United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA738-R-98-004 March 1998

Reregistration Eligibility Decision (RED)

Bacillus thuringiensis

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 0247, which includes the active ingredient *Bacillus thuringiensis*. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this microbial pest control agent, 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 also includes 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, William R. Schneider, at (703) 308-8683, or send eMail to schneider.william @epamail.epa.gov

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,** if available for that study.

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

Microbial Pesticides:
Bacillus thuringiensis

LIST D

CASE 0247

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BACILLUS THURINGIENSIS REREGISTRATION ELIGIBILITY DECISION TEAM

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Use Profile

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Registration Eligibility Document, team leader

William R. Schneider, Ph.D.	Biopesticides & Pollution Prevention Division

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
μg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPCA	Microbial Pest Control Agent
MPI	Maximum Permissible Intake

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable 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.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the group of microbial pesticides registered as *Bacillus thuringiensis*. This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. *Bacillus thuringiensis* is a group of similar bacteria that act as insecticides which are used on growing agricultural crops, harvested crops in storage, ornamentals, bodies of water, and around the home to control various groups of insects, depending on the particular toxins produced by the specific isolate of *Bacillus thuringiensis*. The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and therefore, all uses are eligible for reregistration. In addition to the toxins that are active against the insect pests, *Bacillus thuringiensis* may produce undesirable toxins. To mitigate risks of potential toxicity to the public and/or non target species from these toxins, the Agency is requiring continuation of the production batch quality control testing that originally appeared in the tolerance exemption and is requiring the reevaluation and standarization of the manufacturing process for each registered technical grade of the active ingredient. In addition, several label changes are required for all *Bacillus thuringiensis* microbial products. The method for determining percent active ingredient has been standardized. The revised percent active ingredient, a statement of explanation, and the specific toxins responsible for the pesticidal activity must now be included on the labels of all *Bacillus thuringiensis* products.

Before reregistering the microbial pesticide products containing *Bacillus thuringiensis*, the Agency is requiring certain product specific data (product analysis and acute toxicity), a revised Confidential Statement of Formula (CSF) and revised product labeling be submitted within eight months of the issuance of this document. After reviewing these data and revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

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.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of the microbial pesticide, *Bacillus thuringiensis*. The document consists of six sections. Section I is the introduction. Section II describes *Bacillus thuringiensis*, 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 *Bacillus thuringiensis*. Section V discusses the reregistration requirements for *Bacillus thuringiensis*. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

This Reregistration Eligibility Decision covers the group of bacterial products (considered as pesticidal active ingredients) classified as *Bacillus thuringiensis*. *Bacillus* is a genus of rod-shaped bacteria that produce not more than one endospore per cell and the sporulation is not repressed by exposure to air, have a gram-positive cell wall, and are aerobic or facultatively anaerobic. The species *thuringiensis*, in the genus *Bacillus*, is distinguished by the production of one or more protein parasporal crystals in parallel with spore formation. The parasporal protein crystals are delta endotoxins that are generally toxic to a variety of insects. Some isolates of *Bacillus thuringiensis* produce other toxins that, in some cases, may contribute to the insecticidal activity.

The regulatory decisions described in this Reregistration Eligibility Decision document, particularly those involving labeling changes, tolerance reassessment, and manufacturing processes, will apply to all microbial products registered as a *Bacillus thuringiensis*. When additional generic and/or product specific data are needed to support 1984 and earlier registrations, the data will be described in the data call-in attached to this document. Data will be called in, when required, for post-1984 registrations by means of notifications sent directly to registrants.

! Common Names and OPP Chemical Codes*:

Microbial Pesticide Name: *Bacillus thuringiensis* (all subspecies)
OPP Chemical Code: 006400
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *israelensis*
OPP Chemical Code: 006401
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki*
OPP Chemical Code: 006402
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *aizawai*
OPP Chemical Code: 006403
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *tenebrionis*
OPP Chemical Code: 006405
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* BMP123
OPP Chemical Code: 006407
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* EG2424
OPP Chemical Code: 006422
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* EG2371
OPP Chemical Code: 006423
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* EG2348
OPP Chemical Code: 006424

Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *aizawai* GC-91
OPP Chemical Code: 006426
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* EG7673
OPP Chemical Code: 006448
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* M200
OPP Chemical Code: 006452
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* EG7841
OPP Chemical Code: 006453
Microbial Pesticide Name: *Bacillus thuringiensis* subspecies *kurstaki* EG7826
OPP Chemical Code: 006459

* In the internal file numbering system, EPA has grouped several of the earlier *Bacillus thuringiensis* registrations under the same OPP Chemical Codes. The *Bacillus thuringiensis* registrations issued after the Registration Standard was published have all been assigned separate OPP Chemical Codes. To maintain consistency, The Agency intends to assign new Chemical Code numbers to each active ingredient that was formerly assigned to a previously-used chemical code. This internal renumbering will not affect any opportunity to share data from one registration to another if scientifically justified.

! Trade Names:

Vectobac, Dipel, Biobit WP, Biobit FC, Skeetal FC, Foray, Futura, Javelin, Bactospeine, Bactimos, M-one, Thuricide-HPC, Larvo-BT, Trident, Ditera, Novodor, Xentari, BMP 123, Condor, Cutlass, Foil, Agree, Raven, Able, Crymax

! Basic Manufacturers:

Abbott Laboratories
Chemical & Agricultural Products Div
1401 Sheridan Rd
D-28R, Bldg A1
North Chicago, IL 60064

Becker Microbial Products, Inc.
9464 NW 11th St
Plantation, FL 33222

Ecogen, Inc.
2005 Cabot Blvd West
Langhorne, PA 19047

Novartis Crop Protection
PO Box 18300
Greensboro, NC 27419-8300
(Note: All Novartis Bt products have recently been transferred.)

Thermo Trilogy
7500 Grace Drive
Columbia, MD 21044-4098

Troy Corporation
8 Vreeland Rd
Florham Park, NJ 07932-0955

B. Use Profile

The following is information on the currently registered uses with an overview of

use sites and application methods. A detailed table summarizing the use by site for ***Bacillus thuringiensis*** is in Appendix A.

Type of pesticide: Insecticide (microbial pest control agent)

Use sites: Terrestrial food and non-food crops, aquatic food and non-food crops, greenhouse food and non-food crops, forestry, domestic outdoor, indoor stored product use. Based on available pesticide survey usage information for the years of 1987 through 1996, an average of about 1.4 million base acres of traditional agricultural crops are likely treated with Bacillus thuringiensis (B.t.) annually. A reasonable upper bound for possible acres treated would be about 2.1 million acres. An additional 30,000 (50,000 likely maximum) acres of nursery and greenhouse plants and cut flowers and greens are treated annually. B.t. is also applied for mosquito and black fly control on an average of approximately 1 million acres (1.5 million likely maximum) and for use in forests and parks, mostly for gypsy moth control. The forest and park average use is 750,000 acres (1.5 million likely maximum). Base acres are those treated at least once. Some crop acreage is treated more than once annually.

Agricultural sites with a large number of base acres treated are corn, cotton, grapevines and leafy vegetables. Crops with a high percent of the total U.S. crop treated include artichokes (90 + %), blackberries (50%), raspberries (30%), celery (46%), spinach (40%), and cabbage (39%). The remaining usage is primarily on fruits and vegetables. Areas with the largest usage are California, the Pacific Northwest (Oregon and Washington), and Florida.

Target Pests: Lepidoptera, coleopteran and dipteran insects

Formulation Types Registered: Water Dispersible Granule, Dry Flowable, Aqueous Suspension, Granule, Technical Powder, Dust, Wettable Powder, Emulsifiable Suspension, Aqueous Flowable, Bait, Oil Flowable.

Methods of Application: Hand sprayer; water treatment by aerial or ground equipment; soil application by drip or overhead irrigation systems; foliar application by aerial, conventional ground or hand-held equipment and center-pivot irrigation systems; sprayer or sprinkler cans.

Use Practice Limitations: Restricted Entry Intervals (REIs) of 4- 48 hours for agricultural uses; direct water application is not to be applied directly to treated, finished drinking water reservoirs or drinking water receptacles; certain terrestrial uses are limited to terrestrial use only due to potential aquatic hazard.

C. Estimated Usage of Pesticide

The table in Appendix A summarizes the best estimates available for the pesticide uses of *Bacillus thuringiensis*. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

D. Data Requirements

The December, 1988, Registration Standard for *Bacillus thuringiensis* required submission of studies on characterization data. These data were required to enable EPA to reclassify registered strains into groups of strains with similar characteristics. In addition, data was requested which included studies on product analysis, nontarget organisms, environmental fate, and residue analysis to support the uses listed in the Registration Standard. This additional data was not required to be submitted within the time frames indicated in the Registration Standard if the company wished to share data between different strains or wished to utilize data already submitted to the Agency. In this case, the timeframe for submissions would begin once the Agency has determined whether sharing of data is warranted or whether testing performed prior to the Registration Standard was done on strains sufficiently similar to strains currently in registered pesticide products. Based on information from the scientific literature published subsequent to the Registration Standard, the Agency believes that decisions on data sharing and strain similarity should be based on the similarity of delta endotoxins and other toxic/synergistic components contributing to the pesticidal activity of the particular strain of *Bacillus thuringiensis*. Furthermore, the Agency now has sufficient information to simplify the registration requirements for isolates of *Bacillus thuringiensis*. As a result, many of the toxicity/pathogenicity and ecological effects tests are eligible for data waivers.

The submitted data plus data from the literature, which was not available at the time of the data call-in for the registered products, has shown the Agency that testing a laboratory-grown culture of the active ingredient as specified by 40 CFR 158.740 is not reliable to detect the presence of certain undesirable toxins that may be produced by *Bacillus thuringiensis* because their synthesis appears to depend on unpredictable aspects of the fermentation process. Thus, one reliable method to detect these undesirable toxins is to test each production batch. Production batch testing to detect some of the undesirable toxins, as well as to detect contamination by pathogenic bacteria, has been required under the tolerance exemption, 40 CFR 180.1011, and was extended to all products in the Registration Standard, of December, 1988. Since 1988, the Agency has identified a new concern for the heat labile exotoxins that are toxic to *Daphnia*, but the Agency has no information on whether the current battery of production batch tests will detect these. The Agency does believe that the presence of heat labile exotoxins should be minimized in products (see section IV(B)(2)(b)). *In lieu* of requiring a *Daphnia* test on each production

batch, this Registration Eligibility Document specifies that registrants optimize and control their manufacturing process sufficiently to prevent production of significant amounts of these heat labile exotoxins. Accordingly, each new manufacturing process must be tested by a *Daphnia* study as an indicator of the heat labile exotoxin levels produced under those conditions. This will assure that heat labile exotoxin levels will not exceed the levels used by the Agency in its risk assessment. Appendix B summarizes these data requirements.

E. Regulatory History

An isolate of *Bacillus thuringiensis* was first registered in the United States in 1961 for use as an insecticide. At that time, the 7th edition of Bergey's Manual of Determinative Bacteriology (1957) did not recognize any subdivisions of *Bacillus thuringiensis*. Later, other isolates of *Bacillus thuringiensis* were discovered to contain differently shaped protein toxin inclusion bodies (delta endotoxins) which affected different insects. Thus, the 8th edition of Bergey's Manual of Determinative Bacteriology (1974) subclassified *Bacillus thuringiensis* into 11 varieties based on the serotype of antigens found on the flagella, and the latest edition, Bergey's Manual of Systematic Bacteriology, Vol 2 (1986) acknowledged a larger number of these varieties but recommended they be called subspecies. Thus the isolates of *Bacillus thuringiensis* registered prior to 1984 were grouped under the following subspecies names: *Bacillus thuringiensis* subspecies *kurstaki*, *Bacillus thuringiensis* subspecies *israelensis* and *Bacillus thuringiensis* subspecies *aizawai*. Others, such as *Bacillus thuringiensis* subspecies *tenebrionis*, were registered later.

The Agency no longer groups new isolates under the subspecies name because it is now known that the delta endotoxin genes, which generally reside on transferable genetic elements (plasmids) can be readily moved from one isolate to another, regardless to which subspecies they belong. Therefore, isolates registered since 1989 have been registered as individual active ingredients. Furthermore, some of the delta endotoxins from *Bacillus thuringiensis*, when produced by genetic sequences inserted into other bacteria or plants, have also been registered separately. However, this Reregistration Eligibility Document includes genetically manipulated delta-endotoxins only when they are contained in *Bacillus thuringiensis* bacteria. The primary scientific issues addressed by this document involve the exotoxins that may be produced by *Bacillus thuringiensis*; issues which are not at all relevant to other kinds of organisms engineered to contain the delta-endotoxin genes.

