United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-96-33
July 1996

Reregistration Eligibility Decision (RED)

Strychnine

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case strychnine. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in

the tolerance is necessary, that tolerance, too, will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Ed Setren at (703) 308-8166. Address any questions on required generic data to the Special Review and Reregistration Division representative Bonnie Adler at (703) 308-8523.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

STRYCHNINE

LIST C

CASE 3133

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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STRYCHNINE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Eric Maurer	Economic Analysis Branch
Gabe Patrick	Biological Analysis Branch
William Gross	Biological Analysis Branch

Environmental Fate and Effects Risk Assessment

Mary Powell	Science Analysis and Coordination Staff
John Jordan	Environmental Fate and Groundwater Branch
Jim Goodyear	Ecological Effects Branch

Health Effects Risk Assessment

Jane Smith	Risk Characterization and Analysis Branch
John Redden	Risk Characterization and Analysis Branch
Tom Myers	Risk Characterization and Analysis Branch
John Leahy	Occupational and Residential Exposure Branch
Jerome Blondell	Occupational and Residential Exposure Branch

Registration Support Assessment

Shyam Mathur	Registration Support Branch
Bill Jacobs	Insecticide-Rodenticide Branch

Risk Management

Bonnie Adler	Accelerated Reregistration Branch
Kathy Davis	Accelerated Reregistration Branch

Office of General Counsel:

Phil Ross	Pesticides Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
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.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide strychnine. This decision includes a comprehensive reassessment of the required target data for only the below-ground uses of strychnine. Strychnine products labeled for uses above-ground have been temporarily cancelled by the Agency as part of a U.S. District Court injunction. The use of strychnine above-ground is not considered in this eligibility assessment and decision.

Certain products containing strychnine are classified as restricted-use for use only by or under the direct supervision of certified applicators. Other products are available for use by the general public. Strychnine is used primarily to control pocket gophers in their below-ground tunnels. The Agency has concluded that the restricted-use products used below-ground by certified applicators, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, these products are eligible for reregistration. To mitigate risks of potential toxicity to handlers, the Agency is requiring, among other changes, the use of personal protective equipment.

For the unclassified general use products, the Agency has determined that a decision of reregistration eligibility cannot be made at this time. More information on product-specific acute toxicity, poisoning incidents, and benefits is needed before a determination can be made. Also, the Agency is requiring a dermal subchronic toxicity study on technical strychnine to confirm the presumption of low absorbency.

Before reregistering the restricted-use strychnine products labeled for below-ground uses, the Agency is requiring that product specific data and revised Confidential Statements of Formula (CSF) be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each product registration. Revised labeling to reflect the changes required by this RED will be required at a later date. After reviewing these data and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product.

Before the Agency will make a determination of eligibility for the unclassified below-ground uses of strychnine products by the general public, the additional data mentioned above are required. This information includes poison control center data for products used by homeowners, incident reports for poisoning of children, and end-use product acute toxicity. A Data Call-In for this information is included with this document. Upon review of this information and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will consider whether to reregister these products.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

Because strychnine products labeled for uses above-ground are temporarily cancelled by the Agency as part of a U.S. District Court injunction, these uses were excluded from this eligibility assessment and decision. This document presents the Agency's decision regarding the reregistration eligibility of the currently registered below-ground uses of strychnine. The document consists of six sections. Section I is the introduction. Section II describes strychnine, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for strychnine. Section V discusses the reregistration requirements for strychnine. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Chemical Name:** Strychnine; strychnine alkaloid
- **CAS Registry Number:** 57-24-9
- **OPP Chemical Code:** 076901
- **Empirical Formula:** $C_{21}H_{22}N_2O_2$

B. Use Profile

The following is information on the currently registered below-ground uses with an overview of use sites and application methods. A detailed table of these uses of strychnine is in Appendix A. All end-use strychnine products are classified as Restricted-use pesticides except for those products which contain strychnine at nominal concentrations no greater than 0.5% and which are limited by their labels to manual, below-ground applications only. For purposes of this classification, use of hand-operated mechanical probes which dispense bait is considered to be a manual application. Restricted-use products are limited to sale and/or use by or under the supervision of certified pesticide applicators.

Type of Pesticide: Poison, single dose

Mode of Action: Chemical blocks inhibitory neurons causing excessive excitation which manifests itself as convulsions.

Use Groups and Sites:

The use categories listed below for strychnine include food and feed crop sites. Because strychnine products are allowed for use only below-ground, exposure to food and feed crops is not expected.

Terrestrial Food Crop Sites: orchards

Terrestrial Food+Feed Crop Sites: agricultural crops/soils

Terrestrial Feed Crop Sites: grass (forage/fodder/hay), pastures, rangeland, and alfalfa.

Terrestrial Non-Food Sites: nonagricultural rights-of-way (fencerows and hedgerows), and non agricultural uncultivated areas (soils).

Aquatic Food Sites: irrigation systems

Forestry: forest trees (all or unspecified)

Outdoor Residential: household/domestic dwellings (outdoor premises) and residential lawns.

Use Site unspecified: site not specified on label. Labeling amendments to specify sites are addressed in Section V.

Target Pest: pocket gopher

Formulations Types Registered:

Technical Grade Active Ingredient: Dust/Powder (100%)

Manufacturing-Use Product: Dust/Powder (98.4%)

End-Use Product: Bait/Solid (0.44-1.8%), Granular (0.5%) and Paste Concentrate (3.2-10.0%).

Methods of Application:

Type of Treatment: bait application; paste is mixed with cabbage to use as a bait.

Equipment:

Manual: Spoon, manually operated bait dispensing probe

Mechanical: "Burrow builder" - Burrow builders create tunnels which intersect pocket gopher tunnels and 'plant' the bait below ground.

Timing: as needed

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of strychnine. Due to the use pattern of strychnine, data have been collected at the pest level rather than at the different sites of application. Usage data provided by the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS), from 1989 to 1991 show that 1,000 to 1,500 pounds of strychnine (active ingredient) were used annually to control gophers, ground squirrels, prairie dogs and voles. Currently, only products to control pocket gophers are registered. A trend towards reduced use has been noted over the years, possibly as a result of the 1988 injunction against the above-ground uses of strychnine.

D. Data Requirements

The Agency applied the data requirements specified in 40 CFR §158 and the Reregistration Phase II Guidance to the active ingredient in this chemical case. Studies on the active ingredient (generic) were generated and submitted to the Agency. The data from these studies along with other available information form the basis for the Agency's scientific assessment and regulatory decisions. Appendix B includes the generic data requirements to support reregistration of currently registered uses.

E. Regulatory History

1. Origin and Early Use

Strychnine alkaloid is obtained from the seeds of *Strychnos nux vomica*, a small tree found in India, North Australia, Sri Lanka, and Vietnam. Although seeds of the plant were used "at least as early as 1640" to kill birds, cats, and dogs in Europe, strychnine alkaloid itself was not discovered until 1817. In one form or another, strychnine has been used for centuries to poison vertebrate animals in many parts of the world. (Clark, 1975)

2. U.S. Regulatory History of Strychnine

The first Federal registrations for strychnine alkaloid products were issued in 1947, the year in which the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was passed to require that pesticides be registered. Strychnine had been used in the U.S. to control vertebrate animals for many years prior to 1947. As many as 35 strychnine sulfate and 717 strychnine alkaloid registrations (including transfers, and intrastate and Special Local Needs products) have been known to exist in the U.S. However, in 1996, less than 50 active strychnine alkaloid registrations

remain.

(a) Classification of Strychnine Products

In 1978, EPA classified all strychnine products as Restricted Use pesticides except for baits containing strychnine alkaloid at concentrations of 0.5% or less which were labeled for manual below-ground applications only (40 CFR, §152.175).

(b) Uses to Control Predators

All uses of strychnine to control predators in the U.S. were canceled in 1972 following the issuance of PR Notice 72-2 with a cancellation order. This PR Notice was issued shortly after a report on predator control and an executive order banning use of toxicants to control predators on Federal lands were issued.

In 1973, EPA issued the first of many emergency exemptions under §18 of FIFRA to permit use of strychnine alkaloid egg baits to control skunks in rabies epizootic areas in Montana. Other emergency exemptions were issued for this use in Wyoming and South Dakota through the mid 1980's. Applications for §3 federal registrations of strychnine for use in egg baits to control skunks were submitted to EPA in the 1970s and the 1980s.

In 1986 and 1987, EPA held Subpart D hearings concerning use of strychnine in egg baits to control skunks. On June 18, 1987, Administrative Law Judge Marvin E. Jones issued an Initial Decision modifying the 1972 executive order:

> "to permit registration of strychnine to reduce populations of skunks as a means of suppressing the spread of rabies to humans and domestic animals." (Jones, 1987)

Applications for §3 registrations which would permit use of strychnine in egg baits in Montana and Wyoming remain pending. Most potential placement locations for strychnine egg baits would be above-ground and, therefore, are prohibited by an injunction against above-ground uses of strychnine, discussed below.

