United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA-738-R-96-026
May 1997

Reregistration Eligibility Decision (RED)

Colletotrichum gloeosporioides f.sp. *aeschynomene*

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 4103, which includes the active ingredient *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, 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 ingredient 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 date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account the new safety standard set by the FQPA for establishing and reassessing tolerances. However, it should also be noted that in continuing to make the reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rule-making that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in the RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the generic and product specific data requirements or wish to meet with the Agency, please contact the Biopesticides and Pollution Prevention Division representative, Shanaz Bacchus, at (703) 308-8097.

Sincerely yours,

Janet L. Andersen, Ph. D., Director
Biopesticides and Pollution
Prevention 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-BPPD)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-BPPD)**
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

Colletotrichum gloesoporioides f. sp. *aeschynomene*

LIST D

CASE 4103

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

TABLE OF CONTENTS

Colletotrichum gloeosporioides* f. sp. *aeschynomene
REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

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Neil Anderson	Biological Analysis Branch
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Biopesticides and Pollution Prevention Division

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Gail Tomimatsu	Microbials and Plant Pesticides Team
Shanaz Bacchus	Microbials and Plant Pesticides Team
John Tice	Pollution Prevention Team

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
FQPA	Food Quality Protection 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.

GLOSSARY OF TERMS AND ABBREVIATIONS

N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
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

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision on the active ingredient, *Colletotrichum gloeosporioides* f. sp. *aeschynomene* (referred to as *C.g.a.*) American Type Culture Collection (ATCC) 20358. This decision includes a comprehensive reassessment of the required target data and the use patterns of the currently registered active ingredient. This decision also considered the requirements of the of the recently enacted "Food Quality Protection Act of 1996" which amended the Federal Food and Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3, 1996 are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, FQPA requires the Agency to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibility of infants and children to the toxic effects of pesticide residue.

The Agency has reassessed the food and feed tolerances for *C.g.a.* ATCC 20358 under the standards of FQPA and determined that, based on available information, there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to the microbial pesticide residues. EPA evaluated only dietary and drinking water exposure in the aggregate assessment, since other non-occupational exposures to *C.g.a.* ATCC 20358 are unlikely. EPA has no information to indicate that the toxic effects produced by the microbial pesticide would be cumulative with those of any other compound, and therefore has considered only *C.g.a.* ATCC 20358 exposures in the aggregate assessment.

Pesticidal products whose sole active ingredients qualify as biological agents may be exempt from certain generic data requirements necessary for conventional chemical pesticides. The data requirements relating to toxicology, residue chemistry, human exposure, ecological effects and environmental fate of the active ingredient are outlined in 40 CFR § 158.740 -- Guidelines for Microbial Control Agents.

C.g.a. ATCC 20358, a fungus, has been registered and used as a herbicide on rice and soybeans since 1982, the sole registered product being *Collego*™. An exemption from the requirement of a tolerance for *C. gloeosporioides* f.sp. *aeschynomene* ATCC 20358 on rice and soybeans has been established (40 CFR §180.1075). In reaching the determination of safety for infants and children, the Agency found that the toxicity database for this microbial pesticide is complete based on current requirements. Moreover, because of its limited usage

on two crops in three states, and the potential for loss of residues during processing of these raw agricultural commodities, dietary exposure to human infants, children and adults is expected to be minimal. EPA has reassessed the tolerances for *C.g.a.* ATCC 20358 as required by FIFRA 4(g)(2)(E) and considers these reassessed tolerances to be qualifying Federal determinations under FFDCA 408(n)(2).

Species in the genus *Colletotrichum* are common in the environment and frequently parasitize higher plants, causing anthracnose disease. There are no indications, however, that *C.g.a.* ATCC 20358 presents any pathogenic potential to animal species. No adverse effects have been reported as required by section 6(a)2 of FIFRA. Recreational areas are not registered for this microbial pesticide. The pesticide is short-lived in the environment and is not likely to persist in aquatic systems. Although the potential exists for some minimal amount of the microorganism to enter ground water or other drinking water sources, the amounts present would in all probability be undetectable or at least several orders of magnitude lower than those levels tested for safety. Also, drinking water is not screened for this microorganism as a potential indicator of microbial contamination or as a direct pathogenic contaminant.

Geographical limitations are not stated on the current label of the sole registered product *Collego*. However, there is some concern about the potential phytopathogenicity if this microbial herbicide is directly applied to peas or to certain non-target species of plants as discussed in this RED document. For these reasons, the use of all products containing this active ingredient is limited to Arkansas, Louisiana and Mississippi. In addition, the Agency recommends that *C.g.a* ATCC 20358 must not be applied to peas and peas must not be planted in rotation to crops which have been treated with products containing the active ingredient *C.g.a* ATCC 20358. On the basis of data currently available, the Agency has concluded that those registered uses, as described in this document, will not cause unreasonable risks to human infants, children or adults or the environment and, therefore, the currently registered products, containing this active ingredient, are eligible for reregistration.

Label revisions and a revised Confidential Statement of Formula (CSF) to reflect the current reregistration status and nominal limits of *C.g.a.* ATCC 20358 are required as part of this RED document. Workers exposed to this low acute and low subchronic toxicity microbial are not likely to be at risk. To comply with the Worker Protection Standards (WPS) for pesticides used on agricultural crops, the Agency is requiring, among other changes, the use of Personal Protective Equipment (PPE) for handlers and early-entry workers. A four (4) hour Restricted-entry Interval (REI) is required for early-entry workers engaged in postapplication activities following treatment of agricultural crops with this pesticide. If necessary, other WPS requirements will be set during the product reregistration process.

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.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances, but FQPA does not obligate the Agency to consider the factors set forth in the new section 408 of the FFDCA when making decisions under FIFRA with respect to pesticides that do not have any food uses. However, the FQPA did not amend any of the existing reregistration deadlines in section 4 of FIFRA. Therefore, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC 20358. The document consists of six sections. Section I is the introduction. Section II describes *C.g.a.* ATCC 20358, 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 *C.g.a.* ATCC 20358. Section V discusses the reregistration requirements for *C.g.a.* ATCC 20358. Finally, Section VI contains 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:

- **Common Name:** Collego, *C.g.a.* ATCC 20358.
- **Biological Name:** *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC strain 20358
- **Biological Family:** Melanconiaceae
- **OPP Chemical Code:** 226300
- **Trade and Other Names:** Collego™, *C.g.a.* ATCC 20358
- **Basic Manufacturer:** University of Arkansas
  Office of Research and Sponsored Programs
  120 Ozark Hall, Fayetteville, Arkansas 72701

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of *C.g.a.* is in Appendix A.

For ***C.g.a.*** ATCC 20358:

Type of Pesticide: Herbicide (microbial control agent)

Use Sites: Rice, soybean. This RED limits use to Arkansas, Louisiana, and Mississippi to protect non-target plants.