A Data Call-In was issued in conjunction with a Registration Standard in December, 1988, (#540/RS-89-023) for *Bacillus thuringiensis* requiring additional data for Product Analysis, Toxicology, and Nontarget Organisms. This Reregistration Eligibility Decision is based on an assessment of data which were submitted in response to the Registration Standard.

III. SCIENCE ASSESSMENT

A. Product Analysis Assessment

1. Identification of Active Ingredients

a. Product Identity

For a new isolate to be classified in the group of bacteria called *Bacillus thuringiensis* it must be a gram positive, aerobic or facultatively anaerobic, rod shaped bacterium containing a crystalline insecticidal protein (delta-endotoxin). Historically, flagellar antigen serotype analysis was used to classify individual *Bacillus thuringiensis* subspecies. For example, all *Bacillus thuringiensis* subspecies *aizawai* strains have a flagella antigen of serotype H7; the serotype for *Bacillus thuringiensis* subspecies *israelensis* is H14; *Bacillus thuringiensis* subspecies *kurstaki* is 3a3b and *Bacillus thuringiensis* subspecies *tenebrionis* is 8a8b. However, genetic engineering techniques now allow genetic material encoding the delta-endotoxin insecticidal protein to be moved among subspecies to give different host spectrum ranges. Thus, the Agency will no longer use the subspecies taxonomic unit as a primary differential characteristic of the species. The Agency will consider each new strain (a pure culture of descendants of a single isolation) of *Bacillus thuringiensis* as a new active ingredient. However, its similarity to currently registered strains/isolates of *Bacillus thuringiensis* may allow the toxicology and ecological effects data for those registered active ingredients to support the new registration. Identification of the delta-endotoxins produced by each strain will be useful to users of these products in pesticide resistance management. On request by the registrant, the Agency may allow a certain amount of genetic variation, intentional or unintentional, from the recorded characteristics of the registered strain if documented well enough to perform an incremental risk assessment. This type of variant might be handled through a change in the confidential statement of formula (CSF), and, if the changes involve characteristics of delta-endotoxins or other chemical substances that contribute to the toxicity to the target pest, may warrant a modification to the label .

The Registration Standard for *Bacillus thuringiensis*, published in 1988, required nine kinds of characterization data in an attempt to provide an identity profile for each active ingredient. The following five, out of the nine, kinds of product identity data subsets (McClintock, J.T., C.R. Schaffer, J.L. Kough, & R.D. Sjoblad (1995) Relevant Taxonomic Considerations for Regulation of *Bacillus thuringiensis*-Based Pesticides by the U.S. Environmental Protection Agency. *In* T-Y Feng, et al. (eds.), "*Bacilus thuringiensis* Biotechnology and Environmental Benefits.", Vol. I, 313-325.) were useful in distinguishing different isolates as follows.

(1) Biochemical and Nutritional Characteristics.

The biochemical and nutritional characteristics (as referenced in Bergey's reference manual) are useful to differentiate *Bacillus thuringiensis* from other similar *Bacillus* species (i.e. *B. cereus*, *B. anthracis*); and can be useful in differentiating closely related varieties of subspecies of the same species.

(2) Antibiotic Susceptibility.

Antibiotic susceptibility determinations also may be useful in characterizing *Bacillus thuringiensis* strains. Each *Bacillus thuringiensis* strain was evaluated for sensitivity against and up to a total of 33 various antibiotics. Very little difference between these strains of *Bacillus thuringiensis* was observed, however these tests are inexpensive and are likely to be useful in differentiating other strains of *Bacillus thuringiensis*. This information is also useful for isolation of these strains from environmental or clinical samples.

(3) Host Range Spectrum.

Historically, *Bacillus thuringiensis* subspecies have been differentiated by their pesticidal activity against species in the following four insect orders: Lepidoptera, Orthoptera, Diptera and Coleoptera. For example, *Bacillus thuringiensis* subspecies *kurstaki* show strong activity against Lepidopteran species and limited activity on Coleopteran and Orthopteran species; *Bacillus thuringiensis* subspecies *israelensis* strains exhibit against Dipteran species with limited activity against Lepidopteran and Coleopteran; *Bacillus thuringiensis* subspecies *aizawai* strains display some activity against Coleopteran species but more activity on Lepidopteran; and *Bacillus thuringiensis* subspecies *tenebrionis* is active on only Coleopteran species. These generalizations were confirmed for these particular active ingredients by these characterization data.

(4) Beta-exotoxin Activity.

Bacillus thuringiensis isolates may also produce a heat stable beta-exotoxin called thuringiensin. The registrants must provide data demonstrating the lack of beta-exotoxin activity in the TGAI. The presence of beta-exotoxin, thuringiensin, has been evaluated by HPLC and/or fly larvae bioassay. Beta-exotoxin was observed in one *Bacillus thuringiensis* subspecies *aizawai* strain under laboratory conditions by demonstrating up

to 24% mortality in the fly larvae assay. This strain may require production batches to be discarded if beta-exotoxin is not eliminated during production and is detected in the batch quality control testing (see section V, Actions Required of Registrants).

(5) Intraperitoneal Assays.

The Intraperitoneal (ip) injection assay of *Bacillus thuringiensis* in mice is used as a quality control measure to demonstrate the lack of mammalian toxicity of the TGAI, but the protocols were not fully validated at the time of the 1988 Registration Standard. The Agency has subsequently found that high dose levels of 10^8 colony forming units (CFU) per animal in this assay often show mortality, even for bacteria generally regarded as nonpathogenic and nontoxic, such as *Bacillus subtilis*. Some of the submitted ip assays showed this mortality at high doses; however, they supported the lack of toxicity at doses of 10^7 and below for these isolates of *Bacillus thuringiensis*.

(6) Other Product Identity Data.

The following four kinds of product identity data subsets requested in the 1988 Registration Standard did not prove to be sufficiently consistent, or lacked useful information for distinguishing strains of *Bacillus thuringiensis*: (1) History of the strain, (2) Insecticidal toxins produced, (3) Plasmid profiles, and (4) Description of crystalline proteins. These data are no longer required for registration, although identification of the insecticidal toxins using more recent methods will be required for proper labeling.

b. Manufacturing Process

The technical grade active ingredient of each *Bacillus thuringiensis* product is generally manufactured using a standard fermentation batch process. The material is then concentrated, and either dried, or mixed with inerts in a liquid form, and then packaged. Registrants have not been required to adhere to a standardized fermentation protocol. However, the Agency is concerned about the potential for the production of various undesirable *Bacillus* exotoxins because their synthesis appears to depend on unpredictable aspects of the fermentation process. Accordingly, through this document the Agency is implementing measures to mitigate these risks. Refer to Section IV, Risk Management and Reregistration Decision, and V, Actions Required of Registrants.

c. Discussion of Formation of Unintentional Ingredients

Generally, fermenter solids and soluables may be present in the final product. An exemption from the requirements of a tolerance has been granted for these (40 CFR 180.1001(c)) and has been reassessed in this document (see section IV(B)(1)). It is the Agency's opinion that quality control procedures, as described in Section V, Actions Required of Registrants, for each product which test for the presence of contaminants such as human pathogens, or undesirable toxins in each batch will adequately mitigate potential risks to humans. Any production batch containing unwarranted levels of contaminants must be discarded.

B. Human Health Assessment

1. Toxicology Assessment

a. Acute toxicity/pathogenicity

The Agency has an historical toxicology data base for *Bacillus thuringiensis* (See 4/23/86 Memorandum from William Woodrow to Arturo Castillo). In addition, a summary review of mammalian toxicity studies was published by Agency reviewers (McClintock, J.T., C.R. Schaffer, & R.D. Sjoblad (1995) A Comparative Review of the Mammalian Toxicity of *Bacillus thuringiensis*- Based Pesticides. Pestic. Sci. 45, 95-105). To date, no known mammalian health effects have been demonstrated in any infectivity/pathogenicity study (Table 1, Acute Mammalian Toxicity for *Bacillus thuringiensis*). The sum total of all toxicology data submitted to the Agency complete with the lack of any reports of significant human health hazards of the various *Bacillus thuringiensis* strains allow the conclusion that all infectivity/pathogenicity studies normally required under 40 Code of Federal Regulations, Part 158, for the use patterns of the registered products be waived in the future as long as product identity and manufacturing process testing data indicated there is no mammalian toxicity associated with the strain. In accordance with standard practices when these studies are waived, label language will be required assuming a Toxicity Category of III.

Table 1: Acute Mammalian Toxicity for *Bacillus thuringiensis*

Guideline Numbers*	Study	Results	Toxicity Category	MRIDs
152A-10 (885.3050)	Acute Oral Toxicity/ Pathogenicity	No adverse toxic effects, infectivity, or pathogenicity seen at doses up to $4.7x10^{11}$ spores/kg.	IV	142733 96520 41046704 96527 42006502 96533 43186101 109492 40951102 246968
152A-12 (885.3200)	Acute Pulmonary Toxicity/ Pathogenicity	No adverse toxic effects, infectivity, or pathogenicity seen at doses up to $2.6x10^{7}$ spores/kg.	IV	96529 41308603 42006503
N/A (generally received under 151A-10, Product Analysis)	Acute Intraperitoneal Toxicity/ Pathogenicity	Non toxic at dose levels below 10^{6} colony forming units (CFU) per animal. No infectivity or pathogenicity.	N/A	66178 41441609 66179 41441611 90207 41441612 90208 41722507 41590302 41826608 41270301 41826609 41308607 41994303 41441504 42750401 41441505 42791301 41441506
152A-15 (885.3400)	Hypersensitivity Incidence Reporting	Two possible incidences reported, neither one was caused by *Bacillus thuringiensis.*	N/A	420271
81-2 (870.1200)	Acute Dermal Toxicity	No dermal toxicity observed at doses up to $4.7x10^{11}$	IV	142734 419943 109493 41412705 404974

* 1988 Subdivision M (1995 Harmonized Guidelines)

Primary dermal irritation (81-5, 870.2500) and primary eye irritation (81-4, 870.2400) were not required under the 1988 Registration Standard because these studies are not required for the TGAI (40 CFR 158.740). These studies are required and will be reviewed for the manufacturing-use and the end-use products. In general, slight to moderate skin irritation has occasionally been observed in product tests, which may be attributed to other ingredients in the formulation, and occasionally eye irritation has been seen in primary eye irritation tests. This is often associated with dry, anhydrous forms of the product and may be due to physical irritation effects as might be caused by sand or drying agents rather than caused by traditional toxicity.

b. Potential for producing *Bacillus cereus* enterotoxins

The Agency is aware of research results that indicate that registered *Bacillus thuringiensis* products may be able to produce the diarrhoeal enterotoxin usually associated with *Bacillus cereus*. A comparison of commercial *Bacillus*

thuringiensis strains with a clinical isolate of *Bacillus cereus* reported that all commercial products tested could produce the diarrhoeal enterotoxin, but at very low levels compared with the clinical isolate (Damgaard, D.H. (1995), Diarrhoeal enterotoxin production by strains of *Bacillus thuringiensis* isolated from commercial *Bacillus thuringiensis*-based insecticides. FEMS Immuno. and Med. Microbiol. 12, 245-250). However, at this time the Agency has no valid evidence to link actual usage of *Bacillus thuringiensis* insecticides with episodes of diarrhoea following ingestion of food. *Bacillus cereus,* and other naturally-occurring toxigenic microorganisms, can normally be found on many kinds of foods, but must multiply in the foods in order to produce the toxins responsible for the symptoms. For this reason, standard food handling practices have been developed to minimize the potential for microbial growth in foods. The *Bacillus thuringiensis* isolates examined in the cited study, above, produce much less diarrheal toxin than the verified toxigenic *Bacillus cereus*. The Centers for Disease Control and Prevention has recently compiled morbidity data for food-borne diseases. For the five year period from 1988 through 1992,the average number of reported outbreaks per year attributed to *Bacillus cereus* is 4.2 and the proportion of the total is 0.64%. No deaths were attributed to these outbreaks. Thus the incidence of reported disease due to *Bacillus cereus* is a very small amount of the total food-borne diseases. For these reasons, the Agency believes that the current uses of *Bacillus thuringiensis* are not likely to contribute to the prevalence of diarrhoea induced by microbial toxins in improperly stored processed food. The Agency will continue to survey the scientific literature, including publications from the Centers for Disease Control on incidents of *Bacillus* food poisoning, and will reexamine these conclusions if valid evidence is found that suggests a direct association between *Bacillus thuringiensis* usage and illness. In addition, the Agency emphasizes that, under section 6 (a)(2) of the Federal Insecticide Fungicide and Rodenticide Act, registrants are required to report any information regarding unreasonable adverse effects following registration and these effects would clearly fall under this provision.

c. Effects on the Immune and Endocrine Systems

The Agency is not requiring information on the endocrine effects of this microbial pesticide at this time; the Food Quality Protection Act has allowed three years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, the Agency has considered, among other relevant factors, available information concerning whether *Bacillus thuringiensis* may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. No known toxins or metabolites of *Bacillus thuringiensis* have been identified to act as endocrine disrupters or immunotoxicants. Therefore, adverse effects to the endocrine or immune systems are not expected.

