and frog larvae, the EEC for endangered species must be less than 0.05 times the respective LC_{50}s of 2.4 ppm or 0.12 ppm. In the absence of fully acceptable environmental fate data, conservative assumptions were made in order to derive model input values, tabulated below.

No data were available to estimate the application rate that would trigger acute or chronic concern for marine/estuarine invertebrates. Additionally, no chronic data were available to estimate the application rate that would trigger chronic concern for freshwater invertebrates or marine/estuarine vertebrates.

While no data exists to address chronic risk for freshwater invertebrates and marine/estuarine vertebrates and invertebrates, use patterns are such that it is unlikely that sufficient amounts of 4-AP will be available in the aquatic environment to generate significant chronic exposure. Some uncertainty remains over how the replacement and renewal rates for the baits would affect chronic exposure for these taxa. The estimated application rates needed to exceed aquatic levels of concern for 4-AP are found in Table 12.

Table 12. Tier I, GENEEC2, Estimated Application Rates Needed to Exceed Aquatic Levels of Concern for 4-Aminopyridine					
Taxonomic Group and Most Sensitive Test Species	Toxicity Endpoint MRID Classification	Estimated Single Application Rate to Trigger a Concern	Targeted 1-in-10-year annual exceedence probability		
			Estimated Peak EEC to Trigger a Concern[a]	Estimated 21-day EEC to Trigger Concern[a]	Estimated 60-day EEC to Trigger Concern[a]
Freshwater vertebrates Freshwater fish: Channel catfish *Ictulurus Punctutus* Frog larvae: Southern leopard frog larvae *Rana sphenocephala*	2.4 ppm (LC_{50}) 00004083, 00003985, 00004101 Supplemental ECOTOX Ref. # 7412 Supplemental	≥23 lb. ai/acre	≥1.2 ppm (acute risk)	ND	ND
		≥2.3 lb. ai/acre	≥0.12 ppm (endangered species)		
Freshwater vertebrates Frog eggs: Southern leopard frog eggs and larvae *Rana sphenocephala*	1.0 ppm (NOAEC)	≥19.3 lb. ai/acre	ND	≥1.0 ppm[b]	ND
	2.0 ppm (LOAEC) ECOTOX Ref. # 7412 Supplemental	≥38.6 lb. ai/acre	ND	≥2.0 ppm[b]	ND
Freshwater invertebrates Juvenile glass shrimp *Palaemonetes kadiakensis*	0.37 ppm (EC_{50}) ECOTOX Ref. # 7412 Supplemental	≥3.6 lb. ai/acre	≥0.19 ppm (acute risk)	ND	ND
		≥0.37 lb. ai/acre	≥0.019 ppm (endangered species)		
Marine/estuarine vertebrates Cowfish *Lactophyrs tricornis* Globe fish *Chilomycterus sp.*	7.6 ppm (LC_{50}) 00004111 Supplemental	≥73 lb. ai/acre	≥3.8 ppm (acute risk)	ND	ND
		≥15 lb. ai/acre	≥0.76 ppm (restricted use)		
		≥7.3 lb. ai/acre	≥0.38 ppm (endangered species)		
Marine/estuarine invertebrates	ND	ND	ND	ND	ND

ND = no data for class of organism and/or endpoint value
[a] = LOC (acute risk (0.5), restricted use (0.1), endangered species (0.05) or chronic (1.0)) ÷ toxicity endpoint
[b] = exposure period of amphibian study was less than 21 days but greater than 1 day
[c] = estimated application rates presented are for a single application, replacement of bait after rainfall event was not considered

2. Aquatic Plants

No ecotoxicity data are available for either freshwater or marine/estuarine plants. Risk to aquatic plants cannot be assessed due to a lack of data. Risk to aquatic plants is not expected because of the impracticality of using large amounts of the bait in a single drainage area, thus providing limited opportunities for significant aquatic exposure.

3. Aquatic Animals

Based on the current use patterns and labels, acute risk to aquatic animals is not expected; however, uncertainty exists for local populations because the labels do not specify the number of times the treated bait can be replaced at any one use site, which might result in locally higher concentrations of 4-AP. Chronic data are not available for aquatic animals. Risk to aquatic animals is not expected because of the impracticality of using large amounts of the bait in a single drainage area, thus providing limited opportunities for significant aquatic exposure.

b. Secondary Exposures to Birds and Mammals

Although labeling precautions are provided, use of 4-AP in densely populated areas does not preclude exposure of non-target terrestrial species. 4-AP is targeted for ground-feeding granivorous birds. Other non-target granivores and omnivores with similar feeding patterns might consume the bait. Predators and scavengers that consume pigeons and other birds are also at risk of exposure if their prey has fed on 4-AP. Non-target species with these feeding patterns have been observed in highly populated urban areas, some of which may also be habituated to consuming food provided by humans.

The incident data from Ecological Incident Information System (EIIS) indicate that predatory birds have been exposed to 4-AP-poisoned prey birds. Four predatory bird deaths are listed in EIIS. One of the predatory birds was a peregrine falcon, which was a listed species at the time of the incident report (1998). The reports contain necropsy and chemical analysis records which indicate that the predatory bird deaths were due to ingestion of poisoned birds. The secondary hazard studies were conducted with poisoned red-wing blackbirds, the most sensitive bird tested (LD_{50}: 2.4 mg/kg). The ingested birds found in the dead predatory birds included a house sparrow (LD_{50}:7.5 mg/kg), pigeon (LD_{50}: 7 mg/kg) and starling (LD_{50}: 4.9 mg/kg).