Target Pests: Weeds: northern jointvetch

Formulation Types Registered: A two component product consisting of:
Component A: a water-soluble rehydrating agent, which is a nutrient solution, and

Component B: a dried fungal spore preparation of *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC 20358. This component can be suspended in water and contains fermentation solids, mycelial fragments and inerts.

Method and Rates of Application: See Appendix A: post emergence, flooded area treatment; air, ground applications; high volume spray (dilute); low volume spray (concentrate). (See **Appendix A** for details)

Equipment - fixed wing aircraft, helicopter; high volume ground sprayer; low volume ground sprayer

Method and Rate - To treat 10 acres: One quart of Component A and 2 parts of water to make the rehydrating solution for 1 bag of Component B (75.7×10^{10} viable spores).

Timing - post emergent, when northern jointvetch are 8 to 24 inches tall.

Use Practice Limitations:

On the current label:

Apply when the leaves of northern jointvetch are moist and can be expected to remain so for at least 12 hours.

The pesticide is not to be applied under the following conditions:

(a) after rice heads emerge from the boot or after pods form on the lower nodes of soybeans.

(b) when rice and soybeans are under stress for moisture or when drying conditions are likely to occur.

(c) to northern jointvetch previously treated with phenoxy herbicides

Do not apply fungicides for at least three weeks following application of *C.g.a.* ATCC 20358.

Proposed label amendments

Additional Agency-proposed use practice limitations resulting from the evaluation of the data for this RED and to comply with the Worker Protection Standards are discussed in Sections IV and V.

C. Estimated Usage of Pesticide

C.g.a. ATCC 20358 is registered in the United States as a sole product, *Collego*™, for control of Northern jointvetch (NJV) in rice and soybeans. The current label does not place any geographical limitation on the use of *C.g.a.* ATCC 20358 NJV, the target pest, is endemic to Arkansas (AR), Louisiana (LA) and Mississippi (MS).

Prior to 1993, *Collego* was applied to 1,000 to 10,000 acres of rice annually in Arkansas to control Northern joint vetch. Spradley and Windham, 2-CA-95, report the use in Arkansas as less than 0.1 percent of acres of treated rice. Soybeans is the other registered site for *Collego*; however, no usage data were found on soybeans.

In this RED, because of potential phytotoxicity to non-target plants (as discussed under **Ecological Exposure and Risk Characterization** in **Section III**) the Agency is limiting the use of *C.g.a.* ATCC 20358 to AR, LA and MS. Appendix A summarizes the currently registered pesticide uses by agricultural site.

D. Data Requirements

A Data Call-In, which was issued in September, 1993, for reregistration of *C.g.a.* required additional product chemistry, acute mammalian, avian and freshwater fish and invertebrate toxicity/pathogenicity data, as well as information to assess the effects of its use on some non-target plants and insects. All data were reviewed as summarized in this RED document. Appendix B includes all data requirements identified by the Agency to support reregistration of currently registered uses. The Agency obtained additional information on the host range specificity of *C.g.a* for the reregistration process. This information was useful in evaluating the phytopathogenicity of the fungus to non-target plants. No further generic data are required for reregistration of *C.g.a.* as currently marketed.

E. Regulatory History

The sole registered product, *Collego*™, contains the active ingredient *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC strain 20358. It is a post-emergent herbicide for control of Northern jointvetch (NJV) in rice and soybeans. There is no technical or manufacturing use product registered.

Collego™ was conditionally registered in June 1982, with unconditional registration depending on resolution of issues regarding avian toxicity and freshwater fish and freshwater invertebrate toxicity/pathogenicity. An unconditional registration was granted to Tuco Products Co., a Division of Upjohn, for the use of the microbiological pesticide in the United States in October, 1982.

The registration for this microbiological herbicide was transferred to AGREVO USA Co., in April, 1985, and later in January of 1989 to Ecogen. The current registrant as of June, 1996, is the University of Arkansas (EPA Reg. No. 69843-1).

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

The Agency has found that the uses of *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC strain 20358 are eligible for reregistration under the conditions specified in this RED. However, it should be understood that the Agency may take additional appropriate regulatory action, and/or require submission of additional data to support the registration of products containing this active ingredient, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

III. SCIENCE ASSESSMENT

A. Product Identity and Characterization

The product identity and characterization information for *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (also known as *C.g.a.*) ATCC strain 20358 shows that this microorganism is a naturally occurring fungus, originally isolated from diseased northern jointvetch (*Aeschynomene virginica*) growing as weeds in Arkansas rice fields. The fungus is an imperfect or asexual fungus in the *Melanconiaceae* family, producing slipper-shaped, hyaline non-septate phialospores (approximately 15.8 x 5.5µm in size) from thickened, brown pseudoparenchyma that develops into stromatic tissue under the host epidermis. The conidia are produced in a slimy exudate which is pink to orange in color and arise from an acervulus which lacks setae. Spores landing on suitable host tissue become two-celled, then germinate to form an appressorium and infect the host tissue causing the typical anthracnose or leaf spot disease under proper conditions. No sexual stage of this fungus is known in nature, but other strains of *Colletotrichum gloeosporioides* have been related to the perithecial ascomycete *Glomerella cingulata.* The active ingredient has been deposited in the American Type Culture Collection as strain 20358.

The taxonomy of fungal plant pathogens is unusual in that description of the organism beyond the species level is possible only by designating the range of plants that can be infected. This is especially important in imperfect fungi such as *C. gloeosporioides* which have a very wide described host range. Fungi are allowed by the rules of botanical nomenclature to employ the "*formae speciales*" (f. sp.) designation to specify this added information. Consequently, the microbe causing the anthracnose disease in northern jointvetch is named *C. gloeosporioides* f.sp. *aeschynomene* to refer to its restricted host range for the plant genus *Aeschynomene* (MRID 00083879, 00084478, 00084340, 00084481, 00084482, 00084483, 00084484). The studies performed to demonstrate the restricted host range impinge on both the proper taxonomic description of the active ingredient and the hazards posed to non-target plants. Therefore, some of the discussion will be cross referenced between the two sections.