2. Dietary Exposure and Risk Characterization

The use patterns for *Bacillus thuringiensis* may result in dietary exposure with possible residues of the bacterial spores on raw agricultural commodities. However, in the absence of any toxicological concerns, risk from the consumption of treated commodities is not expected for both the general population and infants and children.

3. Occupational, Residential, School and Daycare Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

The application methods suggest that the potential for eye, dermal and inhalation exposure to mixers, loaders and applicators does exist. The label for *Bacillus thuringiensis* based products may recommend wearing gloves, goggles, and a dust mask or equivalent pulmonary tract covering. However, because of a lack of mammalian toxicity, the risk from occupational exposure is minimal. No additional exposure data or changes in the proposed labels to restrict exposure are recommended at this time.

b. Residential, School and Daycare Exposure and Risk Characterization

No indoor residential, school or daycare uses currently appear on the label. Nondietary exposure to these other use sites could occur where children are present, but the health risk is expected to be negligible due to: (1) The lack of toxicological concerns associated with *Bacillus thuringiensis*, and (2) *Bacillus thuringiensis* has been used as a pesticide for approximately 50 years with no known adverse effects.

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4. Drinking Water Exposure and Risk Characterization

There is minimal potential for *Bacillus thuringiensis* to enter ground water or other drinking water sources, and the bacterium does not proliferate in aquatic habitats. Thus, the potential for drinking water exposure is negligible (section III (C) (3)(e), Environmental Assessment, Water Resources). In addition, the health risk is expected to be negligible due to: (1) The lack of toxicological concerns associated with *Bacillus thuringiensis*, and (2) *Bacillus thuringiensis* has been used as a pesticide for approximately 50 years with no known adverse effects.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations

Particularly Infants and Children

A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for microbial pesticides. Furthermore, the *Bacillus thuringiensis* delta-endotoxins affect insects via a well known mechanism in which they bind to unique receptor sites on the cell membrane of the insect gut, thereby forming pores and disrupting the osmotic balance. There are no known equivalent receptor sites in mammalian species which could be affected, regardless of the age of the individual. Thus, there is a reasonable certainty that no harm will result to infants and children from dietary exposure to residues of *Bacillus thuringiensis*.

6. Aggregate Exposure from Multiple Routes Incl uding Oral, Dermal and Inhalation

Bacillus thuringiensis is a naturally occurring soil bacterium. Anyone coming in contact with the soil is likely to be exposed to this microorganism. Because the health risk is expected to be negligible for oral, dermal, and inhalation exposure routes, as stated above, aggregate exposure by these routes, from naturally-occuring populations in the soil and from the use of pesticidal products, should not pose a threat to human health.

DISCUSSION:

The intraperitoneal injection data and the other product characterization information submitted for reregistration are adequate to corroborate the lack of pathogenicity/toxicity associated with many years of use of the previously registered active ingredients and no further toxicology data are required for previously registered technical grade of the active ingredient. However, acute toxicity studies continue to be part of the data requirements for end-use and manufacturing-use products. These may be new studies or registrants may cite previously submitted studies.

C. Environmental Assessment

There are no outstanding data requirements. The available data from the literature and from the sum total of all submissions is sufficient for the Agency to make an assessment of the environmental effects for the currently registered uses of *Bacillus thuringiensis*.

1. Ecological Toxicity Data

The Agency concludes that toxicity and infectivity risks due to delta-endotoxin effects to nontarget avian, freshwater fish, freshwater aquatic invertebrates, estuarine and marine animals, arthropod predators/parasites, honey bees, annelids and mammalian wildlife will be minimal to nonexistent at the label use rates of registered *B. thuringiensis* active ingredients. However, other toxins which may be produced by *Bacillus thuringiensis* can produce adverse direct toxic effects on nontarget species. Mitigation measures to alleviate these risks are specified in Section IV. Despite the potential for immediate toxic effects on target, and possibly some nontarget, organisms, there is no evidence that *Bacillus thuringiensis* can cause epizooatics in the field. A summary of the studies reviewed for the formal ecological assessment, by delta-endotoxin source, is provided below. Although the studies submitted in support of reregistration are adequate to make an ecological assessment for the intrinsic delta-endotoxin-based properties of *Bacillus thuringiensis*, the Agency's inability to assess the potential for nontarget effects by the exotoxin(s) from the available data has resulted in the following decisions. (1) Based on all available data, the Agency is waiving the ecological effects data requirements for the reregistration of *Bacillus thuringiensis*. (2) The Agency has concluded that there will be no potential for adverse effects on nontarget organisms for *B. thuringiensis*-based products if the the presence of soluble, heat labile exotoxins and beta-exotoxin is minimized. (3) However, the production process must be closely controlled and monitored or certified to assure these exotoxins are not present at levels that can cause significant adverse ecological effects.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

Table 1 *B. thuringiensis* subspecies *kurstaki*

GUIDELINE NUMBER		MRID NUMBER	RESULT
154-16	water fowl (mallard duck)	414434-03	Practically nontoxic after 2.9 g/kg/day for 5 days
		435830-03	Practically nontoxic after 1.6 g/kg/day for 5 days
		416570-08	Practically nontoxic after 2.5 g/kg/day for 5 days
		417511-08	LC_{50} > 1.8 x 10^{10} spores/kg
	upland game bird (bobwhite quail)	414434-04	Practically nontoxic after 2.9 g/kg/day for 5 days
		435830-02	Practically nontoxic after 1.6 g/kg/day for 5 days
		416570-07	Practically nontoxic after 2.5 g/kg/day for 5 days
		417511-09	LC_{50} > 1.8 x 10^{10} spores/kg

Table 2 *B. thuringiensis* subspecies *israelensis*

GUIDELINE		MRID	RESULT
154-16	mallard	414390-05	Practically nontoxic after 3.1 g/kg/day for 5 days
		418427-02	Practically nontoxic after 5 ml/kg/day for 5 days
	bobwhite	414390-06	Practically nontoxic after 3.1 g/kg/day for 5 days
		418427-03	Practically nontoxic after 5 ml/kg/day for 5 days

Table 3 *B. thuringiensis* subspecies *tenebrionis*

GUIDELINE		MRID	RESULT
154-16	mallard	404974-09	No mortality following a single 10 g/kg dose
154-17	mallard	404974-10	No mortality after 3 mg/kg injection

Table 4 *B. thuringiensis* subspecies *aizawai*

GUIDELINE		MRID	RESULT
154-16	mallard	419943-14	LC_{50} > 16.7 g/kg
		419748-05	LC_{50} > 8570 mg/kg
	bobwhite	419943-13	LC_{50} > 16.7 g/kg
		419748-04	LC_{50} > 8570 mg/kg

The avian study results summarized above indicate that *B. thuringiensis* subspecies kurstaki, *B. thuringiensis* subspecies *israelensis*, *B. thuringiensis* subspecies *tenebrionis* and *B. thuringiensis* subspecies *aizawai* are not toxic or pathogenic to the northern bobwhite quail or mallard duck after acute or subacute testing. No additional avian testing is required to support the current *B. thuringiensis* delta-endotoxin reregistration effort. No avian respiratory data were submitted in response to the Registration Standard. Although avian respiratory data had been required by the Standard, these data are not currently needed to support reregistration.

(2) Birds, Chronic

Due to the lack of toxicity/pathogenicity in the acute and subacute testing, avian chronic study requirements were not triggered for *Bacillus thuringiensis* delta-endotoxins.

(3) Mammals

The acute toxicity studies performed on the laboratory rodent with different *Bacillus thuringiensis* subspecies indicate that there are not likely to be any adverse effects on wild mammals. The wild mammal studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals.

(4) Insects

(a) Nontarget Insect Susceptibility

Table 1 *B. thuringiensis* subspecies *kurstaki*

GUIDELINE		MRID	RESULT
154-23	predaceous neuroptera	435830-10	NOEL = 3000 ppm
		416570-11	practically nontoxic at 1 x 10^8 cfu/g food for 9 days; NOEL = 1 x 10^8 spores/g diet
		417511-11	practically nontoxic at 1.2 x 10^8 spores/g diet for 5 days; NOEL > 1.2 x 10^8 spores/g diet
		414434-11	slightly toxic; 10x field rate resulted in 18% mortality
	parasitic hymenoptera	435830-08	practically nontoxic at 3000 ppm of food for 15 days; NOEL = 3000 ppm
		417511-10	practically nontoxic at 2.4 x 10^8 spores/ml diet for 23 days; NOEL > 2.4 x 10^8 spores/ml diet
		416570-13	practically nontoxic at 1 x 10^8 spores/g diet for 30 days; NOEL = 1 x 10^8 cfu/g
	predaceous coleoptera	435830-09	NOEL = 1500 ppm, slightly toxic
		417511-12	practically nontoxic at 2.4 x 10^8 spores/ml diet for 28 days; NOEL > 2.4 x 10^8 spores/ml diet
	arthropod predators and parasites	414434-10	Slightly toxic (6.2 g/L resulted in 12 to 21% mortality)
		414434-09	Toxic; 10x field rate resulted in 100% mortality within 6 days
154-24	honey bee	419835-01	48-hour LD_{50} > 23.2 ug/bee; NOEL = 7.7 ug/bee
		419833-01	48-hour LD_{50} > 23.2 ug/bee; NOEL = 7.7 ug/bee
		435681-01	10-day LC_{50} 118 ug/bee (consumed)
		434917-02	No significant effects noted at 10x field rate

Table 2 *B. thuringiensis* subspecies *israelensis*

GUIDELINE		MRID	RESULT
154-23	green lace-wing larvae	418427-08	16-day LC_{50} > 1.5 x 10^8 cfu/g diet; 16-day NOEL = 2.5 x 10^7 cfu/g
	parasitic hymenoptera	418427-09	30-day LC_{50} > 7.9 x 10^7 cfu/g diet
	predaceous coleopteran	418427-10	9-day LC_{50} > 1.8 x 10^8 cfu/g diet
154-24	honey bee	418427-11	5-day LC_{50} > 7.0 x 10^7 cfu/g diet

Table 3 *B. thuringiensis* subspecies *tenebrionis* (CryIIIA)

GUIDELINE		MRID	RESULT
154-24	Honey bee larvae	441247-02	NOEL = > 100 ppm (100x field conc.) (18 day test)
	Earthworm	441247-01	NOEC = > 100 ppm (120x in 1 kg soil) (14 day test)

Table 4 *B. thuringiensis* subspecies *aizawai*

GUIDELINE		MRID	RESULT
154-23	green lace-wing larvae	419943-21	NOEL = 10,000 ppm
		422453-01	Toxic to larvae at 10x field rate
	parasitic hymenoptera	419943-19	NOEL = 100 ppm
	predatory mite	419748-09	1x field rate resulted in 24% corrected mortality
	predaceous coleoptera	419943-20	NOEL = 10,000 ppm
		429421-01	NOEL = 1566 ppm
154-24	Honey bee	419748-08	Highly toxic; LE_{50} = 15 ppm

With the exceptions of MRIDs 414434-09 and 422453-01, the nontarget insect *B. thuringiensis* subspecies *kurstaki*, *B. thuringiensis* subspecies *israelensis*, *B. thuringiensis* subspecies *tenebrionis* (CryIIIA) and *B. thuringiensis* subspecies

aizawai studies show little to no toxicity or pathogenicity in the tested neuroptera, hymenoptera, coleoptera, arthropod and annelida group indicator species. The above honey bee data indicate a high degree of toxicity for *B. thuringiensis* subspecies *aizawai* and minimal toxicity for *B. thuringiensis* subspecies *kurstaki*, *B. thuringiensis* subspecies *israelensis* and *B. thuringiensis* subspecies *tenebrionis*.

With the exception of honey bee and earthworm testing, all of the nontarget insect studies listed above were graded as supplemental. However, since the Agency currently waives the requirement for nontarget insect data (but not honeybee testing) for registration, no additional data are required. These data are routinely waived because *Bacillus thuringiensis* does not cause epizooatics in the field; it functions by a toxic mode-of-action.

(b) Target Insect Host Range Susceptibility

B. thuringiensis subspecies are differentiated by their pesticidal activity against insects. Generally, only insect species within one order (Lepidoptera, Coleoptera, Diptera, and Orthoptera) are susceptible to a given insecticidal delta-endotoxin protein. Therefore, insect susceptibility results provide general information about the delta exotoxin(s) expressed by a particular *B. thuringiensis* strain.