Secondary Toxicity and Risk to Birds and Mammals

A secondary hazard study was conducted where 4-aminopyridine-killed blackbirds were fed to canines, rats, sparrow hawks, and red-tailed hawks, among other species. In some cases, the blackbirds were fed treated bait and in other cases, they were administered the test material by gavage. No effects were observed in any of the predatory species; however, for those animals which were fed birds that had died from consuming a bait formulation, the amount of the treated corn that the blackbirds ate was either not measured or not reported. However, the amount of 4-AP needed to kill blackbirds was not sufficient to kill predators through secondary ingestion. Less sensitive birds could pose a greater risk, as they would presumably have consumed more 4-AP before they died. The ecological incident report, as described below, indicates that there is some risk to predators due to secondary effects from 4-AP. Table 13 summarizes the results of the secondary hazard study.

Table 13. Secondary Toxicity of 4-aminopyridine to Predatory Birds and Mammals

Test Organism	Test Substance	Endpoint	Value	Comments and Affected Endpoints	MRID Classification
Canine *Canis familiaris-Canis Iatrans* mix and *Canis familiaris*	4-Aminopyridine (purity not reported)	Chronic Feeding NOAEC	0.4 mg/ kg bw/ day	1 female beagle-coyote cross & 1 male beagle fed 175 g of mixture containing 75% ground 4-AP poisoned blackbird & 25% dog chow 2x/day for 8 days. Additional dog chow *ad lib*. between feedings. 0.39-0.4 mg/kg/day 4-AP. No effects; however, birds had been fed mixture of 1 part 3.0% 4-AP treated cracked corn with 99 parts untreated cracked corn. Unclear on how many pieces of treated corn birds ate, so unclear on how much dogs received.	0004001 0004006 Supplemental
Rats *Rattus norvegicus*	4-Aminopyridine (purity not reported)	Acute Feeding NOAEC	67.5 mg/ kg bw	5 rats fed 1 ground bird dosed with 100-300 mg/kg by gavage. Treated feed mixed with oatmeal and consumed within 3 hours. Mg/kg bw dose of 4-AP from birds ranged from 14.31-67.49. No effects.	0004001 0004006 Supplemental
Rats *Rattus norvegicus*	4-Aminopyridine (purity not reported)	Chronic Feeding NOAEC	1.23 mg/ kg bw/ Day	10 rats fed *ad lib* mixture containing 75% ground 4-AP poisoned blackbird & 25% oatmeal for 21 days. Mean 1.23 mg/kg/day 4-AP. No effects; however, unclear on how many pieces of treated corn birds ate, so unclear on how much rats received.	0004001 0004006 Supplemental
Sparrow hawk *Falco sparverius*	4-Aminopyridine (purity not reported)	Chronic Feeding NOAEC	6.05 mg/kg bw/day	For 7, 21, 45 days, 3 sparrow hawks were fed poisoned birds. One control bird. Up to 6.05 mg 4-AP/kg bw/day tested. No observed effects; however, see comment under chronic feeding dog.	0004001 0004006 Supplemental
Red-tailed hawk *Buteo jaraicansis*	4-Aminopyridine (purity not reported)	Chronic Feeding NOAEC	1.06 mg/kg bw/day	One hawk received field poisoned birds (4% solution of 4-AP sprayed on husked ripening ears of corn) for 2 weeks. Amounts of 4-AP present/bird unknown but was enough to kill them. Based on LD_{50} of 2.4 mg/kg, authors surmised that hawk received > 0.17 mg 4-AP/bird. No toxicological symptoms.	0004001 0004006 Supplemental

d. Ecological Incidents

Ecological incidents are reported to the Agency by local, state, other federal agencies, or at times, submitted under FIFRA sec. 6(a)2. The Ecological Incident Information System (EIIS) was accessed on in November 2006 to review the reported incidences for 4-AP.

Aquatic Organisms

No incidences involving aquatic organisms were reported; however, two incidences involving terrestrial birds around aquatic areas were reported. One was reported in 1987 in Saratoga New York where 2 ring-billed gulls were killed after ingesting bait. This was recorded as a misuse (intentional) and was determined to be probable. A residue analysis was conducted. The second was 2 mallards that were killed in Wisconsin in 1995. The legality was undetermined. A residue analysis was conducted. The certainty was highly probable.

Terrestrial Organisms

One hundred twenty-one incident reports involving exposure of terrestrial animals are available from 1971 to 2005. The certainty index classification was given for all reported incidents: 5 possible, 40 probable and 76 highly probable. All reported 4-aminopyridine incidents for terrestrial species involve exposures to wild birds, which included Cooper's hawks (1), starlings, American crows, rock doves, doves, red-tailed hawks (2), song sparrows, grackles, red-winged blackbirds, house sparrows, mourning doves, ring-billed gulls, white-throated sparrows, peregrine falcons (1 in 1998, which was a listed species at the time of the report), Canada goose and blue jays. The majority of reported incidents involved direct toxicity to birds listed as target species on 4-AP labels. For the predatory birds, the individual incidence reports provided necropsy evidence and chemical analyses that indicated that these birds were killed by ingesting poisoned birds. The weight of evidence suggests that such secondary effects can occur, although the frequency with which they could occur is not clear.

During the reporting period, a total of 121 calls were made regarding possible exposure of birds to 4-aminopyridine; of these, 3 reported that animals were either having seizures or incapacitated, 1 had no report and the remainder reported death of animals.

The treatment sites include barns, buildings, corn, granary, hardware store, home, municipal operation, parks, parking lot, residential areas, rooftop, street and urban areas. Many of the reports involved treated baits.