To verify the restricted host range of *C.g.a.*, data on individual host plant response after inoculation were provided to circumscribe the potential host range using the centrifugal phylogenetic testing scenario. This method first tests those plant species most closely related to the known target plant, (in this case other *Aeschynomene* species, members in the tribe Hedysareae and other legume species) then proceeds with testing of more distantly related species until plant immunity is generally found. For the original submission this included thirteen species in the genus *Aeschynomene* and another member of a taxonomically related group (*Lespedeza stipulacea* also in the Hedysareae tribe). Nine other species in the Leguminosae were tested including 22 cultivars of soybean (*Glycine max*) and 6 cultivars of cowpea (*Vicia unguiculata*). In addition, 26 agronomic or horticultural species with from 1 to 3 cultivars within each species were tested. This testing group comprised 16 families with 32 genera and included pot marigold (*Calendula officinalis*), a plant species known to be infected by *C. gloeosporioides* (no formae speciales designation and a broader host range for this fungal strain). The immunity of the species tested except for *Aeschynomene virginica*, *A. indica*, *A. evenia*, *A. pratensis*, *A. rudis*, *A. scabra* and *A. sensitiva* allowed the determination of safety to non-target plant species to be made for the original registration (MRID 00083879, 00084478, 00084340, 00084481, 00084482, 00084483, 00084484).

Subsequent to this original submission, the published literature has indicated that the host plant range for *C.g.a.* is greater than described in the original submission. To identify further the host range of *C.g.a.* within the Leguminosae, 82 species from 47 genera and 24 tribes within the Leguminosae were tested by inoculation (MRID 43965601). These tests suggest the host range of *C.g.a.* includes several other species in the Leguminosae including *Lupinus arboreus*, *L. nanus*, *Vicia ervilia* and the Mammoth Melting Sugar, Sweet Snap, Mars, Snowbird, Thomas Laxton and Venus cultivars of *Pisum sativum*, all of which show more than 50% of the leaf tissue infected (MRID 43965601). *Lupinus alba* and *Pisum sativum* cultivar Little Marvel

were tested in the original host range determination and found to be immune to *C.g.a.*. Other species (*Lupinus alba, L. polyphyllus, L. regalis, L. densiflorus, L. subcarnosus, Indigofera hirsuta, I. tinctoria, Lotus tetragonolobus, Lathyrus odorata, Lens esculenta, Vicia benghalensis, V. faba, V. narboensis, V. pannoiae* and *V. sativa*) were found to sustain lesser degree of infection upon inoculation. It is important to note that the results of the individual inoculation tests indicate that only *A. virginica* is killed outright by *C.g.a.*.

While these results do not significantly alter the host range of plants that are expected to be exposed to *C.g.a.* in use, it does call into question the selection of species and cultivars during phylogenetic centrifugal testing for non-target plant effects. It is also important to consider that the testing of numerous cultivars within a species such as *Pisum sativa* implies the sampling of a larger range of genotypes within the susceptible population. In the absence of selection for host resistance during cultivar development, it could be expected that some cultivar variation in pathogen susceptibility will be displayed if any potential for infection was in the genetic background of that plant species. The importance of this susceptibility and the biological meaning of low levels of virulence expressed under artificial inoculation is unclear, but it does not alter the original findings for reregistration purposes. Host range specificity with regards to *Pisum sativa* is further discussed in the **Ecological Effects Section** under **Toxicity to Plants**.

The proof that *C.g.a.* is genetically stable is cogent to the determination that the demonstrated host range cannot be drastically altered. To verify this claim, the ability of *C.g.a.* to form heterokaryons, diploids and undergo mitotic recombination was examined using auxotrophic mutants of *C.g.a.* and *Colletotrichum gloeosporioides* f.sp.*jussiaeae* (*C.g.j.*), a specific fungal strain infecting *Ludwigia decurrens.* The use of *C.g.j.* is relevant due to its occurrence in the same habitat as northern jointvetch. All of the environmental *C.g.a.* isolates, including the registered active ingredient, were in the same vegetative compatibility group, which indicates that they can form anastomoses and possibly undergo asexual or mitotic recombination. None of the *C.g.a.* auxotrophs were able to form heterokaryons with *C.g.j.* which supports the fact that these strains are genetically separate. Even between mutants derived from the same *C.g.a.* parent, stable heterokaryons were rarely formed ($<10^{-4}$ heterokaryotic colonies per colony plated) and none of these heterokaryons displayed reversion to prototrophy, indicating diploid formation and mitotic recombination were not occurring (MRID 43965601).

Further experimental evidence showed that *C.g.a.* isolate Clar-5a and *Colletotrichum gloeosporioides* isolated from pecans (and capable of infecting apples) in Louisiana or from *Ludwigia decurrens* (referred to as *C.g.j.* above) were able to form fertile *Gomerella cingulata*-type perithecia. *C.g.a.* Clar-5a was unable to form perithecia with 21 isolates of *C. gloeosporioides* from 8 other host plants (including

the *C.g.a.* strain used as the active ingredient) or with 19 isolates from other *Colletotrichum* species (MRID 43965601). The single ascosporic colonies dissected from these perithecia displayed outcrossing, not homothallic perithecial formation, with characters segregating for both parental types. However, there was a much lower frequency of fertile perithecia in these crosses than normally occurs with *Glomerella cingulata*. The asci present were few, rarely had 8 ascospores and displayed low germination rates (about 33%). These results indicate that *C.g.a.* is probably not solely an asexual fungus and should probably be more properly described as *Glomerella cingulata* but that the sexual state is probably very rare and produces few viable ascospores.

These results also do not indicate the biological significance of this potential for gene exchange by sexual recombination in nature. The colonies resulting from the laboratory crosses had reduced pathogenicity on *A. virginica* and variable pathogenicity to apples. Although *C.g.a.* and these two *C. gloeosporioides* strains occur in the same habitats, *C.g.a.* has been shown to be relatively stable and homogenous by pathogenicity and DNA analyses (43965601). Examination of 174 isolates from the Arkansas area, and several from Louisiana, indicated that none differed when probed with markers for glyceraldehyde-3-phosphate dehydrogenase, ribosomal DNA and mitochondrial DNA. These isolates were also not discernably different by pathogenicity testing on *A. virginica*. There were distinguishable banding patterns to identify individuals within the 174 isolates produced using a telomeric DNA probe from *Fusarium oxysporum* or a DNA probe consisting of repetitive DNA from *C.g.a.* itself. Based on these results, if the sexual stage of *C.g.a.* (*Glomerella cingulata*) is occurring in nature, it is not having the same effect on *C.g.a.* that occurs in culture (i.e., loss of pathogenicity to *A. virginica* and recombination of traits).

The new information generated on the host range of this fungus (discussed above), represents a more thorough analysis of the host range within the family *Leguminosae*, rather than an entirely new and unexpected shift of this pathogen's host range.

B. Human Health Assessment

1. Toxicology Assessment

Adequate mammalian toxicology data on *Colletotrichum gloeosporioides* f.sp. *aeschynomene* are available and will support a Reregistration Eligibility Decision (RED).

a. Acute Toxicity

Certain mammalian toxicity studies conducted with *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 have been submitted and adequately satisfy the requirements as set forth in 40 CFR § 158.740 -- Microbial Pest Control Agents. All studies were conducted with the technical grade of the active ingredient (Table 1).