The submitted data on insect susceptibility to the various *B. thuringiensis* subspecies and varieties are summarized below.

As expected, *B. thuringiensis* subspecies *aizawai* strains displayed minimum activity to Coleoptera (0% to 5%) and Orthoptera (0% to 7.5%) species, some activity against Diptera (0% to 57%), and the greatest activity towards Lepidoptera (100%).

Two of three *B. thuringiensis* subspecies *israelensis* strains exhibited strong activity against Diptera (80% and 100%) with one strain displaying minimum efficacy (20%). Minimum activity against Lepidopteran (2.6%, 13.3%, and 28%), Coleopteran (2.8%, 4%, 10%), and Orthopteran (0% to 6.4%) species was observed for all *B. thuringiensis* subspecies *israelensis* strains.

B. thuringiensis subspecies *kurstaki* displayed the greatest activity against Lepidopteran (95% and 100%) species and limited activity against Coleopteran (0%, 5%, and 17.5%) and Orthopteran (0% and 20%) species. Although three strains displayed strong activity (100%) against *Manduca sexta*, a Lepidopteran species, one strain exhibited minimum activity (7.9%) when bioassayed against the same insect at the same dose level. Two of the seven *B. thuringiensis* subspecies *kurstaki* strains exhibited a range of activity (30% and 100%) against *Aedes*

aegypti, a Dipteran species.

B. thuringiensis subspecies *tenebrionis* was active against Coleoptera (100%) with only slight activity (3.1%) observed against *M. sexta*, a Lepidopteran species.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

Table 1 *B. thuringiensis* subspecies *kurstaki*

GUIDELINE		MRID	RESULT
154-19	trout	414434-06	LC_{50} > 1.5 x 10^{10} cfu/l
		418991-01	Practically nontoxic; Aqueous LC_{50} > 4.9 ul/l and oral LC_{50} > 2.5 nl/g of food
		416570-09	practically nontoxic with an aqueous LC_{50} > 4.6 x 10^{10} cfu/l of dilution water
	bluegill	414434-05	practically nontoxic at 1.5 x 10^{10} cfu/l of dilution water and at 1.2 x 10^{10} cfu/g of food for 32 days

Table 2 *B. thuringiensis* subspecies *israelensis*

GUIDELINE		MRID	RESULT
154-19	trout	414390-08	Aqueous LC_{50} > 8.7 x 10^{9} cfu/l; oral LC_{50} > 1.7 x 10^{10} cfu/g food Slightly toxic
		419801-05	Aqueous LC_{50} > 1.4 x 10^{10} cfu/l; oral LC_{50} > 5.3 x 10^{9} cfu/g food
	bluegill	414390-07	Aqueous LC_{50} > 8.9 x 10^{9} cfu/l; oral LC_{50} > 1.3 x 10^{10} cfu/g food
		418427-04	Aqueous LC_{50} > 1.6 x 10^{10} cfu/l; oral LC_{50} > 4.3 x 10^{9} cfu/g food

Table 3 *B. thuringiensis* subspecies *tenebrionis*

GUIDELINE		MRID	RESULT
154-19	trout	404974-11	Aqueous NOEC = 100 mg/l

Table 4 *B. thuringiensis* subspecies *aizawai*

GUIDELINE		MRID	RESULT
154-19	trout	419943-15	Aqueous LC_{50} > 3.9 x 10^7 cfu/ml; oral LC_{50} > 1.5 x 10^{10} cfu/g food
		419749-03	96-hour LC_{50} > 100 mg/l

With aqueous LC_{50}'s ranging from 8.7 x 10^9 to 4.6 x 10^{10} cfu/l, no toxicity or pathogenicity was evident in the bluegill or the rainbow trout with the *B. thuringiensis* subspecies *kurstaki*, *B. thuringiensis* subspecies *israelensis*, *B. thuringiensis* subspecies *tenebrionis* and *B. thuringiensis* subspecies *aizawai*.

(2) Freshwater Invertebrates

Table 1 *B. thuringiensis* subspecies *kurstaki*

GUIDELINE		MRID	RESULT
154-20	daphnia	414434-07	moderately toxic; 21-day LC_{50} is between 5 ppm and 50 ppm
		418991-02	aqueous LC_{50} > 4.9 ul/l

Table 2 *B. thuringiensis* subspecies *israelensis*

GUIDELINE		MRID	RESULT
154-20	daphnia	414390-09	moderately toxic; 21-day LC_{50} is between 5 ppm and 50 ppm

Table 3 *B. thuringiensis* subspecies *tenebrionis*

GUIDELINE		MRID	RESULT
154-20	daphnia	404974-12	48-hour EC_{50} > 100 mg/l

Table 4 *B. thuringiensis* subspecies *aizawai*

GUIDELINE		MRID	RESULT
154-20	daphnia	419943-16	Highly toxic; 21-day NOEC = 6.4 x 10^{8} cfu/l*
		419748-02	Highly toxic; 21-day estimated EC50 is 0.8-2.7 ppm

With LC_{50} estimates between 5 and 50 ppm, the data indicate that *B. thuringiensis* subspecies *kurstaki* and *B. thuringiensis* subspecies *israelensis* are moderately toxic to daphnia. *B. thuringiensis* subspecies *aizawai* studies (MRIDs 419943-16 and 419748-02) with EC_{50} estimates ranging from 0.8 to 3 ppm, demonstrate a high level of toxicity to aquatic invertebrates. In all cases examined, the toxicity was due to factors other than the delta-endotoxin.

(3) Estuarine and Marine Animals

Table 1 *B. thuringiensis* subspecies *kurstaki*

GUIDELINE		MRID	RESULT
154-21	grass shrimp	435830-07	Practically nontoxic; NOEL > 3.6 x 10^{7} cfu/g food
		418991-03	Aqueous LC_{50} > 4.9 ul/l; oral LC_{50} > 2.5 nl/g food
		415408-02	NOEL > 2.9 x 10^{9} cfu/g diet
	sheepshead minnow	435830-06	Practically nontoxic; aqueous LC_{50} > 4.9 x 10^{10} cfu/l; oral LC_{50} > 3.7 x 10^{7} cfu/g food
		418991-04	Aqueous LC_{50} > 4.9 ul/l; oral LC50 > 2.5 nl/g food
		415408-01	aqueous and oral NOELs are > 2.9 x 10^{10} cfu/ml and > 2.9 x 10^{9} cfu/g, respectively
	copepod	414434-08	NOEL = 500 mg/kg sediment

Table 2 *B. thuringiensis* subspecies *israelensis*

GUIDELINE		MRID	RESULT
54-21	grass shrimp	415404-02	NOEL > 2.0×10^{10} cfu/g food
		418427-06	practically nontoxic; NOEL > 4.2×10^{9} cfu/g food
	sheepshead minnow	415404-01	NOEL > 2.0×10^{10} cfu/g food; oral LC_{50} > 2×10^{10} cfu/g food
		418427-07	practically nontoxic; LC_{50} > 7.2×10^{9} cfu/g food
	copepod	414390-10	NOEL = 50 mg/kg sediment

Table 3 *B. thuringiensis* subspecies *aizawai*

GUIDELINE		MRID	RESULT
154-21	grass shrimp	419943-18	NOEL > 1.6×10^{10} cfu/g food
	sheepshead minnow	419943-17	aqueous LC_{50} > 1.6×10^{10} cfu/g food; oral LC_{50} > 1.6×10^{10} cfu/g food

The estuarine and marine studies performed with *B. thuringiensis* subspecies *kurstaki*, *B. thuringiensis* subspecies *israelensis* and *B. thuringiensis* subspecies *aizawai* do not demonstrate toxicity or pathogenicity to the copepod, grass shrimp or sheepshead minnow.

c. Toxicity to Plants

Although non-target plant toxicity testing was required in the Registration Standard, these data are being waived to support reregistration, because a review of the literature on *B. thuringiensis* and its byproducts indicate no known detrimental effects on plant life, including Terrestrial, Semi-aquatic and Aquatic plant life.

2. Exotoxin Effects

Nontarget organism toxicity has not been found with delta-endotoxins when these are separated from the bacterial growth medium. Specifically, data submitted to the Agency in support of registrations involving plants genetically engineered to express delta-endotoxins show that the pure Cry delta-endotoxin does not exhibit detectable deleterious effects upon nontarget species. A number of *B. thuringiensis* fermentation-based products tested at high dose levels have shown intrinsic toxicity to nontarget organisms. Investigations conducted to determine

what is responsible for the nontarget activity have implicated heat-labile soluble substances contaminating the technical material. Toxic effects have been seen in aquatic invertebrate *Daphnia magna*, the honeybee, some beneficial insects and fish (rainbow trout, bluegill) and wild mammal (mouse and rat) studies, with Daphnia being the most sensitive indicator of toxicity. The impurities are found in the supernatant fluids separate from the delta-endotoxins. The toxicity does not appear to be due to the heat stable beta-exotoxin since autoclaving of the test material renders the supernatant fluids innocuous.

The heat-labile, soluble toxic impurities have thus far been seen in *B. thuringiensis* subspecies *kurstaki*, *aizawai*, and *israelensis*, but may possibly be present in other *B. thuringiensis* varieties. A journal article reports varying levels of at least one soluble exotoxin in all commercial *B. thuringiensis* products tested (H. Damgaard. 1995. FEMS Immunology and Medical Microbiology 12:245-250). *B. thuringiensis* subspecies *aizawai*-based products show the greatest negative effects on nontarget organisms. With *B. thuringiensis* subspecies *kurstaki*, the manifestation of the toxin(s) appears to be at least partly related to production methodology, especially the composition of the growth media used in industrial fermentation.

3. Environmental Fate

Formal environmental fate data is not generally required for microbial pesticides because it is not usually needed and it is difficult to evaluate due to the potential for microbial growth under suitable environmental conditions. However, the behavior of *Bacillus thuringiensis* and related bacilli has been thoroughly studied and is well known. With regard to risk characterization it is known that *B. thuringiensis* toxins degrade rapidly in the phyllosphere as a result of exposure to UV light. *B. thuringiensis* toxins may persist in soil for several months, yet a half-life for typical *B. thuringiensis* products on foliage is approximately 1-4 days. As a result, exposure to most above-ground nontargets organisms is expected to be minimal. *B. thuringiensis* spores, which are nontoxic, may persist in the environment, yet infection of insects from environmental dose levels is minimal.

4. Exposure and Risk Characterization

The available data and published literature indicate that certain *B. thuringiensis* products containing fermentation by-products may cause toxicity/pathogenicity in daphnia, the honey bee and other nontarget beneficial insects. Since *B. thuringiensis* formulations used mainly for terrestrial application are not expected to appear at significant levels in aquatic environments, daphnia sensitivity to these subspecies, (*kurstaki*, *aizawai* and *tenebrionis*) does not pose an aquatic environmental concern, although percautionary labeling may be required

for some uses to ensure that no inadvertent exposure occurs. (However, daphnia studies are a useful screen for terrestrial species and may indicate that additional testing is justified.) In contrast, *B. thuringiensis* subspecies *israelensis* is typically applied to water for mosquito control. As a result, aquatic invertebrate sensitivity is more likely to need to be addressed through label mitigation or by minimization of soluble exotoxin production depending on the production (manufacturing process) testing (see section V(A)(1)(b)).

a. Exposure and Risk to Nontarget Terrestrial Animals

Due to the relatively short insecticidal half-life of *B. thuringiensis* spores and crystals, the exposure and subsequent risk to nontarget wildlife is limited to the time immediately after application. *B. thuringiensis* delta-endotoxin has a direct adverse effect on the target insect orders (Lepidoptera, Coleoptera, Diptera), but susceptibility varies widely among individual species. Any one registered product has a narrow susceptible insect range. In general, published literature shows a temporary reduction in susceptible insect populations during the use period. Beneficial insects and avian and mammalian predators are slightly impacted because of reduced food source. Unlike with alternative chemical pesticides, however, no significant population impact from the use of *B. thuringiensis* products is noted. Furthermore, alternative chemical pesticides may have additional direct adverse effects on birds, mammals, and nontarget insects that are not observed with the use of *B. thuringiensis* products.

(1) Birds

Any effects of *B. thuringiensis* delta-endotoxin on insectivorous birds is due to a reduction of food supply. Birds that feed on caterpillars in the spring will have a reduced number of prey on which to feed for a short time. This forces a switch in the diet. The number of nesting attempts per year may be reduced but not necessarily the number of fledglings per breeding territory in the year of application or subsequent years.

No toxicity or pathogenicity to avian species was seen in the studies submitted in support of this reregistration. Based on these results, no unreasonable risk to avian species is expected from the label uses of the registered *B. thuringiensis* products as long as the production process is properly controlled to prevent nontarget effects due to exotoxins.