(c) Above-ground Uses

On December 1, 1976, EPA issued a "Rebuttable Presumption

Against Registration" (RPAR) notice concerning all above-ground, outdoor uses of strychnine covered by registrations in existence at that time. This initial position document (PD 1) was followed by a PD 2/3 issued on November 5, 1980, to note EPA's preliminary findings in the RPAR (now called Special Review) of the above-ground uses of strychnine. Following receipt of responses from concerned parties and reconsideration of certain issues, EPA issued a PD 4 document on September 30, 1983. The PD 4 noted the conclusions that EPA reached during its Special Review of above-ground uses of strychnine. On October 19, 1983, a Federal Register notice was published in which EPA summarized the conclusions reached in the strychnine PD 4 document and announced the Agency's intent to cancel certain outdoor, above-ground uses of strychnine and to impose additional conditions and limitations on others. On October 28, 1983, EPA sent "Notice of Intent to Cancel" (NOIC) letters to certain strychnine registrants pursuant to the Agency's decisions summarized in the PD 4 document.

Many parties requested hearings on the conclusions expressed in the strychnine PD 4. A process of negotiated settlement was initiated. Several environmental groups left the settlement discussions and, in August of 1986, filed suit against EPA in U.S. District Court in Minnesota, charging that the manner in which the Agency was handling registrations for above-ground uses of strychnine products was in violation of several Federal statutes.

On March 4, 1987, EPA announced the results of the negotiated settlement reached with parties other than the groups which had filed suit. This negotiated settlement included modification of certain conditions of the strychnine PD 4 to allow above-ground uses of strychnine to control voles and prairie dogs and to expand the scope of permissible uses to control ground squirrels.

On April 11, 1988, the U.S. District Court in Minnesota issued an injunction against above-ground uses of strychnine compounds, ruling that such uses were in violation of the Migratory Bird Treaty Act, the Bald and Golden Eagle Protection Act, and the Endangered Species Act; and that EPA violated the Administrative Procedures Act by accepting labels which permitted above-ground uses of strychnine. On April 25, 1988, EPA filed a motion with U.S. District Court in Minnesota seeking clarification of the order of April 11, 1988 and other relief. On May 4, 1988, EPA notified registrants of strychnine products registered for above-ground uses that they must comply with the court's order. On May 25, 1988, a Federal Register Notice was issued which publicized and published the District

Court's Decision and stated that compliance with the decision was required.

On July 18, 1988, the U.S. District Court in Minnesota denied requests by EPA and others for a stay of imposition of the injunction against above-ground uses of strychnine pending appeal. On September 30, 1988, EPA sent "Notice of Temporary Cancellation" letters pursuant to the injunction to registrants of strychnine products labeled for above-ground uses. On October 5, 1988, the "Notice of Temporary Cancellation" was published in the Federal Register.

EPA, the Department of the Interior, and the American Farm Bureau Federation appealed the U.S. District Court's decision on October 17, 1988. On August 16, 1989, the appellate court "affirmed in part and reversed in part" the decision of the U.S. District Court in Minnesota (Fagg, 1989). The lower court was reversed on its findings pertaining to the Administrative Procedures Act, the Migratory Bird Treaty Act, and the Bald and Golden Eagle Protection Act. The lower court's decision with respect to the Endangered Species Act (ESA) was upheld, leaving the injunction in place. The appellate court found that a citizen's suit provision in the ESA meant that the environmental groups could proceed against EPA under that statute, that above-ground uses of strychnine had been reported to have resulted in the taking of endangered species, and that EPA had not obtained from the U.S. Fish and Wildlife Service (FWS) written authorization for incidental takings of endangered species at the time that the reported takings occurred.

Acknowledging that incidental taking statements were included in biological opinion documents issued by FWS subsequent to the imposition of the injunction, the appellate court wrote,

> "If the EPA can show that it now has obtained authorization for the incidental takings and has acted in compliance with the requirements of the taking statement, the court should lift the ESA injunction."

Since the injunction was instituted, FWS has issued several biological opinion documents pertaining to above-ground uses of strychnine. The dates of these documents are listed below, along with brief descriptions of their contents.

May 25, 1988: Pertained to most above-ground uses of strychnine. Issued in response to request made by EPA (in 1987) before injunction decision was rendered.

June 24, 1988: Opinion concentrated on reasonable and prudent measures to be taken to avoid jeopardy to black-footed ferrets.

May 10, 1989: Amended and extended 1988 biological opinions pertaining to strychnine.

August 30, 1990: Pertained to use of strychnine alkaloid in egg baits to control rabid striped skunks in Montana and Wyoming. FWS concluded that it would have to approve on a case-by-case basis all proposed strychnine egg bait applications in certain areas of Montana and Wyoming (where grizzly bears and/or gray wolves occur) and that applications could not be made within 1/2 mile of any prairie dog colony, unless a search for evidence of black-footed ferrets was conducted by a biologist trained in a FWS-approved workshop, or within 2.5 miles of bald eagle nests between February 1 and August 15, within 1/4 mile of bodies of water used by summer nonbreeding bald eagles, within 2.5 miles of bald eagle wintering concentration areas from December 1 through February 19, or anywhere in Montana or Wyoming during November or from February 20 to April 30.

July 9, 1991: FWS informed EPA that a plan proposed by Montana Department of Livestock (MDL) pertaining to possible reinstatement of above-ground use of strychnine to control of ground squirrels in Montana was too complex to be workable, adding that EPA could elect to initiate formal consultation on the plan.

July 28, 1992: Pertained to Endangered Species consultation on impacts of Animal Damage Control (ADC) program of the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture. Considered use of strychnine by ADC program including the "temporarily cancelled" above-ground uses claimed on labels for APHIS's own strychnine registrations.

March 30, 1993: FWS assessed revised plan from MDL and found jeopardy to bald eagles and black-footed ferrets for 0.5% strychnine alkaloid use to control ground squirrels in Montana. FWS forbade use within 0.5 miles of prairie dog colonies and within 4.35 miles of prairie dog colonies where FWS had confirmed presence of a black-footed ferret. Otherwise, FWS accepted Montana's proposed maps and restrictions (including prohibition of applications from November 1 of one year through April 30 of the next).

July 15, 1994: "Draft" biological opinion issued in response to EPA's consultation request pertaining to use of strychnine alkaloid baits to control certain passerine birds in California.

The biological opinions issued since the injunction against above-ground uses of strychnine was imposed include provisions for incidental takings, although the levels of incidental take permitted were "unquantifiable" for certain endangered species and zero for others. Prior to the injunction, FWS issued biological opinions pertaining to above-ground uses of strychnine on March 30, 1979, and on November 9, 1984. The biological opinion issued in 1979 was broad in scope. The 1984 opinion concentrated upon the use of ferret searches to avoid risks posed by strychnine to black-footed ferrets.

As of the date of this document, EPA has not approached the U.S. District Court in Minnesota since 1988 with proposals to lift or modify the strychnine injunction. Above-ground pesticidal uses of strychnine remain prohibited in the U.S.

(d) Data Call-Ins

Following completion of the strychnine Special Review, EPA issued several Data Call-Ins (DCIs) for data which were needed to complete assessments of the risks and benefits associated with the various uses of pesticide products containing strychnine compounds. On August 8, 1984, EPA issued a DCI requiring efficacy studies to be performed on strychnine baits which were claimed to control ground squirrels.

The Agency issued a second DCI on October 10, 1986, in which a broad spectrum of data were required. A third DCI was issued on December 15, 1987. In it the Agency required submission of environmental fate data pertaining to strychnine compounds. On December 17, 1987, EPA revised compliance schedules for DCIs previously issued.

On October 6, 1988, EPA sent letters of notice of intent to suspend (NOIS) registrations to the affected registrants with products containing strychnine alkaloid because their responses to the DCIs had been untimely. Many affected registrants requested hearings. EPA entered settlement discussions with the registrants who comprised a strychnine data submitters' consortium which had been formed. By March of 1989, a negotiated settlement agreement was accepted by all parties and by the Administrative Law Judge. The Strychnine Settlement Agreement of 1989 modified and imposed new schedules for meeting data requirements covered under prior data call-ins and included certain requirements and limitations affecting the labeling of strychnine products. Any modification of labeling for registered strychnine alkaloid products currently is

governed by the language of the Strychnine Settlement Agreement of 1989, as modified by Judge Greene's September 27, 1996, Order.

The consortium supported the continued registration of strychnine alkaloid but not strychnine sulfate. No individual registrants or other parties submitted the data needed to retain strychnine sulfate as a Federally registered pesticide chemical. On September 11, 1990, the last remaining strychnine sulfate registrations were cancelled.

In September 1992, under the current reregistration program (Phase IV) EPA issued a DCI that required data for physical chemistry, ecological effects, additional environmental fate and residue chemistry data. The residue chemistry data requirements were later waived because the products are used below-ground and exposure to food and feed crops is unlikely.