TABLE 1: Acute Mammalian Toxicity For *Colletotrichum gleosporioides* f.sp. *aeschynomene* ATCC 20358

Guideline Number	Study	Results	Toxicity Category	MRIDs
152A-10 OPPTS 885.3050 OECD	Acute Oral Toxicity/ Pathogenicity	LD_{50} > 5g/kg Fungal Clearance was observed by day 7; and LD_{50} >8.6 X 10^6 spores	IV	84551 84552 84553 84568 99072
152A-12 OPPTS 885.3150 OECD	Acute Pulmonary (Inhalation) Toxicity/ Pathogenicity	LD_{50} > 6.0 mg/L or 1.8 x 10^6 spores/L	IV	84555 84556 84557
152A-13 OPPTS 885.3200 OECD	Acute Intra-peritoneal Toxicity/ Pathogenicity	Viable spores were no longer present by day 10	N/A	98376
152A-15 OPPTS 885.3400 OECD**	Hyper-sensitivity Incidents	None reported*	N/A	N/A
81-2 OPPTS 870.1200 OECD	Acute Dermal Toxicity	LD_{50} > 5g/kg in rats; > 21.4 g/kg in rabbits	IV	84554 99073
81-4 OPPTS 870.2400 OECD**	Primary Eye Irritation	Corneal opacity and irritation cleared by day 4	III	84558 84559 84560 99075
81-5 OPPTS 870.2500 OECD**	Primary Dermal Irritation	Not a dermal irritant	IV	84560 84561 99074
81-6 OPPTS 870.2600 OECD**	Dermal Sensitization (Modified Buehler)	No sensitizing potential	N/A	84565 84562 84563 84564

* All incidents must be reported to the Agency.

** Not required for the active ingredient, but reported here since the tests were conducted with the technical and the formulated product. The test for OPPTS guideline 81-6 (OECD 870.2600) was conducted with the technical only. There is one registered product and no separate registration for the technical active ingredient.

In the evaluation of the toxicology data base for the reregistration eligibility decision for *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358, the guidelines have been fulfilled and no further information is required.

b. Subchronic Toxicity

The Agency does not currently require the submission of subchronic studies for Microbial Pesticides. However, two subchronic oral toxicity studies in the dog for *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 were reviewed in connection with the initial registration process. No toxicity or signs of disease were observed when dogs were fed 3×10^8 spores/lb per week for six months (84340, 84578). These two studies provide adequate information to determine that the fungus does not have the potential to produce mycotoxins.

2. Exposure Assessment

a. Dietary Exposure

Since *C.g.a* ATCC 20358 is applied to rice and soybeans for weed control, a food tolerance determination is required. An exemption from the requirement of tolerances for residues of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (40 CFR 180.1075) on rice grain and soybeans has been established.

There is limited usage of this microbial, which is registered for use on rice and soybeans only. Current literature shows that *C.g.a.* ATCC 20358 has been used as a pesticide in Arkansas on less than 0.1 percent of the acres of rice grown (Spradley and Windham, 2-CA-95). The trend is for a low-volume use of the microbial herbicide. The pesticide is applied at low rates as a preemergent treatment. Residues of *C.g.a* ATCC 20358 are not likely to remain on the two treated crops because the microbial pesticide is likely to be removed from the crops during processing. Moreover, no hypersensitivity incidents have been reported and the microbe is a plant pathogen with minimal adverse effects on animals. Therefore, dietary exposure to human infants, children and adults is likely to be minimal.

b. Occupational/Residential Exposure

Handlers: On the basis of a lack of human toxicity concerns (**Table 1**), there is no trigger for quantitative estimates of worker exposure data as determined by Subparts U and K of the Pesticide Assessment Guidelines. Based on the application methods which involve ground sprays and aerial applications, there will be potential for dermal and inhalation exposure to handlers. The unit of exposure to the workers who use high and low volume ground sprayers is likely to be moderate. The mixer/loader and the pilot for aerial applications generally treat large acreages. However, because of the low rates of application, exposure to workers who use all types of equipment is likely to be low.

Postapplication (Early-Entry) Workers: Potential exposure to postapplication (early-entry) workers is likely to be low because the herbicide is applied at low rates to short weeds such that foliar dislodgeable residues are likely to be minimal.

3. Risk Assessment

a. Dietary

Given the low acute and subchronic toxicity/pathogenicity potential, the low volume use of the microbial, and the probable lack of residues on the treated crops, the Agency concluded that the potential risk to human infants, children and adults, and to mammals from dietary exposure is expected to be minimal.

b. Occupational and Residential

This microbial is considered an acute Toxicity Category III herbicide on the basis of primary eye irritation studies. It was classified as a Toxicity Category IV microbial on the basis of acute dermal and acute inhalation studies. It shows no potential for dermal sensitization and no hypersensitivity incidents were reported (see **Table 1)**.

Handlers: Occupational risk is likely to be minimal because of the low toxicity, and the potentially low to moderate exposure of handlers exposed to this microbial herbicide.

Postapplication workers: Risk to postapplication (early-entry) workers is also expected to be low because of the low toxicity profile of this pesticide. A Restricted-entry Interval (REI) of 4 hours is required

for *C.g.a.* ATCC 20358 It is recommended that during that interval early-entry workers can conduct postapplication activities if they wear long sleeve shirt, long pants, socks, and shoes.

The proposed precautionary product labeling for a low acute/subchronic toxicity microbial as recommended and required in **Section V** of this RED document will adequately mitigate the minimal risks to all categories of workers.

c. Food Quality Protection Act Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the setting of tolerances. In determining whether a tolerance meets the new safety standard, Section 408(b)(2)(C) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) also required EPA to apply an additional 10-fold uncertainty (safety) factor unless reliable data demonstrate that the additional factor is unnecessary to protect infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess the exemptions from tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources, including drinking water, as well as from non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider the potential cumulative effects of the pesticide for which the exemption from tolerance is being sought as well as other substances that have a common mechanism of toxicity.

Because *C.g.a.* ATCC 20358 has food uses, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

In determining whether a safety factor different from the additional 10-fold factor is or is not appropriate for assessing risks to

infants and children, EPA considers all reliable data and makes a decision using a weight of evidence approach taking into account the completeness and the adequacy of the toxicity database.

Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

The general population may be exposed to naturally occurring *C.g.a* ATCC 20358, as a plant pathogenic fungus, with low or no specificity for animals and man. The pesticidal use is not expected to increase exposure to this microorganism above the naturally occurring levels of the fungus. The Agency considers the toxicity database, together with the low volume use and the removal of the pesticide during processing, sufficient to perform a risk assessment for this mycoherbicide. To date, none of the active ingredients of the microbial pesticides registered by the Agency have required subchronic or chronic exposure studies. Also, for food uses of the microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children. The results of testing done with *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 agree with this conclusion. For this mycoherbicide, no toxicity or signs of disease were observed in dogs studied under subchronic test conditions (see **Subchronic Toxicity**).