(2) Mammals

Mammals, including bats, that feed on susceptible insects might be affected indirectly by reductions in food abundance. This may trigger a switch in diet. Unlike with many conventional pesticides, however, they are not affected by ingestion of moribund insects.

The submitted rodent data and the anticipated low exposure of mammalian wildlife during use of these microbial pest control agents indicates that risk to wild mammals from the label uses of *Bacillus thuringiensis* is minimal to nonexistent as long as the production process is properly controlled to prevent nontarget effects due to exotoxins.

(3) Insects

The use of *B. thuringiensis* delta-endotoxin results in a temporary reduction in susceptible insect populations. In forest uses, there is a significant decrease in numbers of adult and larval Lepidoptera the year of spray, with some reductions extending into the following year in species whose susceptible life stage occurs in the year previous to the appearance of adults. *B. thuringiensis* delta-endotoxin does not, however, affect the overall abundance of arthropods, including beetles, sucking insects such as aphids, leafhoppers, or cicadas and spiders. Direct toxicity to terrestrial insect predators and parasites has not been noted in any studies except some low-level mortality in a laboratory study at doses higher than the recommended label use rates. Any effect on insect predators and parasites appears to be indirect. Field studies on insects other than the target pests and their parasites and predators have found few other species of groups that are affected. Among the susceptible nontarget insect populations that are adversely affected during prolonged *B. thuringiensis* delta-endotoxin applications, recovery takes place soon after cessation of pesticide use.

Direct toxicity to honeybees has been shown for some strains. Exposure to honeybees could occur, but the risk is considered minimal since the pesticide is not considered toxic to adult honeybees at the label use rates. If excessive toxicity is seen in any subsequent product testing, labeling will be required to reduce exposure to honeybees.

Based on these results, the risk to nontarget beneficial insects is expected to be minimal to nonexistent from the label uses of registered *B. thuringiensis* products as long as the production process is properly controlled to prevent nontarget effects due to exotoxins.

b. Exposure and Risk to Nontarget Aquatic Animals

(1) Freshwater Fish

Field studies on *B. thuringiensis* delta-endotoxin contaminated water found no observable effects on resident fish behavior and reproduction. Consumption of delta-endotoxin treated insects has not affected fish to any noticeable degree. Fish that feed on susceptible insects may be affected indirectly by reductions in food abundance. While no toxicity data are available on reptiles and amphibians, *B. thuringiensis* delta-endotoxin is not believed to pose a hazard to these organisms.

No toxicity or pathogenicity was seen in studies submitted in support of this reregistration. As a result, no unreasonable risk to freshwater fish is expected from the label uses of registered *B. thuringiensis* products as long as the production process is properly controlled to prevent nontarget effects due to exotoxins.

(2) Freshwater Invertebrates

B. thuringiensis delta-endotoxin has no appreciable effect on aquatic invertebrates. Field studies have concluded that there is no adverse effect on the abundance and composition of benthic insects. Immature and adult stages of mayflies, caddisflies, dragonflies, damselflies, beetles, midges, and dobsonflies are unaffected. Studies on application of *B. thuringiensis* subspecies *kurstaki* to a forest stream showed no measurable effects on the microinvertebrate community composition or abundance. A brief reduction in populations of mayfly, blackfly and stonefly was noted.

Moderate to high levels of toxicity to daphnia was seen in studies submitted in support of this reregistration. This toxicity was attributed to factors other than delta-endotoxin. However, the risk to daphnids and other aquatic invertebrates is considered minimal to nonexistent based on currently registered label use rates because

the environmental concentration is lower than the observed laboratory effect levels. However, some products may require labeling to reduce exposure if the exotoxin levels can not be sufficiently controlled during the manufacturing process. Based on these results, no freshwater aquatic invertebrate hazard is expected from the label uses of registered *B. thuringiensis* products as long as the production process is properly controlled to prevent higher levels of nontarget toxicity due to the exotoxins.

(3) Estuarine and Marine Animals

B. thuringiensis delta-endotoxin is not expected to have any adverse effects on estuarine and marine animals because of lack of toxicity and exposure. Invertebrates in marine and estuarine ecosystems are not effected by *B. thuringiensis* delta-endotoxin. Published studies report no effect to oysters, mussels, shrimp, and periwinkles.

No toxicity or pathogenicity was seen in studies submitted in support of this reregistration. Based on these results, no unreasonable risk to estuarine and marine animals is expected from the label rate uses of currently registered *B. thuringiensis* products as long as the production process is properly controlled to prevent nontarget effects due to exotoxins.

c. Exposure and Risk to Nontarget Plants

In order for *B. thuringiensis* delta-endotoxin to have a toxic effect, it must be ingested by an organism and exposed to appropriate digestive enzymes at a pH of 9.0 to 10.5. Therefore terrestrial, semi-aquatic or aquatic plants are unaffected by *Bacillus thuringiensis* delta-endotoxin because plants have no mechanism for its ingestion. In addition, the Agency has found no reports of any adverse plant effects caused by any other toxins that might be produced by strains of *Bacillus thuringiensis* despite the extensive pesticidal use of *Bacillus thuringiensis* on plants. An indirect beneficial effect on plants exists as a result of reduction in plant damaging insect populations.

d. Endangered Species

Based on the toxicity and exposure data there will not be a "may effect" situation for endangered mammals, birds, plants and

noninsect aquatic species. All endangered/threatened insect species that are susceptible to the *Bacillus thuringiensis* delta-endotoxins may be adversely affected if exposed.

e. Water Resources

(1) Surface Water

Bacillus thuringiensis occurs naturally in soils worldwide. Applications of *B. thuringiensis* formulations do not increase levels of B.t. in soil, and *B. thuringiensis* spores and crystals persist for a relatively short time. As all soil microbes, *B. thuringiensis* does not percolate through the soil and its presence is confined to the top 10 inches of soil. Thus no ground water contamination concerns are present.

(2) Degradation

The microorganism *Bacillus thuringiensis* (*B. thuringiensis*) is ubiquitous in many soils throughout the world. *B. thuringiensis* is not known as an aquatic bacterium, and therefore is not expected to proliferate in aquatic habitats. Although the potential exists for a minimal amount of the *B. thuringiensis* which is applied to enter ground water or other drinking water sources, the amount would in all probability be undetectable or more than several orders of magnitude lower than those levels which are tested and are considered necessary for safety. Moreover, *Bacillus thuringiensis* is not considered to be a risk to drinking water. Drinking water is accordingly not being screened for *B. thuringiensis* as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Low percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *B. thuringiensis* through drinking water. The protein delta-endotoxin is quickly degraded by soil microorganisms. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

D. Product Performance (Efficacy) Assessment

The Agency has waived all requirements to submit efficacy data for review unless the pesticide product bears a claim to control pests that pose a threat to human health. *Bacillus thuringiensis* is used to control one class of public health pests, i.e. mosquitoes. Product performance data for these uses have not been reviewed for this Reregistration Eligibility

Document because they are conducted on the end-use products. These assessments will be done during product reregistration using the data submitted in response to the Data Call-in associated with this Reregistration Eligibility Document.

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 *Bacillus thuringiensis* active ingredients. 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 *Bacillus thuringiensis*. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of *Bacillus thuringiensis*, 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 *Bacillus thuringiensis* and to determine that *Bacillus thuringiensis* can be used without resulting in unreasonable adverse effects to humans and the environment, providing that an approved manufacturing process be used in order to minimize or eliminate the production of certain toxic unintentional ingredients. The Agency therefore finds that all products containing *Bacillus thuringiensis* as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, and the data identified in Appendix B. Although the Agency has found that all uses of *Bacillus thuringiensis* 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 *Bacillus thuringiensis*, 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 *Bacillus thuringiensis*, the Agency has sufficient information on the health effects of

Bacillus thuringiensis and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that *Bacillus thuringiensis* products, manufactured, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing *Bacillus thuringiensis* for all uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of *Bacillus thuringiensis* are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for *Bacillus thuringiensis*. Where labeling revisions are imposed, specific language is in Section V.

1. Tolerance Reassessment (40 CFR 180.1011 and 40 CFR 180.1001(c))

An exemption from the requirements for a tolerance is currently established for *Bacillus thuringiensis* in or on beeswax and honey and all other raw agricultural commodities when it is applied either to growing crops, or when it is applied after harvest in accordance with good agricultural practices (40 CFR §180.1011). In addition, there is a tolerance exemption (40 CFR 180.1001(c)) for *Bacillus thuringiensis* fermentations solids and/or solubles. The absence of any toxicological/pathogenicity concerns for oral mammalian exposures to *Bacillus thuringiensis* warrants continuation of these exemptions as long as the proper quality control procedures are performed as described in Section V(A)(1)(a) of this Reregistration Eligibility Document.

The specific language in the tolerance exemption, 40 CFR 180.1011, dates from 1971 and does not reflect current taxonomy designations for *Bacillus thuringiensis* isolates. This exemption also includes the quality control specifications for production of *Bacillus thuringiensis* designed to prevent changes in characteristics of the active ingredient, contamination with other microorganisms, and/or presence of detectable levels of beta-exotoxin or other mammalian toxins. These batch testing requirements for production of food use *Bacillus thuringiensis* should also apply to nonfood uses that are not subject to the 40 CFR 1011 tolerance exemption. Therefore, these production testing requirements will now be required under the product analysis data requirements in 40 CFR 158.740(a) and will apply to all registered isolates and all uses of *Bacillus thuringiensis*. An additional benefit of this appearing in only one place

is that if the Agency needs to modify these production batch tests it will only have to change the product analysis requirements for *Bacillus thuringiensis*. To ensure that the production batch tests requirements do not lapse for any products, the Agency will repropose the tolerance exemptions following publication of this Reregistration Eligibility Document.

2. Risk Mitigation

a. Mitigation Measures for Dietary, Occupational and Residential Risk

The potential risk to humans from dietary, non-dietary and occupational exposures of the delta-endotoxins and most of the cellular components of *Bacillus thuringiensis* are considered negligible. However, direct exposure to dry, anhydrous preparations have caused eye irritation effects and those products must require protective eye equipment on the lable to reduce eye exposure.

The Agency is concerned about the potential for the production of various undesirable *Bacillus* exotoxins for environmental effects because their synthesis appears to depend on unpredictable aspects of the composition of the fermentation media or growth conditions. These toxins may be inducible toxins, dependent on the presence of certain chemicals being present to turn on the biochemical pathway to synthesize them, they may be toxic metabolites, requiring the presence of certain chemicals for their synthesis, or their synthesis may depend on physical growth parameters such as temperature. Production batch testing is required in order to detect some of these toxins and to detect contamination by pathogenic bacteria. These quality control testing requirements are described in section V, Actions Required by Registrants. In addition, as described in the Registration Standard, there may be a potential for strains of *Bacillus thuringiensis* to produce beta-exotoxin during subsequent growth in formulated products, despite none being detected in production batches. If the organism is capable of producing beta-exotoxin, the registrant should ensure that none is present in the TGAI and that the product is not put in a medium, including formulated end use products that allows germination and/or growth at any time prior to use. End use product testing options for beta-exotoxin are discussed in section V, Actions Required by Registrants.

b. Mitigation Measures for Nontarget Organisms (Plants an d Wildlife), or Ground and Surface Water Contamination

As described in the environmental assessment, section III(C), there should be no unreasonable adverse effects on nontarget organisms, or ground or surface water contamination concerns, from the delta-endotoxins and most of the cellular components of *Bacillus thuringiensis* when used according to currently approved

label rates. The assessment assumed that the *Bacillus thuringiensis* was produced in accordance with the quality control testing required for each batch produced. However, the Agency has no information on whether the current battery of tests will detect the heat labile exotoxins that have been detected in various non target species tests, but would like to minimize their presence in the product. A *Daphnia magna* test using a 10 day exposure period appears to be the most sensitive assay of those we have reviewed. This test will be required to certify each manufacturing process as described in section V, Actions Required of Registrants.

3. Endangered Species Statement

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

4. Labeling Rationale

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act, section 2(n)(1), the label of each pesticide product must bear a statement which contains the "name and percentage of each active ingredient, the total percentage by weight of all inert ingredients; …". *Bacillus thuringiensis* manufacturers have attempted to meet this requirement by using arbitrary conversions from potency units or by various chemical assay methods as previously specified by the Agency. (Tompkins, et al. 1990). However, because there is no longer any public organization to standardize bioassays and the chemical assays do not adequately reflect potency (see section 6, below), EPA will no longer require these methods to be used to satisfy the legally mandated label statement. Instead, a conversion factor will be used to determine the actual weight per spore-crystal or cell-toxin complex to use in calculating a percent active ingredient for the concentration of the spore-crystals or cell-toxin complexes in the products. In order to avoid misleading the consumer, the label must state that the percent active ingredient

value is not necessarily related to the pesticidal activity of *Bacillus thuringiensis*-based products.