(e) Current Status of Strychnine Registrations

Currently, the only strychnine alkaloid pesticide products which may be used in the U.S. are end-use products labeled only for below-ground uses and manufacturing use products that are used to manufacture such end-use products. The primary use pattern for strychnine end-use products applied below-ground is the control of pocket gophers. The last remaining strychnine alkaloid product claimed to control moles was cancelled in 1995. The last remaining strychnine alkaloid product for control of house mice was cancelled in 1989, thereby fully cancelling all indoor uses of strychnine products.

Above-ground uses of strychnine remain "temporarily cancelled" because of the District Court's injunction. The registrations for some of these products still exist (i.e., they are not cancelled under FIFRA), but the products may not be sold, distributed, or used. Other products for which above-ground uses were claimed were voluntarily cancelled by their registrants after the injunction was imposed.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

TGAI: Strychnine alkaloid

Molecular weight: 334.40

Color:	White
Physical state:	Solid crystalline powder
Odor:	Odorless
Melting point:	273°C
Specific gravity:	0.25 at 25°C
Solubility:	Very insoluble in water (0.0115 g/100 ml) but fairly soluble (20%) in chloroform.
Vapor pressure:	Being solid with a high melting point, the vapor pressure is negligible.
Dissociation constant:	5.49×10^{-9}
Octanol-water partition coefficient:	pH $K_{o/w}$
	5 0.9 ± 0.13
	7 4.0 ± 0.2
	9 114.0 ± 4.0
pH:	9.5
Stability:	Stable

B. Human Health Assessment

1. Toxicology Assessment

Strychnine is a powerful convulsant. Glycine, an important inhibitory transmitter to motorneurons and interneurons in the spinal cord, is affected by strychnine. Strychnine acts as a selective competitive antagonist to block the inhibitory effects of glycine at all glycine receptors. The convulsant action of strychnine results from interference with postsynaptic inhibition normally mediated by glycine.

The human health assessment for strychnine is based on the acute toxicity for the technical and is described below. Because of the high acute toxicity via the oral and ocular routes, subchronic and chronic data were not required. In the

absence of inhalation data and based on the high acute oral and ocular toxicity, a default toxicity category of I was assigned for acute inhalation. A confirmatory 21-day dermal study is required to describe the dermal absorption. Additional data are also required to describe the acute toxicity of the end-use products intended for homeowner use.

a. Acute Toxicity

The generic acute toxicological database for strychnine is adequate and is summarized below in Table 1.

Table 1. Acute Mammalian Toxicity

Guideline	Results	Toxicity Category	MRID #s
81-1 Acute Oral LD50, rat	6.4 mg/kg males 2.2 mg/kg females Death occurred within 1 hr.	I	40908901 41210701
81-2 Acute Dermal LD50, rabbit	2000 mg/kg. No signs of toxicity observed.	III	40908902 41210702
81-3 Acute LC50 inhalation	WAIVED	I*	
81-4 Primary eye irritation, rabbit	Irritation and mortality	I	40908904 41210704
81-5 Primary dermal irritation, rabbit	No irritation, mortality or signs of toxicity were observed.	IV	40908903 41010703

All studies performed with Strychnine Alkaloid Technical (Purity = 99.42%)
* Assigned Toxicity Category I as a default based on high acute toxicity from other routes of exposure.

b. Other Toxicological Considerations

(1) Poisoning Incidents

Approximately 100 cases of accidental exposure to strychnine rodenticides are reported annually to U.S. Poison Control Centers (Litovitz et al. 1986-1994). However, EPA believes this number of accidental exposures is low based on comparisons with other data sources which show that Poison Control Center data generally underestimate the true extent of poisoning.

During a nine-year period (1985 - 1993), 1,359 exposures to strychnine were recorded by the U.S. Poison Control Centers. About one third of these cases were categorized as intentional exposures, such as suicide or homicide, or of unknown intent. Of the accidental exposure cases, where the age of the exposed individuals was available, nearly half of those exposed were under six years old.

Of the accidental cases where medical outcome was determined (from 1985 through 1992), there were nineteen cases which had a moderate outcome, five cases that were major, and one fatality. Among these twenty-five cases with medical outcome, two were confirmed to be children. Age was unknown for some of the cases. None of the twenty-five exposures were described as occupational.

Estimates of lethal dose for strychnine baits as currently formulated (0.5% active ingredient) suggest that a single swallow by a 10 kg child could be lethal. For a typical one-year old child weighing 10 kg, this would mean a dose of 1.1-1.8 mg/kg of strychnine, which is in the potentially lethal range.

The available information from various sources on human poisoning incidents is conflicting and unclear as it relates to accidental exposure to strychnine products. This problem and the uncertainty of the amounts of end-use products which could result in significant toxicity to humans, especially children, do not enable the Agency to determine with confidence the magnitude and seriousness of poisonings from the use of strychnine in the U.S. Additional information to clarify these issues is required.

c. Toxicological Endpoints for Risk Assessment

Because of the high acute toxicity and the current limited use pattern for strychnine, only acute studies for the active ingredient have been required. Previously all normally required subchronic and chronic study requirements have been waived. The risk assessment is, therefore, based on the acute toxicity data and acute concerns. A subchronic dermal toxicity study is required to confirm the presumed low level of dermal absorption.

Based on the severe oral toxicity of this chemical and the nonfood use status, a reference dose and carcinogenicity classification has not been determined at this time. Strychnine has not been reviewed by the Joint FAO/WHO pesticide committee.

2. Exposure Assessment

a. Dietary Exposure

Given the below-ground use pattern, the Agency believes there is no opportunity for strychnine residues on/in food/feed crops when it is applied underground at crop sites. Therefore, the Agency waived the requirements for residue data for the continued registration of the below-ground uses of strychnine. For this reason, a dietary exposure assessment is not appropriate. Appropriate label restrictions and/or residue data will be required for above-ground uses if they become reinstated.

b. Occupational and Residential Exposures

For the purposes of this document, the term "occupational" will represent those persons who are working under the direct supervision of a certified applicator, and the term "homeowner" represents those persons who reside in homes and are not using pesticide products in a professional capacity.

The Agency normally conducts an occupational and/or residential exposure assessment for an active ingredient if (1) certain active ingredient toxicological criteria are triggered and (2) there is potential for exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete; or, if incidence data (acute poisonings) indicate use concerns.

For strychnine all these factors are present: its high acute toxicity by oral, eye, and presumably inhalation routes of exposure; the potential for exposure during mixing and applying end-use products; and, reported incidents as summarized above. Due to these factors, there are concerns for both occupational and residential users.

Occupational-use and Homeowner-use Products

Products containing strychnine are intended for both occupational-use and homeowner-use (i.e., for pocket gopher control in agricultural work areas or residential areas). All products containing a nominal concentration of more than 0.5% strychnine are classified as Restricted-Use pesticides and sale and application are limited to certified pest control operators. Formulations available to homeowners are at nominal concentrations of 0.5%. In this document, the Agency uses the term "occupational-use" to describe those products that are classified as

restricted-use products. Those products which are unclassified are referred to as "homeowner-use" or "residential-use" products.

Handler Exposures

The Agency recognizes four primary exposure scenarios for strychnine: (1) mixing and applying bait formulations; (2) mixing and applying paste formulations; (3) mixing/loading for burrow building applications; and, (4) applying baits using burrow builder equipment. However, due to the absence of exposure data which would be adequate for the Agency to estimate exposures for these four scenarios, a quantified exposure assessment could not be conducted.

While EPA does not have, nor is it requiring, appropriate data for reliable exposure estimates from the use of strychnine products, the Agency believes the minimal poisoning incident information suggests there are exposures. Supplemental incident data should provide at least additional quantitative information about these exposures. Also, the Agency assumes unit exposure from occupational-use products may be less than that from homeowner-use products as the former products are limited to certified applicators who have received training on the appropriate and safe use of pesticides. Also, through this document, labeling is being required to include the use of personal protective equipment (chemical resistant gloves, protective eyewear, and a dust mask).

Post-Application Exposures & Assumptions

Because strychnine use is currently limited to below-ground applications the Agency considers the potential for post-application exposure to be negligible when products are used properly.

3. Risk Assessment

a. Dietary

As explained above, there are no expected dietary exposures from the below-ground use pattern of strychnine. For this reason, a dietary risk assessment is not appropriate.

b. Occupational and Residential

For both occupational and residential uses of strychnine products,

the Agency has concerns for risks to human health. These concerns are based on (1) the high acute toxicity of technical strychnine through the oral, ocular, and inhalation (presumed) routes; (2) data for domestic pets which suggest a very low margin of exposure for young children, as do calculations of potential dose based on a single swallow; (3) the number and severity of poisoning incidents reflected in incident data; (4) the potential for exposure to both occupational and residential handlers of strychnine products; and (5) the absence of exposure data for all exposure scenarios considered and the need for better incident data.