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 (i.e., active ingredient-specific) data required to support reregistration of products containing 4-AP as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing 4-AP.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing 4-AP. The Agency has determined that 4-AP-containing products are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of 4-AP that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of 4-AP, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Requirements for Reregistration

4-AP-containing products are eligible for reregistration provided that registrants comply with the requirements outlined in this document including the following: (1) submit required data and (2) implement risk mitigation measures.

1) Required Data

4-AP-containing products are eligible for reregistration provided that registrants submit data as required by the generic and product-specific data call-ins that EPA intends to issue as a result of this RED (see Section V).

The generic database supporting the reregistration of 4-AP uses has been reviewed and determined to be adequate to support a reregistration eligibility decision; however, generic data will be required to confirm acute toxicity information of the 4-AP technical formulation.

2) Risk Mitigation

Products containing 4-AP are eligible for reregistration provided the measures presented in Table 14 are implemented. Specific labeling requirements to implement these measures are presented in Table 15 (see Section V).

Table 14. Risk Mitigation Measures for 4-Aminopyridine	
Risk of Concern or Potential Risk	Mitigation Measures
Potential for dietary exposure through drinking water	A certified applicator (or a person under their supervision) must remove 4-AP-treated blend at the end of the application period. The following statement will be required on all 4-AP end-use product labels: "Do not apply treated bait within 25 feet of permanent bodies of water."
Potential for risk to occupational handlers	All occupational handlers must wear the following PPE: long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves. The registrant has requested voluntary cancellation for all 4-AP products formulated as powders. The remaining products, all formulated as baits, have a much lower potential for inhalation exposure.
Potential for exposure to children	The following statement is required on all 4-AP end-use product labels: "DO NOT apply treated bait in areas accessible to children." In populated areas and areas open to the public, baiting must be performed at elevated sites. Where baiting at elevated sites cannot be accomplished, a certified applicator or someone under his/her direct supervision (authorized handler) must ensure children, pets, and non-target species do not come in contact with the blend. The authorized handler must not leave the site until all dead/dying birds and unused bait are retrieved from the site. All 4-AP end-use product labels will require that the product is not stored or even temporarily placed in locations accessible to children, pets, or domestic animals.
Potential for food or feed contamination	The following statements are required on all 4-AP end-use product labels: "Do not feed to livestock or poultry. Do not mix with grain for livestock or poultry feed." "Do not apply where livestock and/or poultry may be exposed." "Do not apply to growing food crops." "Do not apply baits made from this product in any way that could contaminate materials to be used as human food or animal feed." "Do not use treated baits as food or feed."

Table 14. Risk Mitigation Measures for 4-Aminopyridine	
Risk of Concern or Potential Risk	Mitigation Measures
Potential for risk to non-target organisms	4-AP end-use product labels will require that a certified applicator or someone under his/her direct supervision ensures that non-target species do not come in contact with the blend during the entire application period. That authorized handler must stay on the site during the entire application period (from the time the 4-AP treated bait is placed in the application site to the time treated bait and any dead or dying birds are removed). The authorized handler must ensure that children, pets, and non-target species do not come in contact with the blend. Birds killed during treatment must be disposed of by burial or incineration. Prebaiting target birds will also be required on all 4-AP end-use product labels. Prebaiting will promote feeding by target species and will provide an opportunity to assess potential exposure to non-target species. Application of 4-AP treated bait will be prohibited if non-target species are observed feeding on the pre-bait. The only label with gulls listed as a pest, label number 11649-11, has been requested for voluntary cancellation by the registrant. This will preclude gulls from being targeted for use with 4-AP. All 4-AP end-use product labels will require both the common names and the scientific names of target birds to clearly distinguish target species from non-target species, including those protected under the Endangered Species Act and the Migratory Bird Treaty Act.

C. Public Comments and Responses

When making its reregistration decision, the Agency considered all comments received in the docket during the public participation phase, and worked with stakeholders and the public to reach the regulatory decisions for 4-AP. During the public comment period on the 4-AP ecological risk assessment which began on May 30, 2007, the Agency received from the Humane Society of the United States, the Animal Protection Institute, and other environmental stakeholder groups for an extension to the comment period. Based on this request, the 60-day comment period was extended an additional three weeks. EPA received comments in favor of the reregistration of 4-AP products from the National Pest Management Association, the National Sunflower Association, and contacts within the USDA Extension Service. EPA received comments expressing concerns about the reregistration of 4-AP products from the Humane Society of the United States, the Animal Protection Institute, People for the Ethical Treatment of Animals, the American Bird Conservancy, and other members of the public.

Public comments in their entirety are available in the public docket (EPA-HQ-OPP-2007-0400) at http://www.regulations.gov. The RED document, supporting documents for 4-AP, and the Agency's response to received comments are also available in the docket. In addition, the 4-AP RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

D. Regulatory Rationale

The Agency has determined that 4-AP is eligible for reregistration provided that the requirements for reregistration outlined in this document are implemented. Provided that registrants comply with the requirements of this RED, EPA believes that 4-AP will not present risks inconsistent with FIFRA and that 4-AP's benefits to public health and safety outweigh the remaining risks. A summary of EPA's rationale for reregistering and managing risks associated with 4-AP is presented below.