Effects on the Immune and Endocrine Systems

The active ingredient is a microorganism. No known metabolite that acts as an "endocrine disrupter" is produced by this microorganism. The submitted toxicity/pathogenicity studies in the rodent indicated that the intact immune system was able to process and clear the active microbial ingredient, as expected, with challenge from non-pathogenic micro-organisms.

Potential for the Transfer of the Pesticide to Drinking Water

C.g.a ATCC 20358 is a naturally occurring plant pathogen. Although the potential exists for some minimal amount of the applied microorganism to enter ground water or other drinking water sources, the amounts present would in all probability be undetectable or at least several orders of magnitude lower than those levels tested for safety. Also, drinking water is not screened for this fungus as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to the microbe through drinking water. Therefore, the Agency considers the potential

of significant transfer of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 to drinking water is minimal to nonexistent.

Cumulative Exposure From Multiple Routes Including Oral and Inhalation

Skin would primarily be a route of exposure for mixer/loader applicators. Unbroken skin is a natural barrier to microbial invasion of the human body. The only way in which skin could be a significant route for exposure would be if the skin were cut, or the microbe were a pathogen with mechanisms for entry through or infection in the skin, or if metabolites were produced that could not be absorbed dermally. Since the submitted intravenous study demonstrated no adverse effects, even cut skin should not pose a risk to health via entry of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 into the body.

Inhalation would be the primary route of exposure for mixer/loader applicators. Because the pulmonary study showed no adverse effects, the risks anticipated for this route of exposure are considered minimal.

Oral exposure would occur primarily from eating treated raw agricultural commodities but minimal risk is expected because residues of the active ingredient are not likely to be present after washing, processing, and cooking treated food, and the acute oral toxicity/pathogenicity study indicates no concern at limit doses.

Risks posed by Potential Residential, School or Daycare Exposure

No residential, school or daycare uses currently appear on the label, which allows use of the mycoherbicide on rice and soybeans for agricultural control of the northern jointvetch (NJV) weed. Therefore, under current agricultural practice, nondietary exposure to sites where children are present is minimal to nonexistent.

C. Environmental Assessment

1. Ecological Toxicity

The database supporting the ecological effects and the environmental fate of *Colletotrichum gloesporioides* f.sp. *aeschynomene* (*C.g.a.* ATCC strain 20358) when used as a microbial herbicide is sufficient to allow reregistration of the pesticide. The potential effects of the microbial on certain non-target

plants which led the Agency to restrict the use of *C.g.a.* ATCC 20358 to AR, LA and MS are discussed in this section (see **Toxicity to plants** and **Endangered species**).

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

The study to establish the acute toxicity to the mallard duck (MRID 00091001) is considered to be acceptable. Mallard ducks which were intubated with a dose of 2 grams (5×10^6 spores) per bird once a week for 5 weeks demonstrated no treatment-related effects (MRID 00091001)

The bobwhite quail study (MRID 00091002) has been found to be supplemental. No adverse effect was observed in bobwhite quail which consumed water containing 2×10^6 spores/ml for 40 days (MRID 00091002).

While the latter study does not meet guideline requirements, the Agency feels that there is sufficient information contained in both studies for the risk assessment. Adverse effects to nontarget avian species would not be expected and further testing for these guidelines is not necessary.

(2) Mammals

Based on toxicity studies submitted for health effects assessment, *C.g.a.* ATCC 20358 is not likely to have acute or subchronic toxic or pathogenic effects on mammals.

(3) Insects

Non-target insect testing was waived because *C.g.a.* is a known plant pathogen and currently available data do not indicate pathogenicity to insects.

(4) Other non-target terrestrial invertebrates

Little, if any, adverse effects were observed in earthworms which consumed approximately 4×10^8 *C.g.a.* ATCC strain 20358 spores over a 40 day period (MRID

00091006). This study was considered supplemental but supports reregistration of the mycoherbicide.

b. Toxicity to Aquatic Animals

Currently available data on this ATCC strain 20358 of *C.g.a* demonstrate that there is no confirmed treatment-related toxicity/pathogenicity effects on aquatic animals.

(1) Freshwater Fish

Both the bluegill (MRID 00091003) and the channel catfish (MRID 00091004) showed no confirmed treatment related effects when they were exposed to 4×10^6 *C.g.a.* ATCC 20358 spores in 60 gallons of water for 30 days. These data, though supplementary, when taken together were sufficient to indicate the likelihood of low or no adverse effects on freshwater fish. Therefore, data requirements in support of acute toxicity to the rainbow trout were waived.

(2) Freshwater Invertebrates

Exposure for three weeks to water containing a spore concentration of 2×10^6 spores/ml *C.g.a.* ATCC strain 20358 produced no treatment related effects in Crayfish (MRID 00091005). This study was considered supplementary.

Data in support of OPPTS Subdivision M Guideline 154A-20 (885.4240 OECD) to evaluate the effects of *C.g.a.* ATCC 20358 on the freshwater aquatic invertebrate, *Daphnia*, were waived because adverse effects would not be expected.

(3) Estuarine and Marine Animals

These studies are conditionally required or required for direct applications of the pesticide to estuarine or marine water or if the pesticide is expected to enter those environments in a high enough concentration to cause concern. The volume of the microbial now in use is very low. Moreover, the fungus has been shown to have a short half-life in water (see **Environmental Fate**). These data requirements were, therefore, waived.

c. Toxicity/Pathogenicity to Plants

(1) Effects on Target Pest

Nontarget plant testing has been satisfied via data from open literature and other information in the referenced submissions (MRIDs 43965601, 43965602). The disease has been reported to be an endemic anthracnose which occurs naturally each year on the leaves of the native populations of its leguminous host, but it rarely kills this herbaceous, hard-seeded annual. It is much more pathogenic on leaves of the original host than on those of alternative crops (Alahakoon *et al*., 1994). Peak levels of the pathogen occur as the weed matures when seeds become infected as pods are shed. In addition to seed infection, the fungus may overwinter as mycelium in dead stems in natural weed colonies. Infected weed debris, a source of primary inoculum, is destroyed in agricultural lands by tillage practices that return the plant refuse to the soil where it is colonized and assimilated by saprobes (G.E. Templeton, *et. al.*, 1979).

The original testing demonstrated that ATCC strain 20358 only affected certain members of the genus to which northern jointvetch belonged (*Aeschynomene*). Although *C.g.a.* ATCC 20358 is endemic to the rice growing regions of Arkansas, and to a much lesser degree, in Mississippi and Louisiana, the fungal spore carryover from season to season is not sufficient to control the NJV. Thus, annual applications of *C.g.a.* ATCC 20358, as registered, or other pest control measures are necessary for control of NJV.