Based on these concerns, personal protective equipment, such as chemical resistant gloves, protective eyewear and dust mask would reduce the potential for occupational-use exposures. EPA is also particularly concerned about potential exposures to homeowners and others in residential settings. The need for additional information including poisoning incident data, end-use product acute toxicity, and benefits information and pest control alternatives is discussed further in the Risk Management and Reregistration Decision, Section IV.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency's ecological toxicity data base for strychnine contains data submitted for above- and below-ground uses of strychnine. However, only acceptable data supporting below-ground uses were considered in the eligibility decision. The above-ground data are provided here only for informational purposes.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

The Agency waived the requirement for an acute oral toxicity study (71-1) because it has already been proven that a bird receiving an acute dose of strychnine would die. It will be assumed that strychnine is very highly toxic to birds on an acute basis.

Two subacute dietary studies using the technical grade of strychnine (99-100%) were submitted and provide data to establish the toxicity to birds. Data submitted include the preferred test species, mallard duck (waterfowl) and bobwhite quail (upland gamebird) (MRIDs 41322602 and 41322601). Results of these

tests are tabulated below in Table 2.

Table 2. Avian Subacute Dietary Toxicity

Species	LC 50 (ppm)	Toxicity Category
Northern bobwhite quail (*Colinus virginianus*)	3536 NOEC 1250	Slightly Toxic
Mallard duck (*Anas platyrhynchos*)	212 NOEC 78	Highly Toxic
Black-billed magpie (*Pica pica*)	99 (65-130)	Highly Toxic
American kestrel (*Falco sparverius*)	234	Highly Toxic

These results indicate that strychnine ranges from slightly to highly toxic to avian species on a subacute dietary basis. The guideline requirement (71-2) is fulfilled (MRIDs 41322601 and 41322602).

(2) Birds, Chronic

Avian reproduction studies using the technical grade of strychnine were required. Strychnine, known to be stable in the environment may pose a threat to birds who may be subject to repeated or continuous exposure from spills. It is possible that potentially toxic amounts of strychnine may persist from spills and be available as food for wild birds. The studies submitted consisted of tests done with the preferred species, the mallard duck and bobwhite quail (MRIDs 42716801 and 42716802). Results of these tests are in Table 3.

Table 3. Avian Reproduction

Species	% ai	NOEC/LOEC (ppm)	Endpoints Affected
Northern bobwhite quail (*Colinus virginianus*)	100	1,114/1,200	none
Mallard duck (*Anas platyrhynchos*)	100	not reported/33	testes

There were no treatment related effects in the bobwhite quail. In the mallard duck, testes were smaller at the LOEC of 33 ppm (low-dose). Also, chick body weights were reduced on day 1 in the 68.9 ppm group (mid-dose) and day 14 in the 140.9 ppm group (high-dose). Egg production and adult female body weight were also reduced at 140.9 ppm.

(3) Mammals

Wild mammal testing was required because of the potential exposure of wild mammals during baiting with strychnine. Acute oral toxicity values from laboratory rat studies (MRIDs 40908901 and 41210701), as reported above in the Human Health Assessment, are included with studies on other mammalian species (MRIDs 40296501, 40296502 and 40296503). The toxicity values and test results are reported in Table 4 below.

Table 4. Mammalian Toxicity

Species	% ai	Test Type	Endpoint
Laboratory rat (*Rattus norvegicus*)	99 unknown	Acute oral Acute oral	LD50 ♀ = 2.2 mg/kg LD50 ♂ = 6.4 mg/kg
Striped skunk (*Mephitis mephitis*)	99	Acute, mg per egg bait	LD100 = 31 mg/egg/skunk
European ferret (*Mustella putorius*)	99	Dietary 5-day	LC50 = 198 ppm
Red fox (*Vulpes fulva*)	99	Dietary 5-day	LC50 = 70 ppm (52-96 ppm)

These results indicate that strychnine is very highly toxic to small mammals on both an acute oral basis and dietary basis. The signs of toxicity, including death, occurred within one hour. This

is considered typical of strychnine.

(4) Terrestrial Field Testing

Pocket gopher (*Thomomys bottae*) control.

In one study, strychnine bait was applied with a burrow builder, a device that creates an artificial burrow, places the poisoned bait underground, and seals the burrow. Strychnine residues were found in the muscle tissue. The mean residue was approximately 0.5 ppm, and residues ranged as high as 5.4 ppm. It was also found in the gastrointestinal tract at a mean of approximately 5 ppm and as high as 35.8 ppm.

Three non-target species were found dead: Horned lark (*Eremophila alpestris*), Brewer's blackbird (*Euphagus cyanocephalus*), and Striped skunk (*Mephitis mephitis*). Residues in the lark were 0.35 ppm in the muscles and 1.61 ppm in the gastrointestinal tract. Residues in the blackbird were 0.56 ppm in the muscle and 23.3 ppm in the gastrointestinal tract. Tissue samples from the skunk were not analyzed.

The results of this study show that:

- Hazards to non-target avian species (and possibly mammals) occur when using the burrow builder because of spillage of the poisoned baits when the builder is removed from the ground or goes around a corner (e.g., at the end of a row). These results are similar to those reported in previous studies (Hegdal and Gatz, 1978; Fagerstone *et al.*, 1980; Matschke *et al.*, 1991, and Evans and Campbell, 1989).

- Residues of strychnine in the gastrointestinal tract of pocket gophers exceed the Agency's unacceptable risk criteria for non-target organisms. Residues at those levels could kill secondary consumers.

- There are sufficient data to presume that the proposed use poses a "may effect" situation to endangered species, and exposure to endangered species is expected if the baiting operation is conducted in their currently occupied habitats.

However, recent instructions for the burrow builder state that operators are to collect spilled bait; therefore, the underground use of strychnine to control pocket gophers does not pose an unacceptable risk to non-target wildlife (MRID 42488601).

In another study, hand baiting of burrows was used to control gophers. The baiting controlled the gophers, but there was non-target mortality that would be of concern in areas inhabited by endangered species (MRID 41478501).

These field studies indicate that strychnine use could pose a risk to non-target and endangered species when the application rate, and other conditions of the studies are used. However, the Agency believes that the risks to non-target terrestrial animals are minimal when strychnine is used below-ground, and according to label directions.

b. Toxicity to Freshwater Aquatic Animals

(1) Freshwater Fish

Two freshwater fish toxicity studies using the technical grade of the active ingredient were submitted (MRIDs 41126502 and 41126501) and provide data to establish the toxicity to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Table 5 lists the results of these studies.

Table 5. Freshwater Fish Acute Toxicity

Species	% ai	LC50 ppm	Toxicity Category
Rainbow trout (*Oncorhynchus mykiss*)	99.9	2.3 (1.7-3.2)	Moderately Toxic
Bluegill sunfish (*Lepomis macrochirus*)	99.9	0.76 (0.61-0.96)	Highly Toxic

These results indicate that strychnine ranges from moderately to highly toxic to freshwater fish on an acute basis.

(2) Freshwater Invertebrates

A freshwater aquatic invertebrate toxicity test using the

technical grade of the active ingredient (99.9%) was submitted. The *Daphnia magna* LC_{50}/EC_{50} value is 10 ppm (MRID 41126503). The results indicate that strychnine is moderately toxic to aquatic invertebrates on an acute basis.

2. Environmental Fate

The environmental fate data available at this time are limited and are not sufficient for a full-scale environmental fate assessment. Acceptable fate data supporting below-ground uses were considered in the eligibility decision. These data satisfy the requirements for below-ground uses only. The majority of these data indicate that strychnine is persistent, but not mobile. The hydrolysis and soil photolysis studies reveal that neither process produces a significant transformation of the parent molecule.

Aerobic soil metabolism data, which are not acceptable, suggest that metabolism can sometimes not occur, or can occur rapidly under as yet undefined conditions which include a significant lag period. It has been suggested that a specific microorganism or an adaptive enzyme system may be responsible. Metabolism may also be very slow, and this process may not be a consistent and dependable means of breakdown. The acceptable batch adsorption/desorption study demonstrates strong binding to a number of soils. With the present below-ground use pattern, strychnine is not likely to reach ground or surface water. For these reasons the Agency's concerns are minimal, in that soil and ground or surface water do not seem likely to be materially affected by the below-ground use of strychnine.

a. Environmental Fate Assessment

Available data satisfy the environmental fate requirements for below-ground uses. In the event that above-ground uses are restored by modification of the existing court order, additional data appropriate to support continued registration of these uses will be required.

b. Environmental Fate and Transport

(1) Degradation

The strychnine molecule (parent) does not hydrolyze at pH 5, 7, or 9 (MRID 41122301). Parent is stable to soil photolysis. Photolysis data indicate that this process does not significantly degrade the parent. The projected half-life is ca. 180 days based on first-order kinetics, which may not apply. The actual kinetic model

could not be determined with confidence, since only a minimal amount of strychnine is transformed within the experimental period. No products of the transformation could be detected (MRID 42973401).