In addition to the percent active ingredient value, above, the label must identify the active ingredient as Bacillus thuringiensis. Furthermore, all toxins and/or chemical substances that are present at levels that are known to contribute to the efficacy of the product against the target pest(s) must be listed on the label. This is particularly important in order to allow consumers to select the most appropriate product for use in conjunction with the plants that express delta-endotoxins derived from Bacillus thuringiensis or with other Bacillus thuringiensis-based microbial pesticides. In addition, the strain identity and a nationally-recognized culture collection accession number must appear in the Confidential Statement of Formula and may be placed on the label.

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 Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

6. Product Performance (Efficacy) Reassessment

The Agency has an established policy that the submission of efficacy data may be waived, unless the pesticide bears a claim to control pests that pose a threat to human health. However, even if the submission of the efficacy data is waived, each registrant must ensure through testing that his products are efficacious when used in accordance with the label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide registered or proposed for registration/reregistration.

Public Health Uses: In this case, the registrants of all *Bacillus thuringiensis* products with label claims to control mosquitoes, blackflies, or other public health pests, are required to either submit/cite product performance (efficacy) data, or delete the label claims for controlling these pests as part of product reregistration.

Public Health and Non-public Health Uses: Because the efficacy of *Bacillus thuringiensis* products may vary greatly from one production batch to another,

each production batch must be analysed for potency. The results of these studies should not be routinely submitted to the Agency for review, but must be available if the Agency requests the the data on a case-by-case basis. The potency (killing power) must be assessed using a bioassay procedure for the following reasons:

Industry has also used chemical analysis methods to quantify the amount of the delta-endotoxins present in their products. However chemical analysis methods do not measure the quality of the toxins which may vary widely in their potency between different production batches. In addition, there are factors other than the delta-endotoxins that contribute to the efficacy of some *Bacillus thuringiensis* products. The spores may germinate and establish an infection secondary to the direct toxic damage. Other toxins, such as the recently-described Vip3A (Estruch, et al., 1996. Vip3A, a novel *Bacillus thuringiensis* vegetative insecticidal protein with a wide spectrum of activities against lepidopteran insects, Proc. Natl. Acad. Sci. USA 93:5389-5394), may have activity similar to, or may be synergistic to, the delta-endotoxins. The genetic control of toxin synthesis may also affect the activity of the toxins, e.g. in some cases the delta-endotoxin is synthesized throughout the growth cycle of the cell rather than during spore formation. None of these factors can be accounted for by the chemical analysis methods.

Industry originally used a bioassay, using a standarized culture of *Bacillus thuringiensis* subspecies *kurstaki* (HD-1) and a standard susceptible insect, *Trichoplusia ni*, to establish the potency which was expressed in International Units. However, the use of the term "international units" may, in some cases, not be appropriate because there is no longer a publicly-available standardized bioassay or standarized cultures. In addition, the proliferation of *Bacillus thuringiensis* isolates that express new types of delta-endotoxins have expanded the range of target organisms so that different insect species may have to be used. In the absence of a public organization to oversee standarization of these assays, industry must be responsible for maintaining appropriate internal standards for these assays. It should be noted that these assays can no longer be relied on to compare one company's products with products from another company.

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

This section specifies the data requirements and responses necessary for the reregistration of manufacturing-use products which, for *Bacillus thuringiensis*, include

additional confirmatory generic data for reregistration of the TGAI. These data requirements apply also to end use products for which there is no manufacturing-use product.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of *Bacillus thuringiensis* for all uses has been reviewed and determined to be substantially complete. Because of potential variation in production batches, confirmatory data are needed to ensure that no unintentional ingredients, e.g. toxins, are present at significant levels. These additional data are specified in Appendix D, the Generic Data Call-In Notice.

a. Qualitity Control Manufacturing Process Data Requirements

Each production batch must be tested by at least the following tests as originally listed in the tolerance exemption, 40 CFR 180.1011. The Agency recognizes that better tests may be developed to detect undesirable toxic contaminants and encourages submission of such tests for evaluation by Agency scientists. If more appropriate tests are found acceptable, the Agency will allow registrants to substitute them for currently required tests or may modify these quality control test requirements for all registrants.

A new manufacturing process must be submitted that includes a description of the qualitity control procedures as follows.

Quality Control Testing Required for each Production Batch: (1) *Bacillus thuringiensis* shall be produced by pure culture fermentation procedures with adequate control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms. (2) Each production batch, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores, or equivalent for asporogenic strains, into each of five laboratory test mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection. ("Evidence of infection or injury" is any indication of either systemic or localized infectivity or toxicity) (3) Production batches shall be free of the *Bacillus thuringiensis* beta-exotoxin when tested with the fly larvae toxicity test ("Microbial Control of Insects and Mites." R.P.M. Bond, et al., p.280ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a *Bacillus thuringiensis* strain which does not produce beta-exotoxin under standard manufacturing conditions or by periodically determining that beta-exotoxin synthesized during the manufacturing process is eliminated by the subsequent

manufacturing process procedure(s). (If the organism is capable of producing beta-exotoxin, the registrant should ensure that none is present in the TGAI and that the product is not put in a medium, including formulated end use products that allows germination and/or growth at any time prior to use.) Some registrants have been authorized to use an HPLC method instead of the fly larvae test. In order to reconfirm the accuracy of Agency records, those registrants must resubmit, or cite, their request to use HPLC and the supporting data to show that the method is at least as sensitive as the fly larvae test.

In addition to the above testing for undesirable components of each production batch, each production batch must be analyzed for potency by bioassay because the efficacy of *Bacillus thuringiensis* products may vary greatly from one production batch to another. The results of these studies should not be routinely submitted to the Agency for review, but must be available if the Agency requests the data on a case-by-case basis.

b. Standarization of Manufacturing Process

Registrants must optimize and control their manufacturing process sufficiently to prevent production of significant amounts of the heat labile exotoxins. The manufacturing process must include the fermentation medium composition and the growth conditions. *In lieu* of requiring a *Daphnia* test on each production batch, as an indicator of the heat labile exotoxin levels, a representative sample of the active ingredient from each manufacturing process is to be tested by a *Daphnia* study incorporating a 10 day exposure period using a maximum hazard dose. If the test shows significant lethality, a dose response *Daphnia* test must be performed to derive an LC_{50}.

A specific, detailed description of the manufacturing process and the *Daphnia* testing must be submitted for approval by the Agency. Further testing or mitigation measures may be required following Agency review (Figure 1).

2. Labeling Requirements for Manufacturing-Use Products

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

> "Only for formulation into an Insecticide for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."

An MP registrant may, at his/her discretion, add one of the following statements

to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA requirements regarding support of such use(s)."

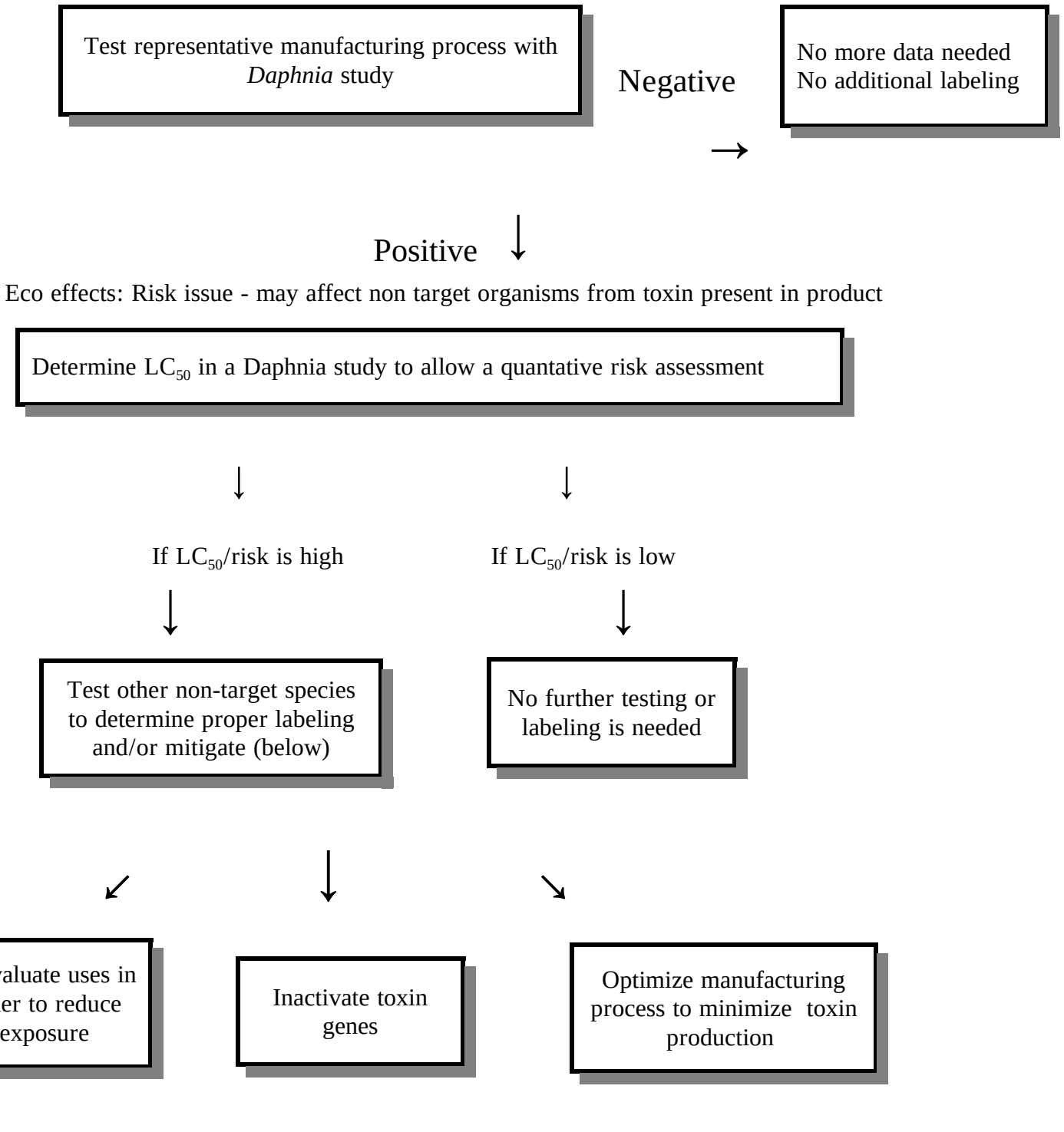
In Addition, for *Bacillus thuringiensis* manufacturing use products, a "point source discharge" is a possibility - where effluent from the manufacturing plant may contain *Bacillus thuringiensis* or toxic fermentation byproducts. The following National Pollutant Discharge Elimination System (NPDES) statement (as outlined in Pesticide Regulation (PR) Notice 93-10 (Reference: PR-93-10)) is required on such products:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NDPES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Further, P.R. Notice 95-1 (Reference: PR-95-01) exempts certain products (i.e., products in containers of less than 5 gallons (liquid), less than 50 pounds (solid, dry weight) and in aerosol containers of any size) from bearing effluent discharge statements specified by P.R. Notice 93-10. P.R. Notice 93-10 still applies to the following kinds of pesticide products that may result in discharges to the waters of the United States or to municipal sewer systems, including but not limited to: (A) all technical grade and manufacturing use products; and (B) end-use products packaged in containers equal to or greater than 5 gallons (liquid) or 50 pounds (solid, dry weight), and registered for industrial preservative, water treatment, other industrial processing uses (such as cooling tower water systems, pulp and paper mill water systems, secondary oil recovery injection water systems, food processing operations, leather tanning, wood protection and textile treatment) and commercial and institutional uses (including, but not limited to, hospitals, hotels/motels, office buildings and prisons).

The exemption of certain containers from the labeling requirements of P.R. Notice 93-10 does not relieve a producer or user of such products from the requirements of the Clean Water Act or state or local requirements.

Figure 1. Testing standardized manufacturing process.



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 and are summarized below.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. In addition to the conventional data requirements, a storage stability study is required for certain end-use products, and, in cases where claims are made for controlling public health pests, product performance studies are required to be submitted.

a. Conventional Data Requirements

Product Analysis data and Acute Toxicology data must be submitted, or cited, to support all manufacturing-use and end-use products. The Acute Toxicology data consists of an acute oral toxicity study in the rat, an acute dermal toxicity study, and acute inhalation toxicity study in the rat, a primary eye irritation study in the rabbit, and a primary dermal irritation study. On a case-by-case basis, the Agency may accept waivers for some of these data requirements based on the known toxicity of the ingredients or other arguments provided by the registrant. For example, the Agency may accept a proposal to require goggles when the product may be predicted to cause adverse eye effects as for a dry hydroscopic powder or silica containing formulations. In other cases, a particular study may not be needed because the formulations contain well characterized ingredients that are not likely to present an unreasonable risk.

b. Storage Stability Study

The Registration Standard of 1989 asked for a storage stability study for end use products to determine concentrations of beta-exotoxin because the Agency suspected that beta-exotoxin may be formed in certain end use products subsequent to formulation. Many registrants requested waivers because they did not believe their product would support microbial growth.

The Agency considered these requests and we have now established standards for requiring the storage stability studies as follows. A storage stability study will be required for all aqueous products that can support gram positive bacterial growth. If the storage stability studies were already submitted in response to the Registration Standard, they may be cited.

c. Product Performance (Efficacy)

The Agency has waived all requirements to submit efficacy data for review unless the pesticide product bears a claim to control pests that pose a threat to human health. Thus, product performance data must be submitted or cited for *Bacillus thuringiensis* products that have mosquito, blackfly, or other public health pest control uses. This product performance data requirement may be satisfied by submission of a properly controlled potency test as discussed in section IV(B)(6) of this Reregistration Eligibility Document.

2. Labeling Requirements for End-Use Products

a. Percent Active Ingredient

Because there currently is no accountable way to factor potency into the required label statement, EPA will no longer require potency as part of the legally mandated label statement. The following method will be used to provide a conversion factor for the weight of an "active" unit for use in converting the product concentration to satisfy the FIFRA requirements: A laboratory culture of the bacterium is grown in a soluble medium, such as trypticase soy broth, and when the culture sporulates and lyses, the number of spores per milliliter (ml) is determined by standard bacteriological counting methods. In the case where the *Bacillus thuringiensis* toxins are being produced in a non-spore forming bacterium, the number of vegetative cells per ml would be determined. Then concentrate the spore-crystal or cell-toxin complex by centrifugation or filtration, dry the concentrate, and determine the weight in grams of the dry spore-crystal or cell-toxin complex. The percent active ingredient by weight for *Bacillus thuringiensis*-based products must then be calculated for label purposes by determining the number of spores or cells per gram of product, multiplying that value by the weight of an individual spore-crystal or cell-toxin complex, and multiplying that value by 100.

100 x conversion factor x Number of units/gram in the product = % active ingredient by weight The conversion factor is "Weight (grams)/unit" and a unit is either one spore-crystal complex or one cell-toxin complex.

In order to avoid misleading the consumer, a statement must appear on the label below the percent active ingredient value: "There is no direct relationship between intended activity (potency) and the Percent Active Ingredient by Weight."

b. Active Ingredients

In addition to the percent active ingredient value, above, the label must identify the active ingredient as *Bacillus thuringiensis*. Furthermore, all toxins and/or chemical substances that are present at levels that are known to contribute to the efficacy of the product against the target pest(s) must be listed on the label. This is particularly important in order to allow consumers to select the most appropriate product for use in conjunction with the plants that express delta-endotoxins derived from Bacillus thuringiensis or with other Bacillus thuringiensis-based microbial pesticides. In addition, the strain identity and a nationally-recognized culture collection accession number must appear in the Confidential Statement of Formula and may be placed on the label. At this time, the Agency recommends that the delta-endotoxins be classified in accordance with the standards being developed by the *Bacillus thuringiensis* delta-endotoxin nomenclature committee which was set up in 1993 in order to update the nomenclature originally devised in 1989 by Hofte and Whiteley (Microbiological Reviews 53:242-255). This new nomenclature is based on the similarities between the full length toxin sequences rather than on the assessment of biological properties. References to this new nomenclature may be found at (1) Revision of the Nomenclature for the Bacillus thuringiensis Pesticidal cry Genes. N. Crickmore, D. R. Zeigler, J.Feitelson, E. Schnepf, B. Lambert, D. Lereclus, J. Baum and D.H. Dean (1995) In: Program and Abstracts of the 28th Annual Meeting of the Society for Invertebrate Pathology. p14. Society for Invertebrate Pathology, Bethesda, MD, and (2) Bacillus thuringiensis delta-endotoxin nomenclature N. Crickmore, D.R. Zeigler, J.Feitelson, E. Schnepf, D. Lereclus, J. Baum, J. Van Rie and D.H. Dean (1997) WWW site: http://epunix.biols.susx.ac.uk/ Home/Neil_Crickmore/ Bt/ index.html. At such time the new nomenclature is validly published and accepted, the Agency may require it to be used for delta-endotoxin classification.

c. Potency Determination

The label for both public health and non-public health uses may include potency statements; however, in accordance with 40 CFR 156.10(a)(5)(ii), the statement must not be false or misleading. See section IV(B)(6) of this Reregistration Eligibility Document for guidance in conducting appropriate tests.

d. 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.

e. Other

(1) A respiratory protection statement must appear on the label for different uses as follows:

(a) ***Agricultural Use Products***

The personal protective equipment (PPE) section must include the statement:

"As a general precaution when exposed to potentially high concentrations of living microbial products such as this, all mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95."

Registrants may add the following engineering control statements to the PPE section if they so choose:

“When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.”

PPE for early entry in the Agricultural Use Requirements box remains unaffected.

(b) ***Non-Agricultural Use Products not Used Around the Home***

Either the PPE section or the precautionary statements of the Hazards to Humans and Domestic Animals section must include the statement:

"As a general precaution when exposed to potentially high concentrations of living microbial products such as this, all mixer/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95."

(c) ***Domestic (Home) Use Products***

Either the PPE section or the precautionary statements of the Hazards to Humans and Domestic Animals section must include the statement:

"As a general precaution when exposed to potentially high concentrations of living microbial products such as this, wear a dust particle mask when mixing or applying this product.”

(2) All commercially applied products with directions for outdoor terrestrial uses must have the following statements in the Environmental Hazards section:

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."

This statement should be preceded by "For terrestrial uses," if the product has aquatic sites in addition to terrestrial, forestry (except aerial application) and/or domestic outdoor uses. This revised statement would then not apply to other general use patterns -- aquatic (e.g., mosquito larvicides or adulticides, aquatic herbicides, piscicides, slimicides, etc.), greenhouse and indoor uses. The "For terrestrial uses," qualifier is not allowed on products which allow aerial application to forests but which have no approved aquatic use sites.

(3) For residential consumer products, the required statement is:

"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."

(4) For direct water application uses, the required statement is:

"Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles."

f. Spray Drift Labeling

The following language must be placed on each product label 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 *Bacillus thuringiensis* 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. Use Sites for the Reregistration of 0247

Bacillus thuringiensis Case #0247 Quantitative Usage Analysis

Site	Acres (000) Grown	Acres Treated (000) Weighted Average	Max	% of Crop Treated Est Average	Weighted Est	Max	States of Most Usage (% of total lb ai # appl used on this site) /year
Blackberries	5	1	2	19%	45%	1.0	
Blueberries	59	4	11	7%	18%	5.4	
Cranberries	29	4	9	13%	32%	1.0	
Raspberries	11	3	11	30%	100%	1.7	
Strawberries	51	8	15	16%	31%	1.0	
Citrus, Other	51	1	2	1%	3%	1.0	CA 100%
Grapefruit	194	0	1	0%	0%	1.3	CA 100%
Lemons	63	0	0	0%	0%	1.0	CA 100%
Oranges	867	21	39	2%	4%	1.0	CA 100%
Apples	572	19	50	3%	9%	1.9	WA MI OH AZ 81%
Pears	78	1	5	1%	6%	1.0	CA CO WA 100%
Pome-Like Fruit, Other	58	3	14	5%	24%	1.2	CA 100%
Avocados	82	1	3	1%	3%	1.0	CA FL
Nectarines	29	10	22	34%	74%	1.0	CA
Apricots	19	4	8	20%	39%	1.0	
Cherries	128	4	8	3%	6%	1.5	WA CA NY 86%
Peaches	212	11	23	5%	11%	1.7	CA 91%
Plums & Prunes	140	8	25	6%	18%	1.2	CA OR 100%
Grapes	825	43	86	5%	10%	1.6	CA 82%
Almonds	429	38	64	9%	15%	1.8	CA 100%
Pecans	488	11	30	2%	6%	1.2	TX OK AL 81%
Walnut	205	2	5	1%	2%	1.1	CA 100%
Vegetables, Bulb	396	16	44	4%	11%	2.0	CA IL 86%
Eggplant	4	1	3	28%	79%	4.2	
Peppers	235	27	45	11%	19%	5.4	FL TX CA 84%
Celery	37	17	24	46%	65%	1.0	
Greens	2	1	0	46%	0%	4.4	AZ MI
Kale	6	0	0	0%	0%	1.0	
Lettuce	268	56	100	21%	37%	2.0	CA AZ FL 85%
Spinach	19	8	16	40%	87%	1.0	
Parsley	2	0	1	15%	66%	1.0	CA
Broccoli	114	22	29	19%	26%	1.1	
Cabbage	85	33	43	39%	51%	1.4	

Site	Acres (000) Grown	Acres Treated (000) Weighted	Est	% of Crop Treated Weighted Est	States of Most Usage (% of total lb ai # appl used on this site)

		Average	Max	Average		Max	/year
Cauliflower	58	13	22	23%	38%	1.9	
Collards	11	4	8	31%	67%	1.0	
Cucumbers	146	11	28	8%	19%	1.0	
Squash	53	1	4	1%	7%	1.0	
Cantaloupes	113	16	32	14%	28%	1.0	
Melons, Honeydew	27	2	6	6%	22%	1.7	
Watermelons	258	11	21	4%	8%	1.0	
Artichokes	9	9	9	93%	100%	1.0	
Asparagus	88	3	9	3%	10%	1.0	
Beets	12	0	1	2%	7%	1.0	CA NY OH OR TX WI .%
Potatoes	1,421	20	45	1%	3%	3.6	RI MA CT VA 85%
Roots/Tubers	244	9	17	4%	7%	3.6	FL TN 91%
Sweet Corn	784	3	6	0%	1%	1.3	MA FL MI NC CA MD 76%
Tomatoes	500	91	171	18%	34%	3.9	FL CA AL 83%
Beans/Peas, Dry	2,181	6	33	0%	2%	1.1	CA FL 100%
Beans/Peas, Green	723	13	23	2%	3%	2.6	FL GA AZ KY 83%
Corn	72,284	151	381	0%	1%	1.1	NE CO OH FL IL 81%
Barley	7,505	1	6	0%	0%	1.0	ND 100%
Oats/Rye	6,133	0	1	0%	0%	1.0	
Rice	2,921	1	2	0%	0%	1.0	LA 100%
Sorghum	11,280	0	0	0%	0%	1.0	
Wheat, Spring	20,799	2	9	0%	0%	1.0	ND 100%
Wheat, Winter	45,854	1	1	0%	0%	1.0	WV 100%
Hay, Other	33,427	0	0	0%	0%	1.0	FL 100%
Pasture	86,960	29	100	0%	0%	1.0	OK 100%
Alfalfa	23,949	54	89	0%	0%	1.0	CA AZ 93%
Peanuts	1,610	2	6	0%	0%	1.0	
Soybeans	62,879	88	275	0%	0%	1.0	MS LA 89%
Sunflower	2,745	3	9	0%	0%	1.0	ND CA 100%
Cotton	12,689	377	787	3%	6%	2.3	AL MS LA TX AR 81%
Sugar Beets	1,415	4	14	0%	1%	1.0	ND 88%
Sugarcane	852	0	0	0%	0%	1.0	FL 100%
Other crops	2,515	16	27	1%	1%	3.2	CA ND 88%
Tobacco	695	32	47	5%	7%	1.4	NC GA FL 89%

Site	Acres (000) Grown	Acres Treated (000) Weighted Average	Est Max	% of Crop Treated Weighted Average	Est Max	# appl/year	States of Most Usage (% of total lb ai used on this site)
Agricultural total	1,350	2,138					
Nursery & Greenhouse	3,717	30	50	1%	1%	1.0	
Woodland	62,825	0	0	0%	0%	1.8	
Water		unknown, probably not significant					
Crp Acres-long term	68,617	1	1	0%	0%	1.0	
Idle Cropland	7,461	0	2	0%	0%	1.4	LA 100%
Landscape maintainance		unknown, probably not significant					
Lots/Farmsteads	49,630	2	4	0%	0%	3.6	NH CA CO LA MN 85%
Public health (mosquito control)		1,250	1,500				
Rights of way		spot treatments, amount unknown					
Structural pest control		unknown, probably not significant					
Non agricultural total		1,283	1,420				
Total	2,632	3,558					

COLUMN HEADINGS

Weighted average--the most recent years and more reliable data are weighted more heavily.
Est Max = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA

Usage data primarily covers 1987 - 1996.

Calculations of the above numbers may not appear to agree because they are displayed as rounded:
to the nearest 1000 for acres treated or lb. a.i. (Therefore 0 = < 500)
to the nearest whole percentage point for % of crop treated. (Therefore 0% = < 0.5%)

0* = Available EPA sources indicate that no usage is observed in the reported data for this site, which implies that there is little or no usage.

A dash (-) indicates that information on this site is NOT available in EPA sources or is insufficient.

* Other/Crop Groups

Bulb Crops include garlic, leeks, and onions.
Citrus, Other includes kumquats, limes, tangelos, and tangerines.
Cucurbits includes cucumber, squash, and pumpkin.
Nut Trees, Other includes chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, pistachios, lychie nuts, and palm.
Pome-Like Fruit, Other includes figs, kiwifruit, persimmons, pomegranates, carambolas, and papaya.
Root and Tuber Crops include red beets, carrots, horseradish, parsnips, radish, rutabagas, sweet potatoes, turnips, and yams.
Other crops include popcorn and rapeseed/canola

SOURCES: EPA data, USDA, and National Center for Food and Agricultural Policy

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0247 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0247 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 *Bacillis thuringiensis*

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
885.1100	Product Identity	All	41439001, 41459403, 41429701, 41435401, 41751101, 42015901, 41441501-31, 41444601-41, 41459401, 41459402, 41459404, 41429601
885.1200	Manufacturing Process	All	41439001, 41459403, 41429702, 41435401, 42080101, 42015901, 41490801-03, 41459401, 41459402, 41459404, 41429602
885.1300	Formation of Unintentional Ingredients	All	41439001, 41459403, 41429703, 41435401, 41751102, 42015901, 41490801-03, 41459401, 41459402, 41459404, 41429603
885.1400	Analysis of Samples	All	41439002, 41880001, 41980101, 41429703, 41939901, 41435402, 41883801, 41751103, 42015901, 41789701, 41653901, 41657002, 41646702, 41429603, 41939901
885.1500	Certification of Limits/Analytical Methods	All	41439002, 41980101, 41429703, 41435402, 41751104, 42015901, 41789701, 41653901, 41657002, 41646702, 41429603

Data Supporting Guideline Requirements for the Reregistration of *Bacillis thuringiensis*

REQUIREMENT		USE PATTERN	CITATION(S)
885.1600	Physical & Chemical Limits	All	41439002, 41503903, 41429704, 41435402, 42080102, 42015901, 41429704, 41653901, 41503902, 41503904, 41429604
TIER I TOXICOLOGY			
885.3050	Acute Oral Toxicity/Pathogenicity	All	waived[1]
885.3150	Acute Pulmonary Toxicity/Pathogenicity	All	waived[1]
885.3200	Acute Intravenous - Toxicity/Pathogenicity	All	waived[1]
885.3400	Hypersensitivity Incidents	All	42027101
NON-TARGET ORGANISMS			
885.4050	Avian oral pathogenicity/toxicity -	ABD	Conditionally waived[2]
885.4200	Freshwater Fish toxicity/pathogenicity - trout	ABD	Conditionally waived[2]

Data Supporting Guideline Requirements for the Reregistration of *Bacillis thuringiensis*

REQUIREMENT		USE PATTERN	CITATION(S)
885.4240	Freshwater Invertebrate toxicity/pathogenicity	ABD	Conditionally waived[2]
885.4280	Estuarine and Marine animal - toxicity/pathogenicity	ABD	Conditionally waived[2]
885.4300	Nontarget plant studies	ABD	Waived[2]
885.4340	Nontarget insect testing	ABD	Conditionally waived[2]
885.4380	Honey bee testing	ABD	Conditionally waived[2]

1. Toxicology studies have been waived based on the sum total of all toxicology studies submitted to the Agency, the scientific literature, and the lack of any reports of significant human health hazards despite considerable exposure from years of use of *Bacillus thuringiensis* products.

2. Nontarget Organism studies have been either waived, or conditionally waived, based on the sum total of all nontarget organism studies submitted to the Agency, the scientific literature, and the lack of any reports of significant adverse effects on nontarget organisms despite considerable exposure from years of use of *Bacillus thuringiensis* products. Because Agency data shows a potential for *Bacillus thuringiensis* to produce exotoxins that can adversely affect nontarget organisms, and the manifestation of these appears to be at least partly related to production methodology, a representative product sample for each specific manufacturing process will be tested by a *Daphnia* test as a screen to rule out excessive exotoxin systhesis. Additional nontarget studies may be required to certify any manufacturing process that results in significant levels of toxicity to *Daphnia*.

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 0181

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 AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A 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. 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 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Reqistrant'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. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

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

Section I	-	Why You are Receiving this Notice
Section II	-	Data Required by this Notice
Section III	-	Compliance with Requirements of this Notice
Section IV	-	Consequences of Failure to Comply with this Notice
Section V	-	Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 -	Data Call-In Chemical Status Sheet
2 -	Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 -	Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
4 -	List of Registrants Receiving This Notice
5 -	Cost Share and Data Compensation Forms

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 ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements).

Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

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

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

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

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose 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 generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

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

b. 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 Reqistrant's Response Form (Attachment 3), 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 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. 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 Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (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, is allowed only if the product bears an amended label.

c. 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 if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. 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:

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

(ii). Every registrant who is the ultimate source of the active ingredient in your product

subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). 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 responding to product specific data requirements.

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 requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not 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.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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 Reqistrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

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

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (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. 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 requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extra-ordinary 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 the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to 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 burden 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 normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 '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, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 (if there are any applicable 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 usually are 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 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 also should 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.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Reqistrant'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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

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 not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 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 low volume pesticides to be only those active ingredients 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 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 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 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:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, 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.

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

(iii) Total direct production cost of product(s) containing the active ingredient 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.

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

(v) 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.

(vi) 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.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, 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 in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient 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.

b. Request for Waiver of Data

Option 9, under Item 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 requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must 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 are not appropriate 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.

2. Product Specific Data

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

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

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

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

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

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

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

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

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

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

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

   i. 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 Reqistrant's Response Form.

ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would 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 also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

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

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms 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, Director
Biopesticides and Pollution Prevention Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - List of Registrants Receiving This Notice
5 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1 Data Call-in Chemical Status Sheet

0247 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have product(s) containing 0247.

This 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 0247. For the Genetic Data Call-In, this attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form, (3) the Requirements Status and Registrant's Form, (4) a list of registrants receiving this DCI, and (5) the Cost Share and Data Compensation Forms in replying to this 0247 Generic Data Call-In. For the Product Specific Data Call-In, this attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form, (4) a list of registrants receiving this DCI, and (5) the Cost Share and Data Compensation Forms in replying to this 0247 Product Specific Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 0247 are contained in the Requirements Status and Registrant's Response. The Agency has concluded that additional data on 0247 are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible 0247 products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic or product specific data requirements and procedures established by this Notice, please contact William R. Schneider at (703) 308-8683.

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

William R. Schneider, Ph.D.
Microbial and Plant Pesticide Branch
Biopesticides and Pollution Prevention Division (7511W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M St S.W.
Washington, D.C. 20460

RE: **0247**

Attachment 2.
Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE FORMS" FOR THE GENERIC AND PRODUCT SPECIFIC DATA CALL-IN

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 3 have been preprinted on the form. Item 4 has been preprinted on the product specific form but must be filled in by the registrant on the generic 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.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, 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 FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS

Generic and Product Specific Data Call-In

Item 1.	**ON BOTH FORMS**: This item identifies your company name, number and address.
Item 2.	**ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.
Item 3.	**ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.
Item 4.	**ON BOTH FORMS:** 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. The number will be preprinted on the product specific form. On the generic form, you must list all technical grade active ingredient and manufacturing use registrations.

Item 5. **ON BOTH FORMS:** Check 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. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and 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. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data 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.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

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

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

Item 8. **ON BOTH FORMS:** 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. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

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

Attachment 3.

Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

3. INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS" FOR THE GENERIC AND PRODUCT SPECIFIC DATA CALL-IN

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

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. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The 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 suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, 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 FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** 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 Reqistrant's Response Form.

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. 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. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	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 Indredient or Pute 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	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** 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.

Option 1. **ON BOTH FORMS:** (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 protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (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-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (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 also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date 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.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite 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.

Option 6. **ON BOTH FORMS:** (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. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

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

Option 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.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that

this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** 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. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled

Attachment 4.
List of Registrants Sent this Data Call-In Notice

LIST OF REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # 0247 Name: *Bacillus thuringiensis*

Company Number	Company Name	Additional Name	Address	City & State	Zip
000004	Bonide Products, Inc		2 Wurz Ave	Yorkville, NY	13495
000016	Dragon Corp.		Box 7311	Roanoke, VA	24019
000070	Sureco, Inc.		10012 N. Dale Mabry, Ste. 221	Tampa, FL	33618
000100	Novartis Crop Protection, Inc		Box 18300	Greensboro, NC	27419
000192	Dexol Industries		1450 w. 228th St	Torrance, CA	90501
000270	Farnam Companies, Inc.		301 W. Osborn Rd	Phoenix, AZ	85013
000275	Abbott Laboratories	Chemical & Agricultural Products Div	1401 Sheridan Rd, D-28R, Bldg A1	North Chicago, IL	60064
000299	C. J. Martin Co		Box 630009	Nacogdoches, TX	75963
000524	Monsanto Co.	Agent for: Monsanto Agricultural Co	700 14th St, N.W. Suite 1100	Washington, DC	20005
000829	Southern Agricultural insecticides, Inc.		Box 218	Palmetto, FL	34220
000869	Green Light Company		P.O. Box 17985	San Antonio, TX	78217
001386	Universal Cooperatives, Inc		P.O. Box 460 7801 Metro Parkway	Minneapolis, MN	55440
002935	Wilbur Ellis Co.		191 W Shaw Ave	Fresno, CA	93704
003342	Cape Fear Chemicals, Inc		Box 695	Elizabeth Town, NC	28337
003772	Bonide Products, Inc	Agent for: Earl May Seed & Nursery L.P.	2 Wurz Ave	Yorkville, NY	13495
005481	Amvac Chemical Corp	Attn: W.F. Millar	2110 Davie Avenue	Commerce, CA	90040
005887	Sureco, Inc.		10012 N. Dale Mabry, Ste. 221	Tampa, FL	33618
006218	Summit Chemical Co		7657 Canton Center Dr	Baltimore, MD 21224	
007401	Voluntary Purchasing Group, Inc		Box 460	Bonham, TX	75418
008329	Clarke Mosquito Control Products Inc		159 N Garden Ave	Roselle, IL	60172
008660	H.R. Mclane, Inc.	Agent For: Pursell Industries Inc	7210 Red Road Suite 206	Miami, FL	33143
010107	Corn Belt Chemical Company		Box 410	McCook, NE	69001
010951	Britz Fertilizers, Inc	Attn: David Britz	Box 60011	Fresno, CA	93794
034704	Cherie Garner	Agent For: Platte Chemical Co Inc	Box 667	Greeley, CO	80632
036208	Loveland Industries, Inc	Scott Baker	Box 1289	Greeley, CO	80632
036488	Ringer Corp.		9555 James Avenue S., Suite 200	Bloomington, MN	55431
042697	Safer, Inc.		9555 James Avenue S., Suite 200	Bloomington, MN	55431
049585	Alljack, Division of United Industries Corp.		Box 15842	St Louis, MO	63114

LIST OF REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # 0247 Name: *Bacillus thuringiensis*

Company Number	Company Name	Additional Name	Address	City & State	Zip
053871	Troy Biosciences, Incorporated		2620 North 37th Drive	Phoenix, AZ	85009
055638	Ecogen, Inc.		2005 Cabot Blvd West	Langhorne, PA	19047
059623	California Dept of Food & Agriculture Pesticide Consultation & Analysis		1220 N Street	Sacramento, CA	95814
060372	City of Stockton	Municipal Utilities Dept	2500 Navy Drive	Stockton, CA	95206
062637	Becker Microbial Products		9464 NW 11th St	Plantation, FL	33322
065247	Calgene, Inc		1920 Fifth St	Davis, CA	95616
067572	Contract Packaging, Inc.		Bldg 1, 4132 U.S. Hwy 278	Covington, GA	30209
068467	Mycogen Plant Sciences		4980 Carroll Canyon Rd	San Diego, CA	92121
069504	Merdian, LLC		5137 14th Ave South	Minneapolis, MN	55417
070051	Thermo Trilogy Corp.		7500 Grace Dr	Columbia, MD	21044

Attachment 5.
Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

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

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

Name of Firm(s)	Date of Offer

Certification:

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

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

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

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

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

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

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

Signature	Date
Name and Title (Please Type or Print)	

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

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)