Benefits and Alternatives

4-AP is a pesticide with killing and flock alarming properties. Birds are pre-baited with untreated grain so that they are accustomed to eating at the treatment site. A blend of treated and untreated grain is then used to replace the untreated pre-bait. The flock feeds on the blend. Since not all of the grains are treated with 4-AP, each member of the flock may or may not eat a particle of treated grain. Consumption of 4-AP-treated baits will cause a reduction in motor control in the affected birds brought on by over stimulation of the nervous system. The birds that have consumed treated bait will exhibit tremors, erratic behavior, periods of inactivity, vocalization, and in many cases will die. Neighboring birds observe this behavior and leave the area. Some species of birds are more reactive than other species upon eating 4-AP-treated bait. Less reactive species are less noticeable to their neighbors. Additionally, some types of birds respond to distress signals of their neighbors, and other species do not respond to the distress signals. In general, crows, blackbirds, and other black species respond well to the distress signals of their neighbors, and pigeons and sparrows do not respond as well to distress signals. Thus, birds that consume 4-AP-treated bait react in such a way that the remainder of the flock is frightened away. Birds that consume the 4-AP-treated bait usually die. Mortality levels depend on the ratio of treated to untreated grain applied, the reactivity of the targeted species, and how responsive the rest of the flock is in reacting to the distress called of its members.

In general 4-AP is used to control "nuisance" species of birds in situations where they may endanger public health and safety (see EPA Pesticide Registration Notice 2002-1) or cause damage to structures. Overpopulation of birds can spread and harbor diseases such as salmonellosis, histoplasmosis, arboviral encephalitis, and West Nile virus. Bird roosts can be infested with flies as well as mites and ticks which can act as disease-spreading vectors as well. Overpopulation of birds may also cause economic losses in urban and agricultural environments. Bird droppings cause damage to automobile paint, buildings, statues, and electrical systems. Registrant-reported information indicates that in Tulsa, Oklahoma crows caused damage to a roof by pecking holes in a soft roofing substance. USDA Animal and Plant Health Inspection Service (APHIS) Wildlife Services reports using 4-AP products in its integrated wildlife management approach to protect human health and safety, and to limit damage to property, equipment and machinery, aviation, livestock feed, buildings, crops, electrical utilities, and livestock. The National Pest Management Association reported use of 4-AP-treated baits by their members to manage bird overpopulation and prevent disease and unsanitary conditions. It was reported that in Massachusetts 4-AP-treated baits are used primarily around office buildings, public transportation buildings, and industrial buildings. Finally, 4-AP-treated baits are used around feedlots where birds are attracted by feed. This can

cause economic losses to producers. Birds may also spread E. coli bacteria present in cattle manure.

4-AP containing products are most frequently used to control nuisance pigeons, starlings, crows, grackles, blackbirds, and sparrows. Non-chemical alternatives to 4-AP include exclusion, habitat modification, frightening devices, devices with spikes, and trapping. Chemical alternatives include Starlicide (3-chloro-p-toluidine hydrochloride), nicarbazin, and methyl anthranilate. Starlicide is a restricted use avicide used to control crows, ravens, and magpies that prey on Federally threatened or endangered species, prey on newborn livestock, or that damage and feed on the contents of sillage bags. Birds that consume Starlicide baits die without eliciting distress signals that frighten away the rest of the flock. Thus, flocks that feed on Starlicide-treated bait would have a higher mortality rate than flocks feeding on 4-AP-treated baits. Nicarbazin is a restricted use pesticide that reduces egg hatchability. Nicarbazin is currently only registered for use on Canadian geese and pigeons. In order to be efficacious, nicarbazin-treated bait must be fed daily to the target species and be consistently consumed by the target species. Daily feedings must continue throughout the entire nesting period, which can last all year. Methyl anthranilate is a bird repellent used on crops as well as on and around structures. Methyl anthranilate has been found to be efficacious in some situations, but it is usually recommended for use as part of an integrated pest management to reduce bird damage in crops. Effectiveness of chemical and non-chemical bird control methods varies depending on the type of device, site, skill of the user, and type of bird species involved in the problem.

2. Human Health and Ecological Risk

4-AP is currently formulated as a treated bait and a powder. The registrant has requested voluntary cancellation of the remaining products formulated as powders. Through the requirements of this RED and associated product reregistration, EPA intends to minimize the potential adverse effects to human health and the environment from the bait formulation.

Because there are relatively few bird control tools available and in most cases they are not direct substitutes for one another, EPA concludes that continued registration of 4-AP products formulated as treated bait, subject to the requirements of this RED, would provide benefit to public health and safety in controlling unwanted bird species in agricultural and urban/suburban areas and that risks to non-target species are not unreasonable.

EPA has conducted human health and ecological risk assessments for 4-AP to support the reregistration eligibility decision. In its assessments, EPA concluded that many risks are below the Agency's level of concern but also identified potential risks that, if left unmitigated, may pose unreasonable risks or adverse effects to humans or the environment.

As a result of this RED, EPA is requiring registrants to implement risk mitigation measures to address ecological risks from unintended exposure and human health risks from accidental exposure and from handling 4-AP. To mitigate risk to non-target organisms, the Agency is requiring that applicators pre-bait the intended target area and observe target birds' feeding habits to determine the optimum time of application and evaluate potential hazards associated with the application. 4-AP-treated bait may not be applied if non-target species are

observed feeding on the pre-bait. To mitigate risk to non-target species during ground applications, a certified applicator or someone under his/her direct supervision (authorized handler) must ensure that pets and non-target species do not come in contact with the blend during the entire application period. The application period starts when treated bait is placed in the application site and ends when the blend and any dead/dying birds are removed. Birds that die as a result of application must be disposed of by burial or incineration in order to minimize secondary poisoning to predatory species. In order to mitigate risk to predatory species, the authorized handler must not leave the site until all dead or dying birds and unused bait are retrieved from the site. All 4-AP labels must list both the common name and the scientific name of target species to avoid confusion of which species are permitted to be controlled.

To reduce the potential for risk to children, the Agency is requiring that treated bait not be applied in areas accessible to children. In addition, EPA is requiring that in populated areas and areas open to the public, baiting be performed at elevated sites. Where it is not feasible to bait at elevated sites and ground applications are necessary, the certified applicator or someone under his/her direct supervision (authorized handler) must ensure that children do not come in contact with the blend during the entire application period. Also, that authorized handler must not leave the site until all dead/dying birds and unused bait are retrieved and removed from the site. In order to reduce potential risk of food or feed contamination from 4-AP applications, EPA is requiring that 4-AP not be applied where livestock and/or poultry may be exposed, that 4-AP baits not be used as feed, and that 4-AP not be applied to growing food crops. Finally, EPA is requiring that handlers of 4-AP products wear additional personal protective equipment.

3. Endocrine Screening

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extend that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, there may be additional screening and/or testing required for 4-AP.

4. Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or

adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data and 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, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for 4-AP result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Risk findings are based solely on EPA's qualitative assessment for 4-AP and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of 4-AP "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). To reduce potential effects to non-target endangered species, EPA is requiring various mitigation measures.

V. What Registrants Need to Do

The Agency has determined that the products containing 4-AP (PC 069201) are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table 15. The Agency intends to issue a Data Call-In (DCI) requiring product-specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of the 4-AP treated bait formulation has been reviewed and determined to be substantially complete. No generic data requirements will be required at this time.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 15.

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 that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Moana Appleyard at (703) 308-8175.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 15. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific

existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 15 describes how language on the labels should be amended.

Labeling Changes Summary Table

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

Table 15: Summary of Labeling Changes for 4-aminopyridine

Description	Amended Labeling Language for Manufacturing Use Products*	Placement on Label
For all Manufacturing Use Products	"Only for formulation into an avicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." "Only for formulation into products classified as restricted use." "Only for formulation into end-use products that are formulated onto bird bait at a maximum of one percent active ingredient in the bait." "Formulation into powder is prohibited." Note to registrant: All species the product targets must be stated on the label. The common and scientific names of each targeted species must be included on the label. For example, if the product targets pigeons, the label would state: "Used for the control of feral pigeons (*Columba livia*)…"	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional	Directions for Use

supported by a formulator or user group	use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is extremely toxic to mammals and birds. This product is toxic to invertebrates. 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 Occupational Use		
RUP	"Restricted Use Pesticide" "Due to acute oral and acute dermal toxicity and due to toxicity to birds and mammals." "For retail sale to and use by only Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."	This statement must appear at the very top of the label's front panel [see 40 CFR 156.10(j)(2)(i) for more information]. No other wording or symbols may appear above the RUP statement.
Note to Registrant	All species the product targets must be stated on the label. The common and scientific names of each targeted species must be included on the label. For example, if the product targets pigeons, the label would state: "Used for the control of feral pigeons (*Columba livia*)…"	
PPE Requirements Established by the RED[1]	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" [*EUP*	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

For Bait Formulations	*registrant, insert correct chemical-resistant material*]. "If you want more options, follow the instructions for category" [*EUP registrant, insert A, B, C, D, E, F, G, or H*] "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, persons picking up dead birds and unused bait, and other handlers must wear the following PPE: - long-sleeved shirt and long pants, - shoes plus socks, and - chemical-resistant gloves." Note: application continues until the dead birds and unused bait are retrieved – all participants in the application are pesticide handlers.	
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."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"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	"Do not apply directly to water, or to areas where surface water is present	Precautionary Statements immediately

	or to intertidal areas below the mean high water mark. This pesticide is extremely toxic to mammals and birds. This product is toxic to invertebrates. Wildlife and pets feeding on treated bait may be killed. Do not contaminate water by cleaning equipment or disposal of waste."	following the User Safety Recommendations
Entry Restrictions	"Keep persons (other than authorized handlers) as well as pets and livestock, away from the treated bait and dead or dying birds at all times. Only protected handlers may be in the area during bait application until all dead birds and unused bait is retrieved."	Directions for Use Under General Precautions and Restrictions
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
Other Application Restrictions (Risk Mitigation)	"Do not feed to livestock or poultry. Do not mix with grain for livestock or poultry feed." "Do not apply where livestock and/or poultry may be exposed." "Do not apply to growing food crops." "DO NOT apply treated bait in areas accessible to children." "Do not apply more than 0.4 lb treated bait per protected acre per application." "Baits must be prepared and applied as specified on this label. Do not apply baits made from this product by air or any mechanical equipment designed to broadcast baits or other pesticides. Users of this product must follow all limitations indicated on this label regarding the	Directions for Use

	placement, monitoring, and retrieval of treated baits." "Before baits made with this product are applied, sites that are to be treated must be observed for evidence of non-target activity and must be pre-baited (see specific instructions for these activities)." "In populated areas, and areas open to the public, where feasible, baiting must be performed at elevated sites." "Where baiting at elevated sites is not feasible and ground baiting is required, a certified applicator or someone under his/her direct supervision (authorized handler) must ensure children, pets, and non-target species do not come in contact with the blend during the entire application period. That authorized handler must not leave the site until all dead/dying birds and unused bait are retrieved from the site. All dead/dying birds must be disposed of by burial or incineration." "Do not apply treated baits within 25 feet of permanent bodies of water." "Do not apply baits made from this product in any way that could contaminate materials to be used as human food or animal feed. Do not use treated baits as food or feed. Do not store or even temporarily place treated bait in locations accessible to children, pets, or domestic animals." "Before applying treated baits in any problem area, carefully observe target birds' feeding habits to locate their preferred feeding sites, determine the optimum time of application, and evaluate options to reduce potential hazards of the application to desirable and/or protected animal species." "Pre-baiting with untreated bait materials is required to promote feeding by target species and to assess potential for exposure of non-target species. Do not apply treated bait if non-target species are observed feeding on the pre-bait."	

* At the time of reregistration, there are no registered 4-aminopyridine manufacturing use products. If in the future, 4-aminopyridine manufacturing use products are registered, label statements from the manufacturing use products section of the Labeling Changes table will be required on those labels.

[1] 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.

Appendix A: Use Patterns Subject to Reregistration of 4-Aminopyridine (PC Code 069201)

Target Birds	Site	Application Rate Restrictions	Formulation	Directions for Use
Pigeons; house sparrows; red-winged, yellow-headed, Brewers, and rusty blackbirds; grackles; cowbirds; and starlings [Bird species must be specified on label with both common and latin species names]	In, on or in the area of structures, nesting, loafing, and roosting sites.	Maximum rate: Ratio 1 part treated bait: 5 parts untreated bait; 0.4 lb treated bait per protected acre per application	Bait	See Table 15 in Section V of the 4-Aminopyridine RED.

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

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the 4-AP case covered by this RED. It contains generic data requirements that apply 4-AP in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.

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

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

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

APPENDIX B.

Data Supporting Guideline Requirements for the Reregistration of 4-Aminopyridine				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity - Quail	All	00003999 00004101
850.2200	71-2A	Avian Dietary Toxicity - Quail	All	00003998
850.2200	71-2B	Avian Dietary Toxicity - Duck	All	00147985
850.2300	71-4A	Avian Reproduction - Quail	All	05003186
850.1300	72-4	Daphnid Chronic Toxicity	All	00003985 00004083 00004111
850.2500	71-5	Field Testing for Terrestrial Wildlife	All	00086682
850.4025	121-1	Phytotoxicity	All	00004001 00004037 00004124 00004132 00004147 00109573 00109577 00109579 00131325 05003440
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	All	00004024 00004025 00004028 00004265 00021901 00021902
870.1200	81-2	Acute Dermal Toxicity-Rabbit	All	00004024
870.3100	82-1A	Repeated dose 28-day/ 90-Day Feeding - Rodent	All	00131328 00004026 00021907
870.3150		90-Day Oral Toxicity – Dog	All	00131329 00004027 00021904
None	84-4	Other Genotoxic Effects	All	Ogawa et al, 1986 Wakabayashi et al, 1982 Sugimura et al, 1982 as summarized in EPA IRIS 2003 and NIC 2005
Non-Guideline	None	Human Clinical Study	All	47093602, Segal et al 1999 47093601, Grijalva et al 2003 47093603, van Diemen et al, 1993

Data Supporting Guideline Requirements for the Reregistration of 4-Aminopyridine				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
ENVIRONMENTAL FATE				
835.4100	162-1	Aerobic Soil Metabolism	All	00109579 05003407
OTHER				
None	None	Non-Guideline	All	00003963 00003964 00003965 00003966 00003967 00003968 00003969 00003970 00003971 00003972 00003973 00003974 00003976 00003977 00003979 00003980 00003981 00003984 00003986 00003987 00003988 00003989 00003991 00003992 00003994 00003995 00003996 00003997 00004000 00004002 00004003 00004006 00004008 00004013 00004014 00004015 00004031 00004032 00004033 00004034 00004035 00004036

Data Supporting Guideline Requirements for the Reregistration of 4-Aminopyridine				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
				00004041 00004042 00004043 00004044 00004045 00004046 00004047 00004051 00004052 00004053 00004054 00004056 00004057 00004058 00004059 00004060 00004061 00004062 00004063 00004064 00004065 00004067 00004068 00004069 00004070 00004071 00004072 00004073 00004074 00004075 00004076 00004077 00004078 00004079 00004082 00004084 00004085 00004086 00004087 00004090 00004091 00004092 00004093 00004094 00004097 00004098 00004099

Data Supporting Guideline Requirements for the Reregistration of 4-Aminopyridine				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
				00004102 00004103 00004104 00004105 00004108 00004109 00004113 00004114 00004115 00004116 00004117 00004120 00004122 00004123 00004126 00004127 00004128 00004130 00004131 00004133 00004138 00004139 00004140 00004141 00004142 00004143 00004144 00004145 00004146 00004267 00004269 00014378 00021884 00021886 00021887 00021888 00021889 00021894 00021895 00021896 00021898 00021899 00022550 00022560 00027851 00030610 00030611

Data Supporting Guideline Requirements for the Reregistration of 4-Aminopyridine				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
				00030613 00030614 00030617 00030618 00033899 00050977 00050978 00050979 00050981 00050982 00050983 00050985 00050986 00050987 00050988 00050989 00050991 00052582 00055447 00074912 00090078 00090081 00107008 00109578 00109580 00131327 00131331 00134510 00134511 00145584 00150203 00150204 00158101 00158103 00158104 05003185 05003191 05003193 40603600 41107900 41107901 41107902 41107903 46789600 46789601 05003185 40603603

Data Supporting Guideline Requirements for the Reregistration of 4-Aminopyridine				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
				00003999 00004101 00003998 00147985 05003186 00086682 00003985 00004083 00004111 00067838 00085360 00004001 00004037 00004124 00004132 00004147 00109573 00109577 00109579 00131325 05003440 00003991 00003997 00004006 00004015 00004032 00004105 00004131 00004269 00021886 00021887 00150203 05003191

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, EPA-HQ-OPP-2007-0400.