(2) Mobility

The data indicate that strychnine is immobile; the parent is adsorbed to organic matter and clay. Using batch equilibrium techniques, strychnine had Freundlich K_{ads} in loamy sand, sandy loam, loam, and sandy clay loam soils of 39.79, 94.65, 118.87, and 168.97, respectively. Adsorption increased with increasing CEC. K_{des} values were 55.0 for the loamy sand, 89.4 for the sandy loam, 114.6 for the loam, and 146.1 for the sandy clay loam soils. Mobility of unaged parent was satisfied (MRID 42366501). The data requirement for aged parent is reserved.

(3) Aerobic Soil Metabolism

Aerobic soil metabolism data are not required for below-ground uses, but one study was submitted. This study is not acceptable because it does not provide a half-life for strychnine, and there is no accounting for material balance. However, the data suggest that aerobic soil metabolism may be limited to microorganisms capable of adaptive enzyme formation; some soils do not appear to have the specific microbes necessary for metabolism. There is a considerable lag period preceding metabolism in those soils that metabolize parent (MRID 42234201).

c. Water Resources

(1) Ground Water and Surface Water

Neither ground water nor surface water seem to be at risk from contamination under the current use pattern of applying strychnine into specific below-ground burrows. Also, as summarized above, strychnine is essentially immobile.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

(1) Exposure and Risk to Non-target Terrestrial Animals

Field studies have shown that above-ground use of strychnine could pose a threat to non-target and endangered species. However, the Agency believes that the risks to non-target terrestrial animals are minimal when strychnine is used below-ground. When the recommended precautions are followed, below-ground use of strychnine does not constitute a risk to non-target or endangered species.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has discussed earlier in this document the need for more comprehensive information about human poisoning incidents and the acute toxicity of strychnine products. 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 strychnine for the below-ground uses only, for the reasons described above. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of the Restricted-use products for below-ground uses under the conditions specified in this RED. The use of these products are currently limited to certified pesticide applicators who are required to wear certain personal protective equipment (PPE) according to the product labeling that would mitigate exposure. Additional PPE are required as described in Section V of this document.

The Agency has decided that a determination of reregistration eligibility for the homeowner-use, or unrestricted, strychnine products cannot be made at this time. The Agency is uncertain as to whether these products should be classified as restricted use and/or if other stringent measures are appropriate. Certain measures are considered by the Agency as impractical, problematic, or difficult to implement for products that are used in the homeowner setting. EPA will consider additional required information to reach an eligibility decision and appropriate risk reduction measures.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that the occupational below-ground uses of restricted use strychnine products are eligible for reregistration, it should be understood

that the Agency may take additional appropriate regulatory action, and/or require the submission of additional data to support the registration of these uses and products if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change. Should the Court injunction requiring temporary cancellation of above-ground uses be modified, the Agency will initiate the reregistration process for any affected uses that could be allowed to resume.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the generic data reviews for strychnine and the use of products below-ground, the Agency has concluded it has sufficient information about strychnine's potential to cause adverse effects to humans or the environment. The Agency has concluded that the use of the products classified as restricted use, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable adverse effects to humans or the environment. Therefore, these products are eligible for reregistration.

However, for the remaining products, those unclassified and available for use by the general public, EPA has concluded that it does not have sufficient information regarding the risks to humans to make a decision of eligibility. This additional information is important for EPA to reach a decision on eligibility. For this reason the Agency is requiring, through a DCI notice included with this document, that strychnine product registrants provide poison control center data for products used by homeowners, incident reports on poisonings of children, and end-use product acute toxicity.

Upon receipt, EPA will review the additional information from the DCI and decide whether additional practical measures are prudent to protect the general public users from the risks of poisonings or whether other regulatory action is appropriate. At that time the Agency will reach a decision on reregistration eligibility and determine any further action.

Regarding environmental risks, the Agency is able to conclude that the use of these products underground by the general public would not result in unreasonable adverse risks to the environment.

The following summary statements support the Agency's decisions on reregistration eligibility at this time:

a. Strychnine is useful to control pocket gophers and therefore there are benefits to farmers from the use of strychnine restricted use

products to protect agricultural areas. Benefits of strychnine products for use by the general public at residential sites are not available at this time.

b. Technical strychnine is highly acutely toxic to humans through the oral and ocular routes of exposure; inhalation toxicity is presumed to be high.

c. Adequate acute toxicity data are unavailable for end-use strychnine products that are available to the general public. Thus, EPA is unable to accurately estimate toxicity values to people, especially children, who may be exposed to these products.

d. Various sources of information about poisoning incidents in humans give a conflicting and incomplete description of the magnitude and characteristics of poisonings associated with the use of strychnine products.

e. Strychnine is highly toxic to non-target wildlife as shown in the toxicity data for birds, mammals, fish, and invertebrates. However, the Agency believes that the use of strychnine below-ground adequately limits exposure to non-target animals, and risk is, therefore, minimal under this condition.

The following requirements are based on the Agency's decision:

a. Personal protective equipment is required for handlers of strychnine products. Long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks and protective eyewear are required for all persons who handle paste formulations. Occupational handlers of grain baits must also wear a dust mask.

b. EPA is allowing strychnine end-use products formulated as ready-to-use grain baits to be sold to and used by homeowners at levels of no greater than 0.5% strychnine concentration for manual baiting only. However, such end-use products must be contained in child-resistant packaging during sale and storage.

2. Eligible and Ineligible Uses

The Agency has determined that the restricted use products for the below-ground use are eligible for reregistration when labeled and used as specified in this

Reregistation Eligibility Decision. The Agency can not make a determination of eligibility at this time for the unclassified products for below-ground use by the general public. Further data are being required.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for strychnine. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Restricted Use Classification

Strychnine is highly acutely toxic to humans and other non-target mammalian and avian species, and poses potential risks to these populations. Consequently, all strychnine products are classified as restricted use pesticides except for ready-to-use bait formulations which contain strychnine at nominal concentrations no greater than 0.5%, and which are labeled only for below-ground manual applications. This classification determination was made in 1978 and is not altered by this RED document.

2. Child-Resistant Packaging

Because EPA has concerns about potential risks of acute poisonings to children from products available to the general public, the Agency believes the use of child-resistant packaging for these products is prudent as a precautionary measure. Rather than wait until the receipt and review of required additional information for these products, the Agency is imposing this requirement now through this document. Specifically, unclassified ready-to-use grain baits must be contained in child-resistant packaging based on concerns for exposures to children and strychnine's high acute toxicity.

3. Personal Protective Equipment

The Agency establishes handler safety requirements when risk assessments or general concerns suggest such requirements are appropriate. Although the Worker Protection Standard (WPS) of 1994 was developed for agricultural pesticides, the measures in this standard for addressing worker protection are applicable to the uses of strychnine.

a. Personal Protective Equipment/Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers

are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are usually required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

(1) <u>Occupational-Use Products</u>

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for strychnine when formulated as a grain bait because of its presumed

high acute inhalation toxicity and potential exposure concerns from open-pouring such formulations. Dust masks are required PPE for occupational users of strychnine grain baits. Dust masks are appropriate for the mixer because the remnants of the mix are 100% strychnine.

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for strychnine when formulated as a paste due to its high acute oral and ocular toxicity. The Agency is requiring the use of chemical-resistant gloves and protective eyewear for all persons who handle such paste formulations.

(2) Homeowner-Use Products

EPA is not establishing minimum (baseline) handler PPE for strychnine end-use products that are intended primarily for homeowner use at this time, because the Agency has not completed its risk assessment for these products and PPE may not be practical for homeowners.

b. Post-Application/Entry Restrictions

EPA is not establishing entry restrictions at this time for strychnine end-use products, since strychnine currently is registered for use only below-ground in pocket gopher tunnels. Post-application exposures are unlikely following applications below-ground.

c. Other Labeling Requirements

The Agency believes it is appropriate to retain the restricted use classification for these products and to add to the products' label the reason for this classification -- acute toxicity. Refer to Section V below for the specific wording of this label statement. The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing strychnine. For the specific labeling statements, refer to the following section.

4. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse

impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of strychnine for occupational below-ground uses has been reviewed and determined to be substantially complete. A subchronic dermal study is required to confirm the Agency's assumption that dermal absorption of strychnine is low. If and when reinstatement of the above-ground use for strychnine occurs, the Agency may require additional generic data necessary to characterize potential risks from the above-ground uses.

2. Labeling Requirements for Manufacturing-Use Products

In order to remain in compliance with FIFRA, manufacturing-use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

> "This product may be used only to formulate end-use rodenticide concentrates of ready-to-use baits which are limited by labeling to below-ground applications to control pocket gophers."

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 product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice. In addition, product-specific data are being requested prior to making a determination for the use of strychnine products by homeowners. This information includes poison control center data, incident reports for poisoning of children, benefits and usage information, end-use product acute toxicity data, and information concerning pest control alternatives. A DCI to all end-use product registrants for this information is included with this document.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

In order to remain in compliance with FIFRA, end-use products labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The EP labeling must bear the following statement under Directions for Use:

> "This product may be used as end-use rodenticide concentrates of ready-to-use baits which are limited by labeling to below-applications to control pocket gophers."