(2) Effects on Nontarget Species

The species *Colletotrichum gloeosporioides* is a ubiquitous plant pathogen with a wide host range (see **Product Identity and Characterization**). In addition to northern jointvetch, the target weed of the sole registered microbial, the following crops are affected by this species of pathogen:

Pea, Olive, Nutmeg, Papaya, Statice, Grape, Guava, Mango, Pepper, Strawberry, Rubber, Clove, Okra, Apple, Tomato, Rambutan, Lavatera species, Cocoa, Conifer Seedlings, Muscadine Grape, Blackberry, Blueberry, Banana Fruit, Lesser

Yam (*Diosorea esculenta*), Water Yam (*Diosorea alata*), Soybeans, Betel Nut Palm, Avocado, Citrus, Peach & Pecans, Wild Oats (*Clidemia hinto*) [Weed], Bitter Gourd, Round-Leaved Mallow (f. sp. *malvae*) [Weed], St. Johns Wort [Weed], Velvet Leaf (f. sp. *malvae*) [Weed], *Stylosanthes guianesis* & *Stylosanthes scabra*, Water Primrose [pest].

(3) Effects of the Actual Strain, ATCC 20358, on Nontarget Plants

In spite of the wide host range of *Colletotrichum gloeosporioides*, the actual host range of this specific strain of *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC strain 20358, is undoubtedly much more narrow.

Some adverse effects of this strain, *C.g.a.* ATCC 20358, were observed on certain pea and soybean varieties in the *Leguminosae* family. These hosts were not tested during the initial registration process, but have recently been the subject of plant inoculation tests (MRIDs 43965601, 43965602). On the basis of the data provided, peas were the only significant agronomic species affected and the exposure of soybeans to the mycoherbicide is not likely to be an environmental hazard.

While *C.g.a.* ATCC strain 20358 did reduce seed germination of soybeans in glass culture plates, infested sand and soil did not affect soybean seed germination (Cerkauskas, 1988). The Agricultural Resources Environmental Indicators (AREI) Updates: Seeds (1995, No. 4) indicates that the majority of soybean seeds planted in Arkansas and the majority of the U.S. is not pretreated with pesticide. Thus, most of the soybean seeds are not protected by a fungicide seed treatment and the potential for fungal infestations of soybeans prior to germination exists. However, since infested sand and soil did not affect soybean seed germination, a hazard to soybeans in the field does not appear to exist.

(4) Genetic Stability and Potential Pathogenicity

Genetic stability affects the potential pathogenicity of *C.g.a.* ATCC strain 20358 on a wider range of hosts.

Individual isolates of *Colletotrichum gloeosporioides* have a very restricted host range. Those isolates which share the same host range are genetically discrete and can be sexually compatible. Alternatively, recombination can occur between strains that are pathogenic to distantly related hosts (MRIDs 43965601, 43965602).

With regards to *C.g.a.* ATCC strain 20358, the sexual state is probably very rare and produces few viable ascospores, as discussed under **Product Identity and Characterization**. It has also been shown to be stable and homogenous by pathogenicity and DNA analysis. Although Cerkauskas' paper demonstrated the latent infection of soybean by this strain, *C.g.a.* ATCC strain 20358 appears quite stable genetically. Thus the potential for selection of a more virulent strain due to carryover of strain 20358 populations from year to year and mating with other *C. gloeosporioides* strains appears to be minimal.

2. Environmental Fate

Environmental fate data are required since adverse effects to nontarget plants have been observed in laboratory/greenhouse studies. Most of the environmental fate data in support of *C.g.a.* ATCC strain 20358 were submitted and evaluated in 1982 (Agency Ecological Effects Review, J. Tice, 1982). Additional literature and pre-publication literature reports have been submitted and evaluated for reregistration.

a. Environmental Fate and Transport

Literature reports (some submitted under MRID No. 43965602) suggest that *C.g.a.* ATCC strain 20358 is spread by wind and splashing rain, frogs, grasshoppers and northern jointvetch seeds. In high density rice fields the dispersal of *C.g.a.* ATCC 20358 per rain event was shown to be about 1.5 meters. Frog, grasshopper, and seedborne dispersal were not quantified (MRID 43965602). However, based on the data, the organism still appears to be limited in its ability to spread in the environment.

In Yang and TeBeest's 1994 paper regarding distribution and grasshopper transmission of northern jointvetch anthracnose in rice, they indicate that the natural occurrence of the disease is much greater than observed in a survey done in the early 1970s (MRID 43965602). However, the authors speculate that this was due to frequent use of

C.g.a. ATCC strain 20358 as a mycoherbicide in the survey area. They further stated that despite the high incidence in the survey, disease severity was low in most fields. Natural dispersal mechanisms may not spread inoculum from one patch to other distant patches efficiently enough to provide high levels of natural infections early in the season. This was made evident by the patchy and uneven distribution of disease and the low disease severity in individual fields.

Cerkauskas, in his 1988 paper regarding latent colonization by *Colletotrichum* species, has reported the phenomenon of latent colonization of soybean tissue by *C.g.a.* ATCC 20358. This strain was recovered on symptomless plants after surface-disinfestation with bleach and subsequent treatment with paraquat. Thus, dispersal of *C.g.a.* ATCC strain 20358 may not be limited to sites where disease is observed.

However, after application to soybeans and rice, no spores were isolated from either raw agricultural commodity. Infested host plant debris buried in the soil for more than 8 weeks under field conditions did not yield any colony forming units. After application, fungus spores remain airborne for a period of less than 5 minutes (MRID 00091007).

(1) Degradation

Laboratory tests indicated that the fungus can survive in field water for at least 90 days. However, the population numbers declined continually and the survival rate in field water was much lower than sterile water. This suggested microbial degradation/ predation. Irrigation water assayed after aerial application of the fungus at label rates contained less than 1 colony forming unit/ml. Further studies demonstrated a short half life of the fungal spores in the aquatic system. Thus, appreciable build up of the fungal spores in water after application is not anticipated (Agency Ecological Effects Review, J. Tice, 1/29/82).

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

(1) Exposure and Risk to Nontarget Terrestrial Animals

C.g.a. is a well-known plant pathogen, endemic to areas where northern jointvetch occurs. From the above review of the data submitted, the Agency has concluded that *C.g.a.* ATCC strain 20358 is not likely to cause adverse effects to mammalian, avian, aquatic and insect species.

(2) Exposure and Risk to Nontarget Aquatic Animals

The potential risk of aquatic animals exposed to this microbial is likely to be low because this RED limits the use sites to three states only: Mississippi (MS), Arkansas (AR), and Louisiana (LA). There are only two target crops, rice and soybeans, in these states. Less than 1 percent of the rice under cultivation in Arkansas is expected to be treated with the microbial (Spradley, J. Ples *et al*., 2-CA-95). Only a few growers in Arkansas have reported their use of the pesticide. Moreover, the organism appears to be limited in its ability to spread in the environment and has a short half-life in the aquatic system. Therefore, the total environmental residues which will be available to aquatic nontarget animals is likely to be very low. Consequently, the potential risk to non-target aquatic animals, such as freshwater fish, freshwater invertebrates, and estuarine and marine animals is likely to be minimal.

(3) Exposure and Risk to Nontarget Plants

The primary risks are to 1) crops other than soybeans and rice planted in the field and 2) plants outside of the treated field. *Colletotrichum gloeosporioides* f. sp. *aeschynomene* is a potential pathogen of certain species within the pea family. Provided peas are not planted subsequent to soybeans or rice treated with this microbial, the use of this pesticide should pose minimal risk to nontarget plants including endangered species.

(4) Endangered Species

C.g.a. ATCC strain 20358 is not likely to cause adverse effects to endangered mammalian, avian, aquatic and insect species. Several endangered species within the *Leguminosae* may be at risk if the pesticide is used in states other than AR, LA and MS. Price's Potato-Bean, an endangered legume found in Mississippi, is susceptible to *C.g.a.* infection. However, this endangered legume is not found in or around rice or soybean production areas. A list of the at-risk endangered species is on file and should be consulted in the event of additional registrations.

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 previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing the active ingredient *Colletotrichum gloeosporioides f. sp. aeschynomene* (*C.g.a.*) ATCC 20358. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC 20358 for use in Arkansas, Louisiana and Mississippi. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of *C.g.a.*, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of *C.g.a.* ATCC 20358 and to determine that this active ingredient can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing *C.g.a.* ATCC 20358 as the active ingredients are eligible for reregistration as specified in this RED. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the 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 all uses of *C.g.a.* ATCC 20358 are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to

support the registration of products containing *C.g.a.* ATCC 20358, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients *C.g.a.* ATCC 20358, the Agency has sufficient information on the health effects of *C.g.a.* ATCC 20358 and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that *C.g.a.* ATCC 20358 products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants, children or to the general population from aggregate exposure to *C.g.a.* ATCC 20358. Therefore, the Agency concludes that products containing *C.g.a.* ATCC 20358 for all uses described herein are eligible for reregistration and use in Arkansas, Louisiana and Mississippi.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC 20358, as described in this RED document, are eligible for reregistration and use on rice and soybeans in Arkansas, Louisiana and Mississippi.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for *C.g.a.* ATCC 20358. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Considerations

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA did not, however, amend any of the existing reregistration deadlines in section 4.

In determining whether a tolerance meets the new safety standard, section 408(b)(2)(C) directs EPA to consider information concerning the exposure of infants and children to pesticides in food, available information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met; these factors include the consideration of available information on the cumulative effects of the pesticide for which a tolerance is sought as well as other substances that have a common mechanism of toxicity and consideration of available information on the aggregate exposure levels of the population and of major subgroups of the population to the pesticide and related substances.

EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

2. Tolerance Reassessment

There is an existing food tolerance exemption for residues of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* (40 CFR § 180.1075) on rice grain and soybeans. EPA has reassessed this exemption from tolerance as

required by FIFRA § 4(g)(2)(E) and considers these reassessed exemptions from tolerances to be qualifying federal determinations under FFDCA § 408(n)(2).

3. Endangered Species

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.

4. Labeling Rationale

C.g.a. ATCC 20358 is to be applied to rice and soybean, which are agricultural use sites under the scope of the Worker Protection Standards (WPS) 40 CFR § 170 and PR Notices 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)", and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7". These label revisions include Personal Protective Equipment (PPE) based on the acute toxicological profile, the method of application and the volume of use of the microbial pesticide.

For this low toxicity microbial the reduced Restricted-entry Interval (REI) of four hours is applicable according to PR Notice 95-3, "Reduction of Worker Protection Standard (WPS) Interim Restricted Entry Intervals (REIs) For Certain Low Risk Pesticides".

To avoid potential phytopathogenicity to peas and certain non-target plants, the Agency is requiring the following limitations on the use of this microbial pesticide. *C.g.a.* ATCC 20358 can be used only in Arkansas, Louisiana and Mississippi where the target pest, NJV, is endemic and peas are not grown. Also, peas must not be treated with *C.g.a.* ATCC 20358 and must not be planted in rotation to crops treated with *C.g.a.* ATCC 20358.

For details of these required label amendments, the Personal Protective Equipment (PPE) and the Restricted-entry Interval for limited use of the sole registered product, Collego™, see Section V under **Labeling Requirements**.

5. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Spray Drift Task Force completes their studies, submits data, and the Agency evaluation is completed, there may be further refinements in spray drift management practices.

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

While there is currently no registered Manufacturing-Use Product, the generic data base supporting the reregistration of *C.g.a.* ATCC 20358 for the above eligible uses has been reviewed and determined to be substantially complete, except for the following standard confirmatory data requirements:

1. Guideline 151A-15 OPPTS (885.1500 OECD): Certification of Limits. The registrant must provide information to certify that the limits are within the standards required by the Subdivision M Guidelines.

In the event of a change in the manufacturing process or reformulation of the sole registered product, the registrant must submit the relevant data required by the Subdivision M Guidelines and the 40 CFR.

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 D, the Product Specific Data Call-In Notice.

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

a. Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

For *Collego*™ the Personal Protective Equipment (PPE) recommended by the WPS are: long sleeved shirt, long pants, socks, and shoes for the mixer/loader and applicator. In addition the mixer/loaders should wear a dust/mist filtering respirator MSHA/NIOSH approval number prefix TC-21C. Early entry workers should wear long sleeved shirt, long pants, shoes and socks for postapplication activities during the four (4) hour Restricted-entry Interval (REI).

b. Other

1. Since *C.g.a.* ATCC 20358 has been shown to have a wider host range than the target weed, modify the directions for use by replacing "***Collego*** is a selective postemergent mycoherbicide which is a specific biological weed control agent." to read "***Collego*** is a postemergent mycoherbicide which is a biological weed control agent."

2. Add the statement "Do not apply to peas".

3. In the Crop Rotation section of the directions for use, modify the statement "Food, feed and forage crops may be sown in ***Collego***-treated fields immediately after harvest of rice or soybeans." to read "Any food, feed and forage crops **except peas** may be sown in ***Collego***-treated fields immediately after harvest of rice or soybeans. Peas may be planted following the harvesting of a non-***Collego***-treated crop."

4. At the beginning of the Directions for Use section, add the statement "**THIS PRODUCT MAY ONLY BE APPLIED IN THE STATES OF ARKANSAS, LOUISIANA & MISSISSIPPI.**"

5. Insert the current EPA registration and EPA Establishment numbers on the front panel.

c. Spray Drift Labeling

To avoid potential pathogenicity to peas via spray drift, the following language must be placed on each product label for products that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- **Volume** - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- **Pressure** - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- **Number of Nozzles** - Use the minimum number of nozzles that provide uniform coverage.

- **Nozzle Orientation** - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- **Nozzle Type** - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the

field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known

habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

C. Existing Stocks

Registrants 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.

The Agency has determined that registrants may distribute and sell *Colletotrichum gloeosporioides* f. sp. *aeschynomene* ATCC 20358 products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A REPORT

Case 4103[Colletotrichum gloeosporioi] Chemical 226300[Colletotrichum gloeosporioides spores]

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. /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												
RICE											Use Group: AQUATIC FOOD CROP	
Flooded area treatment, Postemergence, Fixed-wing aircraft	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Flooded area treatment, Postemergence, Helicopter	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Flooded area treatment, Postemergence, High volume ground sprayer	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Flooded area treatment, Postemergence, Low volume ground sprayer	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
											Use Group: TERRESTRIAL FOOD+FEED CROP	
High volume spray (dilute), Postemergence, High volume ground sprayer	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Low volume spray (concentrate), Postemergence, Fixed-wing aircraft	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Low volume spray (concentrate), Postemergence, Helicopter	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Low volume spray (concentrate), Postemergence, Low volume ground sprayer	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
SOYBEANS (UNSPECIFIED)											Use Group: TERRESTRIAL FOOD+FEED CROP	
High volume spray (dilute), Postemergence, High volume ground sprayer	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Low volume spray (concentrate), Postemergence, Fixed-wing aircraft	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		
Low volume spray (concentrate), Postemergence, Helicopter	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS		

APPENDIX A REPORT

Case 4103[Colletotrichum gloeosporioi] Chemical 226300[Colletotrichum gloeosporioides spores]

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 Max. Dose	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)											
SOYBEANS (UNSPECIFIED) (con't)				Use Group: TERRESTRIAL FOOD+FEED CROP (con't)							
Low volume spray (concentrate), Postemergence, Low volume ground sprayer	FM?	NA	7.57 billion CGAS A	*	NS	NS	NS	NS	NS	NS	

APPENDIX A REPORT

Case 4103[Colletotrichum gloeosporioi] Chemical 226300[Colletotrichum gloeosporioides spores]
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LEGEND
444444

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

FM?	: FORM NOT IDENTIFIED

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"
CGAS	: Colletotrichum gloeosporioides f. sp. aeschynomene spores

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Colletotrichum gloeosporioides f.sp. aeschynomene 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 *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC strain 20358

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
885.1100	Chemical Identity	All	83879; 84480; 43965601; Weidemann et al., 1988; D.O. TeBeest, 1988.
885.1200	Start. Mat. & Mfg. Process	All	83879, 43965601
885.1300	Formation of Unintentional Ingredients	All	84340, 84578
TIER I TOXICOLOGY			
885.3050	Acute Oral Toxicity/Pathogenicity	All	84551, 84552, 84553, 84568, 99072
870.1200	Acute Dermal Toxicity - Rabbit/Rat	All	84554, 99073
885.3150	Acute Pulmonary Toxicity/Pathogenicity	All	84555, 84556, 84557
885.3200	Acute Intravenous - Toxicity/Pathogenicity	All	98376?
870.2400	Primary Eye Irritation - Rabbit	All	84558, 84559, 84560, 99075
885.3400	Hypersensitivity Incidents	All	None reported

Data Supporting Guideline Requirements for the Reregistration of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC strain 20358

REQUIREMENT		USE PATTERN	CITATION(S)
TIER II TOXICOLOGY			
885.3600	Subchronic tox/pathogenicity[1]	All	84340, 84578
NON-TARGET ORGANISMS - TIER I			
885.4050	Avian oral pathogenicity/toxicity - bobwhite quail	ABD	00091002
885.4050	Avian oral pathogenicity/toxicity - mallard duck	ABD	00091001
885.4200	Freshwater Fish toxicity/pathogenicity - trout	ABD	Waived
885.4200	Freshwater Fish toxicity/pathogenicity - bluegill	ABD	00091003, 00091004 (channel catfish)
885.4240	Freshwater Invertebrate toxicity/pathogenicity	ABD	00091005
885.4280	Estuarine and Marine animal - toxicity/pathogenicity	ABD	Waived

[1] These studies were not required by the new guideline requirements, but were submitted for registration of the pesticide. They are reported here to demonstrate the low subchronic toxicity of the mycoherbicide.

Data Supporting Guideline Requirements for the Reregistration of *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC strain 20358

REQUIREMENT		USE PATTERN	CITATION(S)
885.4300	Nontarget plant studies	ABD	43965601, 43965602; P. W. Alahakoon et al., 1994; R.F. Cerkauskas, 1988; C. R. Cisar et al., 1994; G. E. Templeton et al., 1979.
885.4340	Nontarget insect testing	ABD	Waived
885.4380	Honey bee testing	ABD	Waived

OCCUPATIONAL/RESIDENTIAL EXPOSURE

All Occupational Exposure data requirements were waived based on the low toxicity profile of this active ingredient.

RESIDUE CHEMISTRY

All residue chemistry data requirements have been waived because of the agricultural patterns of use and the potential lack of residues on treated crops, which are exempt from the requirements of a tolerance for this microbial

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, <u>all of the following three criteria must be clearly met</u>:

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 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 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,

Janet L. Andersen, Ph. D., Director
Biopesticides and Pollution
Prevention Division

DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing *Colletotrichum gloeosporioides* f.sp. *aeschynomene.*

This Generic 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 Colletotrichum gloeosporioides f.sp. aeschynomene. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this *Colletotrichum gloeosporioides* f.sp. *aeschynomene* Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Colletotrichum gloeosporioides f.sp. aeschynomene are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Colletotrichum gloeosporioides f.sp. aeschynomene are needed. These data are needed to fully complete the reregistration of all eligible Colletotrichum gloeosporioides f.sp. aeschynomene products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Shanaz Bacchus at (703) 308-8097.

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

Shanaz Bacchus, Regulatory Action Leader
Microbes and Plant Pesticides Team
Biopesticides and Pollution Prevention Division (7501W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460
RE: *Colletotrichum gloeosporioides* f.sp. *aeschynomene*

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 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 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.

Attachment 4. List of Registrants sent this DCI (Insert)

The following is a list of available documents for *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC 20358 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 Phil Hutton at (703)-308-8260.

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 *Colletotrichum gloeosporioides f.sp. aeschynomene* ATCC strain 20358.

The following documents are part of the Administrative Record for *Colletotrichum gloeosporioides* f.sp. *aeschynomene* ATCC strain 20358 and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the 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