It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:www.epa.gov/pesticides/reregistration

These documents include:

HED Document:

4-Aminopyridine: HED Chapter of the Reregistration Eligibility Decision Document (RED). Donovan, Y., Khasawinah, A., and Miller, J., D336326, 08/06/2007.

EFED Documents:

Re-registration Ecological Risk Assessment for Avitrol (4-Aminopyridine) End-Use Products. Shanaman, L., Hurley, P., 01/05/2007.

Transmittal of the Environmental Fate and Effect's Division's (EFED) Re-registration Science Chapter for the Ecological Risk Assessment of the Restricted Use Avicide, Avitrol. Shanaman, L., Hurley, P., D336332, 02/27/2007.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

MRID	Citation Reference
00003999	Schafer, E.W.; Lockyer, N. (19??) The Effects of DRC-1327 Baits on Mourning Doves. (Unpublished study received Dec 18, 1970 under 224-EX-3; prepared by U.S. Fish and Wildlife Service, Denver Wildlife Research Center, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122744-E)
00004101	Besser, J.F. (1968) Compilation of Information on the Chronic Toxicity of 4-Aminopyridine to Pheasant, Quail and Starlings. (Unpublished study received Mar 2, 1973 under 11649-12; prepared by U.S. Fish and Wildlife Service, Denver Wildlife Research Center, submitted by Avitrol Corp., Tulsa, Okla.; CDL:120117-A)
00003998	Schafer, E.W., Jr.; Brunton, R.B.; Lockyer, N. (1970) The Chronic Toxicity of DRC-1327 to Mourning Doves: Preliminary Report No. 16--W. J. DF-102.2. (Unpublished study received Dec 18, 1970 under 224-EX-3; prepared by U.S. Fish and Wildlife Ser- vice, Denver Wildlife Research Center, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122744-D)
00147985	Fink, R.; Reno, F. (1976) Eight-day Dietary LC50 - Mallard Duck 4-Aminopyridine: Final Report: Project No. 684-105. Unpublished study prepared by Hazleton Laboratories America, Inc. 10 p.
05003186	Schafer, E.W.; Brunton, R.B.; Lockyer, N.F. (1975) The effects of subacute and chronic exposure to 4-aminopyridine on reproduction in coturnix quail. Bulletin of Environmental Contamination and Toxicology 13(6):758-764.
00003985	U.S. Fish and Wildlife Service, Denver Research Laboratory (19??) Toxicity of Avitrol to Bluegill and Channel Catfish at Selected Water Qualities and Temperatures: Table. (Unpublished study received May 18, 1971 under 224-EX-3; prepared in cooperation with La Crosse Fish Control Laboratory, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122743-F)
00004083	Schafer, E.W., Jr.; Marking, L.L. (1974?) Long Term Effects of 4- Aminopyridine Exposure to Birds and Fish. (Unpublished study received Nov 11, 1975 under 11649-15; prepared by U.S. Fish and Wildlife Service, Wildlife Research Center in cooperation with Fish Control Laboratories, submitted by Avitrol Corp., Tulsa, Okla.; CDL:225255-C)
00004111	Palazzolo, R.J. (1963) Report to Phillips Petroleum Company: Toxic- ity to Salt Water Life of Compound 1861 Hydrochloride. (Unpublished study received Jan 2, 1968 under 224-12; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Phillips Pe- troleum Co., Bartlesville, Okla.; CDL:229844-F)
00086682	Knittle, C.E.; Besser, J.F.; Guarino, J.L.; et al. (1981) Further Evaluations of 1:29 Avitrol Treatments To Protect Ripening Sun- flower from Blackbird Damage in North Dakota: Bird Damage Research Report No. 202. (U.S. Fish and Wildlife Service, Denver Wildlife Research Center; unpublished study; CDL: 246228-A)
00004001	Starr, R.I.; Cunningham, D.J. (1970) Translocation and Degradation of 4-Aminopyridine in Corn Plants--Its Movement and Degradation in Soil Systems: Third Periodic Report, Avitrol Concentrate|. (Unpublished study received Apr 24, 1970 under 224-EX-3; pre- pared by U.S. Fish and Wildlife Service, Denver Wildlife Re- search Center, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122744-H)
00004037	Starr, R.I.; Cunningham, D.J. (19??) Phytotoxicity. (Unpublished study received Jan 3, 1973 under 1F1013; prepared by U.S. Fish and Wildlife Service, Denver Wildlife Research Center, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:091757-R)
00004124	Starr, R.; Cunningham, D.; Brunton, R. (1966?) Absorption and Translocation of 4-Aminopyridine by Corn Plants. (Unpublished study received Apr 15, 1969 under 224-EX-3; prepared by U.S. Fish and Wildlife Service, Denver Research Center, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122745-H)

00004132 Starr, R.I.; Cunningham, D.J. (1972) Fate of 4-Aminopyridine in Corn, Sorghum, and Soil Systems: A Summary of Research Findings. (Unpublished study received Apr 16, 1973 under 3G1320; prepared by U.S. Fish and Wildlife Service, Bureau of Sport Fisheries and Wildlife, submitted by Avitrol Corp., Tulsa, Okla.; CDL:093548- A)

00004147 Matlock, R.S.; Oswalt, R.M. (1963?) Report of Sunflower Research in Oklahoma. (Unpublished study received Jun 16, 1972 under un- known admin. no.; prepared by Oklahoma State Univ., Dept. of Agronomy, submitted by Avitrol Corp., Tulsa, Okla.; CDL:210151-I)

00109573 Avitrol Corp. (1973) ?Efficacy of 4-Aminopyridine Baits and Other Products Used To Control Blackbird Damage to Sunflowers|. (Compilation; unpublished study received Oct 17, 1973; Mar 5, 1973 under 11649-EX-2; CDL:248060-A)

00109577 Avitrol Corp. (1974) ?Efficacy Testing of Avitrol--Sunflowers|. (Compilation of reports by various government agencies; unpublished study; CDL:248063-A)

00109579 Starr, R.; Cunningham, D. (19??) Fate of 4-Aminopyridine in Corn, Sorghum, and Soil Systems. A Summary of Research Findings. (Unpublished study received Nov 27, 1972 under 11649-EX-5; submitted by Avitrol Corp., Tulsa, OK; CDL:248064-B)

00131325 Starr, R. (1972) The absorption, translocation, and metabolism of 14C-4-aminopyridine in corn and sorghum: Its movement and de- gradation in soil systems. Dissertation Abstracts International (XXIII)6. (Also In unpublished submission received Feb 11, 1974 under 3G1384; submitted by Avitrol Corp., Tulsa, OK; CDL: 071822-A)

05003440 Starr, R.I.; Cunningham, D.J. (1974) Phytotoxicity, absorption, and translocation of 4-aminopyridine in corn and sorghum growing in treated nutrient cultures and soils. Journal of Agricultural and Food Chemistry 22(3):409-413.

00004024 Ives, M. (1962) Report to Phillips Petroleum Company: Toxicity Studies on Compound 1861 Hydrochloride. (Unpublished study received Dec 30, 1968 under 1F1013; prepared by Industrial Bio- Test Laboratories, Inc., submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:091756-B)

00004025 Ives, M. (1962) Report to Phillips Petroleum Company: Acute Oral Toxicity Studies on Compound 1861 Admixed on Grain. (Unpublished study received Dec 30, 1968 under 1F1013; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:091756-C)

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00021902 Ives, M. (1962) Report to Phillips Petroleum Company: Acute Oral Toxicity Studies on Compound 1861 Admixed on Grain. (Unpublished study received Mar 18, 1975 under 11649-12; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Avitrol Corp., Tulsa, Okla.; CDL:094800-Z)

00131328 Kohn, F.; Cervenka, H.; Kay, D.; et al. (1968) Report to Phillips Petroleum Company: 90-Day Subacute Oral Toxicity of Compound 1861 (4-aminopyridine)--Albino Rats: Lifestream Laboratories Project No. 888. (Unpublished study received Apr 13, 1973 under 3G1384; prepared by Lifestream Laboratories, Inc., submitted by Avitrol Corp., Tulsa, OK; CDL:071822-G)

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05003407 Betts, P.M.; Giddings, C.W.; Fleeker, J.R. (1976) Degradation of 4-aminopyridine in soil. Journal of Agricultural and Food Chemistry 24(3):571-574.

00003963 Avitrol Corporation (1975) Avitrol FC Corn Chops--99 Baits for Protecting Sweet Corn from Blackbirds in Ulster County, New York. (Unpublished study including letter dated Sep 12, 1975 from J.E. Forbes to Kelly Swindle, received Feb 18, 1976 under 11649-12; prepared in cooperation with U.S. Fish and Wildlife Service; CDL:224248-A)

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00003965 Schafer, E.W., Jr.; Brunton, R.B.; Lockyer, N.F. (1974) Hazards to animals feeding on blackbirds killed with 4-Aminopyridine baits. Journal of Wildlife Management 38(3):424-426. (Also in unpublished submission received Apr 10, 1975 under 11649-10; submitted by Avitrol Corp., Tulsa, Okla.; CDL:115276-B)

00003966 Avitrol Corporation (1974) Avitrol: Summary Test Results--Gulls. Summary of studies 115276-D and 115276-F. (Unpublished study received Apr 10, 1975 under 11649-10; CDL:115276-C)

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00003968 Ware, J.E. (1971) Report on Avitrol Gull Repellency Test: Salem, Massachusetts, 1971. (Unpublished study received Apr 10, 1975 under 11649-10; prepared by U.S. Bureau of Sport Fisheries and Wildlife, Div. of Wildlife Services, submitted by Avitrol Corp., Tulsa, Okla.; CDL:115276-E)

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00003988 Hanson, R.V. (1971) North Dakota Field Tests: First Periodic Report --Avitrol Concentrate. (Unpublished study received Nov 19, 1971 under 224-EX-3; prepared by U.S. Fish and Wildlife Ser- vice, Div. of Wildlife Services, North Dakota Office, Submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122748-A)

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00003992 Phillips Petroleum Company (1969) Effectiveness Data: 4-Aminopyridine (Avitrol 200). (Unpublished study received Apr 22, 1969 under 224-EX-3; CDL:122747-F)

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00003997 Schafer, E.W., Jr. (1970) A Summary of the Acute Toxicity, Chronic Toxicity, and Secondary Hazards of 4-Aminopyridine (DRC-1327) to Birds and Mammals. Summary of studies 122744-D and 122744-E. (Unpublished study received Dec 18, 1970 under 224-EX-3; prepared by U.S. Fish and Wildlife Service, Denver Wildlife Research Center, submitted by Phillips Petroleum Co., Bartlesville, Okla.; CDL:122744-C)

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

Pesticide Registration Forms are available via the Agency's website at *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 hard copy in accord with the existing policy.

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

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

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

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 (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-35	Data Matrix (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*
8570-37	Self-Certification Statement for the Physical/Chemical Properties (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 §156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR §158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' website.

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

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161-0002

The telephone number for NTIS is (703) 605-6000.

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

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website at *http://www.ncis.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; and
- Product Manager assignment.

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

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