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain strychnine, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

a. Products Intended Primarily for Occupational Use

(1) Restricted Use Classification and Statement

EPA is retaining the restriction of the use of end-use products containing 0.5% or more strychnine intended for use in a burrow-builder or impinger to certified applicators. All restricted use products must bear the following statement in a prominent location on the front panel of the end-use product labeling:

"RESTRICTED USE PESTICIDE

ACUTE ORAL TOXICITY

For retail sale and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's certification. Sale to or use by the general public is prohibited."

(2) Minimum (Baseline) PPE/Engineering Control Requirements

The minimum (baseline) PPE for strychnine end-use products formulated as a paste is:

"Applicators and other handlers must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks, and
--protective eyewear.

The minimum (baseline) PPE for strychnine end-use products formulated as grain-based baits is:

"Applicators and other handlers must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks, and
--dust mask.

* For the glove statement, use the statement established for strychnine through the instructions in Supplement Three of PR Notice 93-7. Although this PR Notice addresses agricultural pesticides, the basis for our decisions for strychnine are similar.

(3) Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

(4) Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

b. Products Intended Primarily for Homeowner Use

(1) Child-Resistant Packaging

Homeowner-use baits must be contained in child-resistant packaging during sale and storage.

(2) Minimum (baseline) PPE Requirements

EPA is not establishing active-ingredient-based minimum (baseline) handler PPE for strychnine end-use products that are intended primarily for homeowner use because the Agency is uncertain as to whether these products should be classified as restricted use and/or if other stringent measures are appropriate.

(3) Determining PPE Requirements for End-Use Product Labels

Any necessary PPE for each strychnine end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

(4) Placement in Labeling

The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section

"Hazards to Humans (and domestic animals)."

3. Other Labeling Requirements

a. Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing strychnine that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers, other persons, pets, or domestic animals.

User Safety Requirements

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing 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."

b. Products Intended Primarily for Home Use

Application Restrictions

"Do not apply this product in a way that will contact any person or pet. Keep people and pets out of the area during application."

User Safety Recommendations

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

c. All End-Use Products

In addition, use sites must be listed on the label. All use sites must be clearly specified on the label, such as orchards, forests, nurseries, and agricultural crop areas.

C. Existing Stocks

Registrants of manufacturing use products may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, 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. Refer to "Existing Stocks of Pesticide Products; Statement of Policy;" Federal Register, Volume 56, No. 123, June 26, 1991. Registrants of end-use products containing strychnine will be subject to these time frames based on the date of resolution of the labeling modification issue from the Strychnine Settlement Agreement.

VI. APPENDICES

APPENDIX A

Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop /year Dose cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	Min. Interv (days) /year cycle	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
FOOD/FEED USES											
AGRICULTURAL CROPS/SOILS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD+FEED CROP							
Bait application, When needed, By hand	RTU	NA	UC	*	NS NS	NS	NS	NS	NV, 013 Geo.013: Humboldt County only.		CAC
Bait application, When needed, Hand probe	B/S	NA	.015 lb A	*	NS 2/1 yr	NS	NS	120	NS		C20, C66, CAC
	B/S	NA	.005 Tsp burrow	*	NS NS	NS	NS	NS	NS		C92, CAC
	B/S	NA	.054 lb A	*	NS NS	NS	NS	NS	NS		CAC
	B/S	NA	UC	*	NS NS	NS	NS	NS	CA		C20, C66
Bait application, When needed, Mechanical burrow builder	B/S	NA	.015 lb A	*	NS 2/1 yr	NS	NS	120	NS		C20, C66, CAC
	B/S	NA	.108 lb A	*	NS NS	NS	.108 lb	NS	NS	AZ, CA	CAC
	B/S	NA	.01 lb A	*	NS NS	NS	NS	NS	NS		C20, C66, CAC
	B/S	NA	.0125 lb A	*	NS NS	NS	NS	NS	NS		C20, CAC
	B/S	NA	.054 lb A	*	NS NS	NS	NS	NS	NS		CAC
	B/S	NA	.01 lb A	*	NS NS	NS	NS	NS	NS	CA	C20, C66, CAC
	B/S	NA	.01 lb A	*	NS NS	NS	NS	NS	NS	CA	C20, CAC
	B/S	NA	.054 lb A	*	NS NS	NS	NS	NS	CA		C20, C66
	G	NA	.01 lb A	*	NS NS	NS	NS	NS	NS	CA	C20, C66, CAC
	RTU	NA	UC	*	NS NS	NS	NS	NS	NV		C20, CAC
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS NS	NS	NS	NS	NS		CAC
Bait application, When needed, Spoon	B/S	NA	.005 lb A	*	NS NS	NS	NS	NS	NS		C20, C66, CAC

APPENDIX A

Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate /crop	/year cycle	Max. Dose [(AI otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
AGRICULTURAL CROPS/SOILS (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)									
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C92, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, CAC
	G	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	P/T	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAU
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
ALFALFA				Use Group: TERRESTRIAL FEED CROP									
Bait application, When needed, Mechanical burrow builder	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
Bait application, When needed, Spoon	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66
	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
GRASS FORAGE/FODDER/HAY				Use Group: TERRESTRIAL FEED CROP									
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
Bait application, When needed, Spoon	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66
	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC

APPENDIX A

Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop /year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION												
FOOD/FEED USES (con't)												
IRRIGATION SYSTEMS				Use Group: AQUATIC FOOD CROP								
Bait application, When needed, Pliers	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	WA	C20, CAC
ORCHARDS (UNSPECIFIED)				Use Group: TERRESTRIAL FOOD CROP								
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		C20, C66
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		C20, C66, CAC
Bait application, When needed, Spoon	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS		C20, C66
	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS		C20, C66, CAC
PASTURES				Use Group: TERRESTRIAL FEED CROP								
Bait application, When needed, By hand	RTU	NA	UC	*	NS Geo.013: Humboldt County only.	NS	NS	NS	NS	NS	NV, 013	CAC
Bait application, When needed, Hand probe	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS		CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS	CA	C20, C66, CAC
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		C20, C66, CAC
	B/S	NA	.0125 lb A	*	NS	NS	NS	NS	NS	NS		C20, CAC
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS		CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS	CA	C20, C66, CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS	CA	C20, CAC
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS	CA	C20, C66, CAC
	G	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS	CA	C20, C66, CAC

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Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
PASTURES (con't)				Use Group: TERRESTRIAL FEED CROP (con't)									
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
Bait application, When needed, Spoon	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, CAC
	G	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	P/T	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAU
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
RANGELAND				Use Group: TERRESTRIAL FEED CROP									
Bait application, When needed, By hand	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV, 013		CAC
					Geo.013: Humboldt County only.								
Bait application, When needed, Hand probe	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS	CA		C20, C66, CAC
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.0125 lb A	*	NS	NS	NS	NS	NS	NS			C20, CAC
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, CAC

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SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
RANGELAND (con't)				Use Group: TERRESTRIAL FEED CROP (con't)									
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS	CA		C20, C66, CAC
	G	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			CAC
Bait application, When needed, Spoon	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, CAC
	G	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	P/T	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAU
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
NON-FOOD/NON-FEED													
FOREST TREES (ALL OR UNSPECIFIED)				Use Group: FORESTRY									
Bait application, When needed, Hand probe	B/S	NA	.015 lb A	*	NS	2/1 yr	NS	NS	120	NS			C20, C66, CAC
	B/S	NA	.005 Tsp burrow	*	NS	NS	NS	NS	NS	NS			C92, CAC
Bait application, When needed, Mechanical burrow builder	B/S	NA	.015 lb A	*	NS	2/1 yr	NS	NS	120	NS			C20, C66, CAC
	B/S	NA	.108 lb A	*	NS	NS	NS	.108 lb	NS	NS	AZ, CA		CAC

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Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop	/year	Max. Dose [(AI unless noted otherwise)/A] /crop	/year	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
FOREST TREES (ALL OR UNSPECIFIED) (con't)				Use Group: FORESTRY (con't)									
Bait application, When needed, Spoon	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C92, CAC
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES				Use Group: OUTDOOR RESIDENTIAL									
Bait application, When needed, Hand probe	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, C67, CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS			C66, CAC
Bait application, When needed, Injection equipment	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS			CAC
Bait application, When needed, Spoon	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, C67, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C66, CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS			CAC
	P/T	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	CAU
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				Use Group: TERRESTRIAL NON-FOOD CROP									
Bait application, When needed, Pliers	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C20, CAC
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				Use Group: TERRESTRIAL NON-FOOD CROP									
Bait application, When needed, By hand	RTU	NA	UC	*	NS Geo.013: Humboldt County only.	NS	NS	NS	NS	NS	NV, 013		CAC
Bait application, When needed, Hand probe	B/S	NA	.015 lb A	*	NS	2/1 yr	NS	NS	120	NS			C20, C66, CAC
	B/S	NA	.005 Tsp burrow	*	NS	NS	NS	NS	NS	NS			C92, CAC
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS	CA		C20, C66

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Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. Dose /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't)				Use Group: TERRESTRIAL NON-FOOD CROP (con't)									
Bait application, When needed, Mechanical burrow builder	B/S	NA	.015 lb A	*	NS	2/1 yr	NS	NS	120	NS			C20, C66, CAC
	B/S	NA	.108 lb A	*	NS	NS	NS	.108 lb	NS	NS	AZ, CA		CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.0125 lb A	*	NS	NS	NS	NS	NS	NS			C20, CAC
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, CAC
	B/S	NA	.054 lb A	*	NS	NS	NS	NS	NS	NS	CA		C20, C66
	G	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			CAC
Bait application, When needed, Pliers	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C20, CAC
Bait application, When needed, Spoon	B/S	NA	.001 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C92, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC

APPENDIX A

Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS (con't)			Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, CAC
	G	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
	P/T	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAU
	RTU	NA	UC	*	NS	NS	NS	NS	NS	NS	NV		C20, CAC
RESIDENTIAL LAWNS			Use Group: OUTDOOR RESIDENTIAL										
Bait application, When needed, Hand probe	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, C67, CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS			C66, CAC
Bait application, When needed, Injection equipment	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS			CAC
Bait application, When needed, Spoon	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, C67, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C66, CAC
	B/S	NA	UC	*	NS	NS	NS	NS	NS	NS			CAC
	P/T	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	CAU
NOT SPECIFIED													
SITE NOT SPECIFIED			Use Group: USE GROUP FOR SITE 00000										
Bait application, When needed, Hand probe	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			CAC
	B/S	NA	1.953E-05 gal burrow	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC

Case 3133[Strychnine] Chemical 076901[Strychnine]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop	/year cycle	Max. Dose [(AI unless noted otherwise)/A] /crop	/year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NOT SPECIFIED (con't)													
SITE NOT SPECIFIED (con't)			Use Group: USE GROUP FOR SITE 00000 (con't)										
Bait application, When needed, Mechanical burrow builder	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	.0044 lb A	*	NS	NS	NS	NS	NS	NS			C66, CAC, CAG
	B/S	NA	.01 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC
Bait application, When needed, Spoon	B/S	NA	1.736E-05 gal 1K sq.ft .005 lb A	*	NS	NS	NS	NS	NS	NS			C20, C66, CAC
	B/S	NA	1.719E-05 gal burrow	*	NS	NS	NS	NS	NS	NS			C66, CAC, CAG
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS			C68, CAC
	B/S	NA	.005 lb A	*	NS	NS	NS	NS	NS	NS		CA	C20, C66, CAC

APPENDIX A

Case 3133[Strychnine] Chemical 076901[Strychnine]

LEGEND

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	Minimum Interval between Applications (days)
Re-Entry Intv.	Reentry Intervals
PRD Report Date	LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	Non-specific
C	Coarse
M	Medium
F	Fine
O	Others

FORMULATION CODES

B/S	BAIT/SOLID
G	GRANULAR
P/T	PELLETED/TABLETED
RTU	LIQUID-READY TO USE

ABBREVIATIONS

AN	As Needed
NA	Not Applicable
NS	Not Specified (on label)
UC	Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	Dosage Can Not be Calculated
No Calc	No Calculation can be made
W	PPM calculated by weight
V	PPM Calculated by volume
U	Unknown whether PPM is given by weight or by volume
cwt	Hundred Weight
nnE-xx	nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

APPENDIX A

Case 3133[Strychnine] Chemical 076901[Strychnine]

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USE LIMITATIONS CODES

C20 : Endangered species restriction.
C66 : Underground application only.
C67 : Do not broadcast product over crops grown for food, feed or other purposes.
C68 : Do not apply in residential areas.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAC : Keep out of lakes, streams, and ponds.
CAG : Do not apply where runoff is likely to occur.
CAU : Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES

013 : Other
AZ : Arizona
CA : California
NV : Nevada
WA : Washington

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 3133 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 3133 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

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

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Strychnine

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	**ALL**	40213901, 40937002, 41499202, 40799301, 41320601
61-2A	**Start. Mat. & Mnfg. Process**	**ALL**	42120401, 40799301, 40937002, 41499201
61-2B	**Formation of Impurities**	**ALL**	41499201, 40799301, 40937002, 40213901, 41499202
62-1	**Preliminary Analysis**	**ALL**	41513901, 41499203, 41320601, 41299301, 40799302
62-2	**Certification of limits**	**ALL**	40799302, 41299301, 41320601,
62-3	**Analytical Method**	**ALL**	41499203, 40799301
63-2	**Color**	**ALL**	40213901, 40799303, 40880701
63-3	**Physical State**	**ALL**	40880701, 40799303, 40213901
63-4	**Odor**	**ALL**	40213901, 40799303, 40880701
63-5	**Melting Point**	**ALL**	42817102, 40799303
63-7	**Density**	**ALL**	40213901, 40799303, 40880701
63-8	**Solubility**	**ALL**	40213901, 40799303, 40880701
63-10	**Dissociation Constant**	**ALL**	40213901, 40799303, 40880701
63-11	**Octanol/Water Partition**	**ALL**	43079801, 40670501, 40864701, 40880701, 43079801
63-12	**pH**	**ALL**	41696201
63-13	**Stability**	**ALL**	40213901, 41268501, 40880701

Data Supporting Guideline Requirements for the Reregistration of Strychnine

REQUIREMENT		USE PATTERN	CITATION(S)
63-17	**Storage stability**	**ALL**	41623201, 40928901
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	**WAIVED**	
71-2A	**Avian Dietary - Quail**	**ALL**	41322602
71-2B	**Avian Dietary - Duck**	**ALL**	41322601
71-3	**Mammalian Toxicity**	**ALL**	40908901, 41210701, 40296501, 40296502, 40296503
71-4A	**Avian Reproduction - Quail**	**ALL**	42716801
71-4B	**Avian Reproduction - Duck**	**ALL**	42716802
71-5B	**Terrestrial Field Study**	**ALL**	42488601, 41478501
72-1A	**Fish Toxicity Bluegill**	**ALL**	41126501
72-1C	**Fish Toxicity Rainbow Trout**	**ALL**	41126502
72-2A	**Invertebrate Toxicity**	**ALL**	41126503
72-4A	**Early Life Stage - Fish**	**WAIVED**	
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	**ALL**	41210701, 40908901
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	**ALL**	41210702, 40908902
81-3	**Acute Inhalation Toxicity - Rat**	**WAIVED**	
81-4	**Primary Eye Irritation - Rabbit**	**ALL**	41210704, 40908904
81-5	**Primary Dermal Irritation - Rabbit**	**ALL**	41210703, 40908903

Data Supporting Guideline Requirements for the Reregistration of Strychnine

REQUIREMENT		USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	Foliar Residue Dissipation		RESERVED
132-1B	Soil Residue Dissipation		RESERVED
133-3	Dermal Passive Dosimetry Exposure		RESERVED
ENVIRONMENTAL FATE			
160-5	Chemical Identity		
161-1	Hydrolysis	ALL	41122301
161-2	Photodegradation - Water	WAIVED	
161-3	Photodegradation - Soil	ALL	42973401
162-1	Aerobic Soil Metabolism	ALL	42234201
162-2	Anaerobic Soil Metabolism	WAIVED	
163-1	Leaching/Adsorption/Desorption	ALL	42366501
165-1	Confined Rotational Crop	WAIVED	
165-2	Field Rotational Crop	RESERVED	
165-4	Bioaccumulation in Fish	RESERVED	
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	WAIVED	
171-4B	Nature of Residue - Livestock	WAIVED	
171-4C	Residue Analytical Method - Plants	WAIVED	

Data Supporting Guideline Requirements for the Reregistration of Strychnine

REQUIREMENT		USE PATTERN	CITATION(S)
171-4D	Residue Analytical Method - Animal	WAIVED	
171-4E	Storage Stability	WAIVED	
171-4J	Magnitude Meat/Milk/Poultry	WAIVED	
171-4K	Alfalfa	WAIVED	
171-4L	Alfalfa	WAIVED	

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form
Attachment 3	-	Requirements Status And Registrant's Response Form
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

   If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In

Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of

both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data --

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the

deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have

made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any

registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you

must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form; or,

b. fulfill the commitment to develop and submit the data as required by this Notice; or,

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received <u>after</u> the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due <u>unless</u> you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review
and Reregistration Division

3133 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you hold a registration(s) of products containing strychnine.

This attachment, the Data Call-In Chemical Status Sheet, contains the supporting information regarding the special requirements of this Data Call-In, why the requirements are being imposed and the contact person for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment 2, the Data Call-In Response Form, (3) Attachment 3, the Requirements Status and Registrant's Response Form, and (4) the Cost Share and Data Compensation Forms in replying to this strychnine Data Call-In. Instructions and guidance accompany each form.

INCIDENT HISTORY

Approximately 100 cases of accidental exposure to strychnine rodenticides are reported annually to U.S. Poison Control Centers (Litovitz et al. 1986-1994). However, EPA believes this number of accidental exposures is low based on comparisons with other data sources which show that Poison Control Center data generally underestimate the true extent of poisoning.

During a nine-year period (1985-1993), 1,359 exposures to strychnine were recorded by the U.S. Poison Control Centers. Of the accidental exposure cases, where the age of the exposed individuals was available, nearly half of those exposed were under six years old. In addition, in 25 cases where medical outcome was determined to be serious (a moderate, major or fatal outcome from 1985 through 1992), two were confirmed to be children. Estimates of lethal dose for strychnine baits as currently formulated (0.5% active ingredient) suggest that a single swallow by a 10 kg child could be lethal. For a typical one-year old child weighing 10 kg, this would mean a dose of 1.1-1.8 mg/kg of strychnine, which is in the potentially lethal range.

The available information from various sources on human poisoning incidents is conflicting and unclear as it relates to accidental exposure to strychnine products. This problem and the uncertainty of the amounts of end-use products which could result in significant toxicity to humans, especially children, do not enable the Agency to determine with confidence the magnitude and seriousness of poisonings from the use of strychnine in the U.S. Additional information to clarify these issues is required by this notice.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for 3133 are:

(1) poison control center data.

This information is to include specific incident data about products used by homeowners, and incident reports on poisoning incidents involving children;

This information requirement is contained in the Requirements Status and Registrant's Response, Attachment C. These data are needed to fully complete the reregistration of all eligible 3133 products.

WHY THESE REQUIREMENTS ARE BEING IMPOSED

Due to the limited data available to the Agency concerning strychnine poisoning incidents EPA believes that the data required by this Notice will assist in more fully understanding the risks associated with the use of strychnine. Since the incident data currently available to the Agency contains some gaps, the Agency is requiring the registrants to provide data to fully assess the risks associated with strychnine use. EPA believes that children may be at risk from the presence of strychnine in and around the treatment site and/or from its storage in the home.

Data to be collected include poison control center data for products used by homeowners; incident reports on poisoning of children; and end-use product acute toxicity.

This information on incidents from strychnine exposure, along with the product-specific acute toxicity data required through the product reregistration, will be used to form the basis of our regulatory decision for the homeowner uses of strychnine.

82-3-SS Human Incident Data:

Data Required

The types of data the Agency is requiring are described below. These data are available from the Toxic Exposure Surveillance System of the American Association of Poison Control Centers (AAPCC) database, which provides an annual compilation of poisoning statistics from around the U.S. The AAPCC database is the most comprehensive, independently generated national poisoning database known to the Agency. The AAPCC can be contacted at 3201 New Mexico Avenue, Suite 310, NW, Washington, DC 20016; phone: 202-362-3867.

Approximately 80 percent of the U.S. population have access to the Poison Control Centers represented in the most recent AAPCC annual report. Reports are indexed by both product brand name (if given by the caller) and by active chemical ingredient (e.g., strychnine, etc.). Each registrant is required to prepare a summary report on its individual products by active ingredient, which will include a summary listing by product of the number of incidents reported. A second summary report will be required providing the same tables and cross-tabulations for all cases involving the active ingredient regardless of whether the registrant was the manufacturer of that particular active chemical ingredient. However, individual product brand names will not be listed in this second report. Where more than one company is involved in the manufacture of an active chemical, they are encouraged to share costs when producing this latter report. Each registrant

is required to submit the following data elements (for each incident listed by the AAPCC) in the format of the tables found in the AAPCC annual report:

1. specific product brand name and active ingredient with concomitant pesticide exposures (exclude cases involving exposure to non-pesticide products),

2. exposure type (e.g., acute, chronic),

3. reason for exposure (e.g., accidental, occupational, adverse reaction, misuse), as defined by AAPCC. Registrants must include all categories of accidental exposure and intentional misuse, (exclude intentional suicide/homicide),

4. exposure site (e.g., residence, work place, school,

5. route of exposure (oral, inhalation, dermal, ocular),

6. initial symptom assessment (present or absent, related; cholinesterase depression, if available),

7. management of patient site (health care facility or not),

8. disposition of patient (treated and released, hospitalized),

9. decontamination provided (e.g., ipecac, charcoal),

10. therapy provided (e.g., oxygen, atropine),

11. medical outcome (none, minor, moderate, major, fatal, unknown), as defined by AAPCC,

12. age and sex of individual involved in each case, and physical and mental state, if available, and,

13. symptoms reported for 1993-1995.

All available incidents involving strychnine listed in this DCI must be provided for the period of 1990 through 1992, in one report and 1993 through 1995 in a second report. The data must be in listing and cross-tabular form (e.g., reason by age, route of exposure by medical outcome - the standard set of cross-tabulations provided by AAPCC), which will facilitate analysis for factors that affect potential exposure or risk. In addition, there must be a one-line summary of each case that resulted in a minor, moderate, major, or fatal outcome. The one-line summary must give case number, date, age, sex, reason, exposure route, and a separate listing by substance or product brand name that indicates the number of times each particular product occurs. It is important to associate incidents with use sites. Data for the years 1990 through 1992 and 1993 through 1995 should be provided in two combined reports, not separately year-by-year.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Bonnie Adler at (703) 308-8523.

All responses to this Notice for the generic data requirements should be submitted to:

Bonnie Adler, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460
RE: 3133

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be

submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

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 crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites

TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of

all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the

request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time

frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you

wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you

wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

3133 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 3133.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 3133. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this 3133 Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 3133 are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 3133 are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible 3133 products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Ed Setren at (703) 308-8166.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Ed Setren
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **3133**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my

product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data

Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA'S BATCHING OF PRODUCTS CONTAINING STRYCHNINE AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient strychnine (also known as strychnine alkaloid) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), product form (liquid, paste, solid, etc.), and labeling (e.g., signal word, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must

select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient strychnine
Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	2935-507	Strychnine ... 99.9%	powder
	27995-1	Strychnine ... 99.9%	powder
	37295-1	Strychnine ... 99.9%	powder
2	30-27	Strychnine ... 0.50%	granular
	299-212	Strychnine ... 0.50%	granular
	299-213	Strychnine ... 0.50%	granular
	322-1	Strychnine ... 0.50%	granular
	322-7	Strychnine ... 0.50%	granular
	641-1	Strychnine ... 0.50%	granular
	641-2	Strychnine ... 0.50%	granular
	814-4	Strychnine ... 0.50%	granular
	909-2	Strychnine ... 0.54%	granular
	2935-508	Strychnine ... 0.50%	granular
	2935-524	Strychnine ... 0.50%	granular

4271-10	Strychnine ...	0.50%	granular
4271-17	Strychnine ...	0.50%	granular
5042-32	Strychnine ...	0.50%	granular
10031-1	Strychnine ...	0.50%	granular
10031-2	Strychnine ...	0.50%	granular
10031-3	Strychnine ...	0.50%	granular
10031-4	Strychnine ...	0.39%	granular
10031-5	Strychnine ...	0.44%	granular
10140-4	Strychnine ...	0.50%	granular
10140-5	Strychnine ...	0.44%	granular
10140-7	Strychnine ...	0.50%	granular
10140-8	Strychnine ...	0.50%	granular
35380-1	Strychnine ...	0.50%	granular
35380-3	Strychnine ...	0.35%	granular
36029-1	Strychnine ...	0.50%	granular
36029-7	Strychnine ...	0.50%	granular
36029-8	Strychnine ...	0.50%	granular
36029-9	Strychnine ...	0.50%	granular
36029-11	Strychnine ...	0.50%	granular
56228-8	Strychnine ...	0.43%	granular
56228-11	Strychnine ...	0.50%	granular
56228-12	Strychnine ...	0.50%	granular
56228-19	Strychnine ...	0.50%	granular

	56228-20	Strychnine ...	0.51%	granular
	NV93000300	Strychnine ...	0.50%	granular

Table 2 lists the products the Agency was unable to batch. These products were not batched because they were not considered to be similar to other products in terms of acute toxicity or because there was insufficient information about the product's formulation. Registrants of these products are responsible for meeting the acute toxicity data requirements for each product individually. These products may not cite acute toxicity/ irritation data derived from any other products in this RED. The registrant may cite pre-existing data conducted on their individual product if it exists and it meets current Agency standards.

Table 2.

Registration Number	Percent Active Ingredient	
56228-27	Strychnine ...	1.6%
NV92000500	Strychnine ...	10.0%
NV83000900	Strychnine ...	3.2%
WA90000400	Strychnine ...	4.90%

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107,
2070-0057
Approval Expires
3-31-96

CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for 3133 that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Ed Setren at (703)-308-8166.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for 3133.

The following documents are part of the Administrative Record for 3133 and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria