United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-99-010
September 1999

Reregistration Eligibility Decision (RED)

Triphenyltin Hydroxide (TPTH)

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 which includes the active ingredients TPTH. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1999, contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the 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 pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that, in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. 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 rulemaking that may be required.

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jane Mitchell at (703) 308-8061. Address any questions on required generic data to the Special Review and Reregistration Division representative Loan Phan at (703) 308-8008.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

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

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

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

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

Triphenyltin Hydroxide (TPTH)

LIST A

CASE 0099

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TPTH REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Tara Chand-Goyal	Biological Analysis Branch
John Faulkner	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Nicholas Federoff	Environmental Risk Branch IV
Dirk Young	Environmental Risk Branch IV

Health Effects Risk Assessment

John Doherty	Risk Characterization and Analysis Branch
Catherine Eiden	Chemistry and Exposure Branch
Sarah Levy	Risk Characterization and Analysis Branch
Kelly O'Rourke	Toxicology Branch II

Registration Support Risk Assessment

Cynthia Giles-Parker	Fungicides Branch
Maria Rodriguez	Fungicides Branch

Risk Management

Loan Kim Phan	Special Review Branch
Nancy Zahedi	Special Review Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison
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
IR4	Interregional Research Project No. 4
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
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse 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
ug/L	Micrograms per liter

GLOSSARY OF TERMS AND ABBREVIATIONS

mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
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 © 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

ABSTRACT

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide triphenyltin hydroxide (TPTH). This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. TPTH is an organotin fungicide used on pecans, potatoes, and sugar beets. 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 products are eligible for reregistration. To mitigate risks of potential developmental toxicity and carcinogenicity to workers the Agency is requiring, among other changes, that a pre-harvest interval of 30 days be established for pecan harvesters, and that the registrant conduct new worker exposure studies for ground and aerial/chemigation application of the wettable powder (water soluble packaging) formulation of TPTH. Also, buffer zones from water bodies and reductions in use are being implemented to reduce the potential for TPTH to enter drinking water and to reduce environmental risks to fish, birds, and water resources. Additional data on human health and the environment are being required to confirm the Agency's dietary (drinking water), occupational, and aggregate risk assessment and conclusions.

The registrants have agreed to amend labels reflecting worker and environmental risk mitigation measures for use in the 2000 growing season. However, before fully re-registering the products containing TPTH, the Agency is requiring that product specific data, and revised Confidential Statements of Formula (CSF) be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister TPTH products. Those products that 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 triphenyltin hydroxide (TPTH). The document consists of six sections. Section I is the introduction. Section II describes TPTH, 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 TPTH. Section V discusses the reregistration requirements for TPTH. Finally, Section VI includes the Appendices that support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CHEMICAL OVERVIEW

A. Regulatory History

Triphenyltin hydroxide (TPTH) was registered in the United States in 1971 for use as a fungicide. The 1984 Registration Standard classified TPTH as a Restricted Use Pesticide based on acute and developmental toxicity concerns; imposed label warnings regarding developmental toxicity and potential adverse ecological effects; established a 24 hour re-entry period; required additional data; and announced the Agency's intent to initiate a Special Review of TPTH. In 1985, the Agency issued a Position Document 1 (PD 1) initiating the Special Review of TPTH, based on potential developmental toxicity risk to mixers, loaders and applicators. In 1988, EPA issued a Data Call-In for studies on immunotoxicity, reproductive and inhalation toxicity, and carcinogenicity. EPA also issued a Reregistration Standard Update in 1992 to require additional data for reregistration purposes. The Carcinogenicity Peer Review Committee classified TPTH as a Group B_2 carcinogen (probable human carcinogen) in March, 1992.

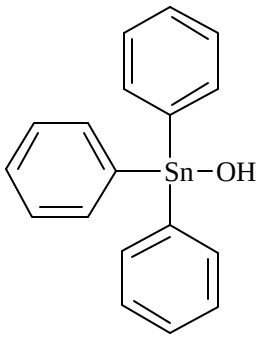
Since the initiation of the TPTH Special Review, the registrants have voluntarily taken actions to reduce worker exposure to TPTH. These actions include deletion of TPTH use on carrots, peanuts and tobacco; requiring closed mixing/loading systems for aerial applications; requiring use of closed cab tractors by applicators of the flowable concentrate formulation; addition of protective clothing requirements to labels; adoption of mechanical transfer systems for liquid formulations; and packaging of the wettable powder formulation in water soluble bags. The registrant also submitted additional data, including a dermal developmental toxicity study and an occupational exposure monitoring study for pecan mixer/loaders and pecan harvesters.

Issues identified in the TPTH Special Review will be resolved in conjunction with this Reregistration Eligibility Decision (RED). Due to voluntary actions by the registrants reducing worker exposure to TPTH, as well as additional data that refine the risk assessment, EPA has determined that the risks of using TPTH are substantially lower than when the Special Review was initiated in 1985. Cancer risks, however, remain, as well as risk to non-target organisms. These remaining risk concerns are addressed in this RED. The RED reflects a reassessment of the current data and use patterns associated with TPTH, and explains further mitigation and data requirements necessary to the determination that current uses of TPTH are eligible for reregistration. Following the TPTH reregistration eligibility decision, the Agency will publish a PD 2 proposing to terminate the TPTH Special Review, based on the conclusions and mitigation outlined in this RED.

B. Chemical Identification

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

Triphenyltin hydroxide



TPTH is a fine white powder with a melting point of 118-120 C, bulk density of 0.2758 g/mL at 25 C, octanol/water partition coefficient (log K_{ow}) of 3.268, and vapor pressure of < $1x10^{-7}$ torr at 25 C. TPTH is practically insoluble in water (0.008 g/L), and is moderately soluble in most organic solvents (acetone 70 g/L; benzene 41 g/L; 1,2-dichloromethane 74 g/L; ether 28 g/L; ethanol 10 g/L; and methylene chloride 171 g/L).

- **Common Name:** TPTH
- **Chemical Name:** Triphenyltin hydroxide
- **Chemical Family:** Organotin
- **CAS Registry Number:** 76-87-9
- **OPP Chemical Code:** 083601
- **Empirical Formula:** $C_{18}H_{16}OSn$
- **Trade and Other Names:** SuperTin®, Pro-Tex®, Photon®, Brestan H®

! **Basic Manufacturer:** AgrEvo; Elf Atochem; Griffin; Agtrol

C. Use Profile

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

For **TPTH**:

Type of Pesticide: Fungicide (non-systemic foliar); Restricted Use Pesticide

Use Sites: Pecans, Potatoes, Sugar beets. No residential, public health, or other non-food uses.

Target Pests: Early and late blight on potatoes, and Colorado potato beetle; leaf spot on sugar beets; scab, brown leaf spot and other diseases on pecans.

Formulation Types Registered: Wettable powder in water-soluble pack; flowable concentrate.

Method and Rates of Application:

Equipment - Ground; aerial; chemigation systems; airblast.

Rates and Timing of Applications:

Crop	Maximum Application Rate (oz ai/acre)	Maximum Applied per Season (oz ai/acre/year)	Maximum number of applications*	Application Intervals (days)
Pecans	6	60	10	14-28
Potatoes	3	12	6	7
Sugar beets	4	12	4	10-14

* Maximum number of applications cannot be applied at maximum application rate for potatoes and sugar beets.

Use Practice Limitations: TPTH is a restricted use pesticide (RUP).

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of TPTH. 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.

The Agency estimates total usage of TPTH in the U.S. is approximately 570,000 pounds of active ingredient (a.i.) per year. The highest crop uses in terms of weight and percent crop treated are on pecans (260,000 lbs a.i., 35% crop treated) and sugar beets (240,000 lbs a.i., 35% crop treated).

The table below summarizes the pesticide's use by site.

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate (ounces ai)			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	oz ai/ acre/yr	#appl / yr	oz ai/ A/appl	
Pecans	490	169	275	35%	56%	262	373	24	4.5	5.4	GA AL TX MS
Potatoes	1410	185	320	13%	23%	66	112	6.4	2.3	2.4	CO NE ID ND AL WA WI MN

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate (ounces ai)			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	oz ai/ acre/yr	#appl / yr	oz ai/ A/appl	
Sugar beets	1477	513	646	35%	44%	241	330	8	2.2	3.4	MN ND
Total	**3377**	**867**	**1241**			**569**	**815**				

COLUMN HEADINGS

Wtd Avg = 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

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.
- to the nearest whole percentage point for % of crop treated.

SOURCES: EPA data (1988-98), USDA (1990-97), and National Center for Food and Agricultural Policy (1992 & 95 data)

III. SUMMARY OF TPTH RISK ASSESSMENT

A. Human Health Risk Assessment (*see* HED revised chapter, September 21, 1999 and attachments)

The Agency conducted a human health risk assessment for the active ingredient TPTH (triphenyltin hydroxide) for the purposes of making a reregistration eligibility decision. In conducting its assessment, the Agency evaluated the toxicological, residue chemistry, and exposure data bases for TPTH and determined that the data are adequate to support a reregistration eligibility decision. The Agency assessed acute and chronic (non-cancer and cancer) dietary risks, and occupational (non-cancer and cancer) risks from the use of TPTH. The Agency also evaluated aggregate risks associated with dietary exposures through food and drinking water.

1. Hazard Characterization

The acute toxicity database indicates that TPTH is moderately to highly toxic via the oral, dermal, and inhalation routes (Toxicity Categories II , II, and I respectively).

Acute Toxicity of Triphenyltin Hydroxide

Guideline No.	Study Type	MRID #(S).	Results	Toxicity Category
81-1	Acute Oral-rat	071364 252512	LD_{50} = 165 mg/kg **%** 156 mg/kg **&**	II
81-2	Acute Dermal-rat	071364	LD_{50} = 1600 mg/kg	II
81-3	Acute Inhalation-rat	071364	LC_{50} =60.3 Fg/L	I
81-4	Primary Eye Irritation	071364	Corrosive	I
81-5	Primary Skin Irritation	071364	Mild Irritant	III
81-6	Dermal Sensitization	Several Studies	Not sensitized in the Buehler assay.	Not considered a sensitizer.

Toxicity Profile of Triphenyltin Hydroxide [1]

Study Type	MRID No.:	Results
21-day dermal - rats (1985)	00142880 258230 (Accession Number)	Systemic: NOAEL > 20 mg/kg/day. No systemic effects at highest dose tested. Dermal: NOAEL < 5 mg/kg/day. Local irritation.
Subchronic feeding - rats (1986)	00157771 261754 (Accession Number)	NOAEL < 0.33 mg/kg/day: decreased IgG antibodies. At 7.63 mg/kg/day: decreased body weight and gain and food consumption.
Subchronic feeding - mouse (1986)	00157952 261753 (Accession Number)	< 0.75 mg/kg/day (lowest dose tested): decreases in IgA and IgM antibodies. At 3.78 mg/kg/day: decreased adrenal weight and at 19.46 mg/kg/day: decreased ovary weight and increased liver weight.
Subchronic feeding - guinea pig (1960)	00086467	NOAEL < 2.5 ppm (estimated 0.1 mg/kg/day) (lowest dose tested): decreased leucocyte counts.
Subchronic feeding -dog		No valid study. Refer to chronic feeding study below.
Subchronic inhalation - rats (1989)	41017701	NOAEL = 0.00034 mg/L. LOAEL = 0.002 mg/L: deaths and lung and respiratory irritation and edema.
Chronic feeding - dog (1987)	40285501	NOAEL and LOAEL > 0.562 **%** and 0.624 **&** mg/kg/day. No effects at the highest dose tested.

Study Type	MRID No.:	Results
Chronic feeding - rat (1970)	00080390 099050 (Accession Number)	NOAEL = 0.1 mg/kg/day; LOAEL = 0.25 mg/kg/day: decreased leucocyte counts.
Chronic/carcinogenicity -rat (1989)	41085702	NOAEL < 0.3 mg/kg/day (lowest dose tested) in **%** and 0.4 in **&** mg/kg/day: deaths in females and decreases in immunoglobulin. **Positive for pituitary and testicular tumors.** Dose levels considered adequate.
Carcinogenicity -mouse (1989)	41087501	NOAEL < 0.85 mg/kg/day (lowest dose tested) based on decreased in immunoglobulins. Particularly IgA and IgM in either males or females. **Positive for hepatocellular adenomas and carcinomas.** Dose levels considered adequate.
Developmental toxicity - (1985) rat representative study, one of several studies	257402 (Accession number)	Maternal toxicity: NOAEL = 1 mg/kg/day; LOAEL = 2.8 mg/kg/day: decreased body weight and food consumption. Developmental toxicity: NOAEL = 2.8 mg/kg/day; LOAEL = 8 mg/kg/day: decreased fetal weight and increased sternebrae unossified. (Typical response at this dose level.) At 8 mg/kg/day may have smaller litter size and less viable fetuses in other studies or poor pup survival.
Developmental toxicity - rabbit/oral (1987)	40104801	Maternal toxicity: NOAEL = 0.1 mg/kg/day; LOAEL = 0.3 mg/kg/day: decreased body weight gain. Developmental toxicity: NOAEL = 0.3 mg/kg/day; LOAEL = 0.9 mg/kg/day: lower fetal body weight and increased incidents of hyoid body and/or arches unossified.
Developmental toxicity - rabbit/dermal (1993) (dermal)	42909101	Maternal and developmental toxicity: NOAEL and LOAEL > 3 mg/kg/day. No effects at highest dose tested.
Reproductive toxicity - rat (1986)	264667 to 264676 (Accession number)	Parental toxicity: NOAEL = 0.925 mg/kg/day; LOAEL = 2.5 mg/kg/day decreased body weight. Developmental toxicity: NOAEL = 0.25 mg/kg/day; LOAEL = 0.925 mg/kg/day: decreased litter size, liver and spleen weights.
Gene Mutation- Ames test (1981)	00125264	Not mutagenic in *S. tymphimurium* or *E. Coli* ± metabolic activation.
Mouse lymphoma assay (1985)	00152226	Borderline positive in the presence of S-9 mix but negative in absence of S-9.

Study Type	MRID No.:	Results
Cytogenetics - human chromosome aberrations (1985)	00152223	Positive for inducing chromosome aberrations in presence of metabolic activation (± S-9). Study demonstrates clastogenic property of TPTH.
Recombinant assay (Convers) (1985)	00155521	Negative in *Sacc. Cerevisiae* ± S-9 metabolic activation.
Bone marrow cells *in vivo* (1987)	40377102	No effect on bone marrow cells.
Micronucleus assay *in vivo* (1985)	00152225	Negative at 140 mg/kg but study did not demonstrate that TPTH went to the bone marrow.
Dominant lethal assay (1978)	00125265	Negative at up to 38 mg/kg/day. At 150 mg/kg/day, high rate of deaths.
Gene mutation (1985)	00152224	Not mutagenic ± metabolic activation in Schizosaccharomyces.
Unscheduled DNA synthesis (1985)	00155522	Negative up to cytotoxic dose levels.
General metabolism (several studies 1986 to 1989)	41309102 40029406 40029405 40029407 41387201 41309101	The contributions from six studies combine to meet the general metabolism requirement for TPTH. The ^{14}C studies are confounded by the fact that the labeled phenyl group splits off and the fate of the parent compound is not followed. Thus, the labeled phenyl may be excreted in the urine but this does not represent excretion of intact TPTH. The ^{113}Sn labeled TPTH studies follow the fate of the tin although this may be as triphenyl, diphenyl or monophenyl or as tin itself. The biliary route is the most important in excretion of ^{113}Sn from TPTH. Most of the label (80-100% in several studies) is recovered in the feces. Little remains in tissues (for example, 0.5%). After 24 hours, the kidneys, liver epididymis and brain had the most label. After 7 days, little remained in the tissues.

Study Type	MRID No.:	Results
Dermal penetration (1986 and 1987)	00156684 40198301 40073001	Studies demonstrate that TPTH adheres to the skin and only a small percentage (<1%) is absorbed in 10 hours. The TPTH remaining on the skin can potentially be absorbed over time. Because of complications involved with adherence to the skin, a dermal absorption factor of 10% was derived by comparing the oral and dermal developmental toxicity studies.
Special Immunotoxicity (Several studies 1982 to 1990	41518200 40303701 00124218 00124217 00141313	<u>In rats (41518200):</u> NOAEL = 1.82 mg/kg/day; LOAEL = 3.4 mg/kg/day: decreases in IgG. At higher doses: decreased spleen weight and white blood cells and circulating lymphocytes. <u>In mice (41518200):</u> NOAEL = 0.23 mg/kg/day, LOAEL = 1.15 mg/kg/day: decreased spleen weight absolute and relative. At higher doses: decreased IgM, WBC, neutrophils and circulating lymphocytes. <u>Immunosuppression: (40303701):</u> No evidence of increased susceptibility to *trichinella spiralia* at 2.5 mg/kg/day.

1. All studies classified as acceptable or otherwise determined to contain useful data.

Developmental toxicity. In developmental toxicity studies, TPTH causes resorptions in pregnant rabbits at dose levels only slightly higher than it caused maternal effects on body weight. There was no evidence of increased susceptibility to fetuses noted in the available rat or rabbit developmental toxicity studies. The slope of the dose response curve in the rabbit developmental toxicity study is considered steep. In the rat multi-generation reproductive toxicity study increased susceptibility to the offspring (based on offspring toxicity [decreased litter size, liver and spleen weight] was seen at a dose lower than parental toxicity [decreased body weight gain]). Because of the immunotoxic potential of TPTH, a special study for developmental immunotoxicity (consult with Agency on protocol) will be required.

Immunotoxicity. TPTH belongs to a class of chemicals (organotins) known to be immunotoxic. The primary treatment related effects via oral exposures are immunotoxicity as indicated by decreases in lymphocytes and immunoglobulins in rats and mice, following both sub-chronic and chronic exposures.

Endocrine disruption. There are several indications that imply that TPTH may cause endocrine disruption. In rats, testicular and pituitary tumors were a marked feature in the carcinogenicity study. In the mouse there were changes in adrenal and ovary weights. There were no specific assays for blood levels of hormones in the studies submitted to further assess for possible endocrine disruption.

Carcinogenicity. TPTH is classified as a B2: probable human carcinogen based on evidence of carcinogenicity in mice (liver tumors) and rats (pituitary and testicular tumors) at dose levels that were adequate for assessment of carcinogenicity. The low dose linear approach (Q_1*) was used for

human characterization and was based on the pituitary tumors observed in rats. The Q_1* is 1.83x10 $(mg/kg/day)^{-1}$. In accordance with Agency policy, this Q_1* will be used for assessing cancer risk for all routes of exposure (oral, dermal and inhalation), and as a default for the dermal and inhalation routes.

Mutagenicity. TPTH is not considered to have a mutagenicity/genetic toxicity concern. Most studies are negative for mutagenic/genetic toxicity effects. Although there were some apparent positive responses, other tests, particularly *in vivo*, conducted to verify the significance of the apparent positive studies *in vitro* were negative.

General metabolism. There are several studies which define the metabolism of TPTH using either ^{14}C or ^{113}Sn labeled TPTH. The contributions from six studies combined to meet the general metabolism requirement for TPTH. The ^{14}C studies are confounded by the fact that the labeled phenyl groups split off and the fate of the parent compound is not followed. Thus, the labeled phenyl may be excreted in the urine but this does not represent the excretion on intact TPTH. The ^{113}Sn labeled TPTH studies follow the fate of the tin although this may be as triphenyl, diphenyl or monophenyl or tin itself. The biliary route is important in excretion of ^{113}Sn. Most of the label (80-100% in several studies) is recovered in the feces. Little remains in the tissues (for example, 0.5%). After 24 hours, the kidneys, liver, epididymis and brain had the most label. After 7 days, very little labeled chemical remained in the tissues.

Metabolites. TPTH is serially metabolized to diphenyl and monophenyl tin and excreted. It appears that all plant metabolites are also animal metabolites. Both diphenyl and monophenyl tin metabolites are of toxicological concern.

Dermal absorption. There are several studies to assess for dermal absorption. However, the high affinity that TPTH has for the skin confounds assessing for the potential for TPTH to be absorbed dermally. A dermal absorption factor of 10% was extrapolated based on the comparison of the LOAELs of the oral and dermal developmental toxicity studies in rabbits.

a. Application of the FQPA 10x Safety Factor

The FQPA Safety Factor Committee recommended two different safety factors for acute and chronic dietary risk assessment. The FQPA Safety Factor was reduced to 3x for acute dietary risk assessment, while the 10x FQPA Safety Factor for chronic dietary risk assessment was retained. The Committee made these recommendations for TPTH because:

1. There was evidence of increased susceptibility to the offspring following pre- and/or postnatal exposure in the two-generation reproduction study in rats.

2. TPTH is considered to affect the endocrine system and there is concern for the possible relationship between TPTH, hormonal effects, and the development of pituitary and testicular tumors.

3. TPTH is considered as an agent that may cause immunotoxicity. The chronic dietary RfD is based on decreases in white blood cells and both the rat and mouse chronic feeding and/or oncogenicity studies indicate decreases in immunoglobulins.

4. The Hazard Identification Assessment Review Committee (HIARC) required a developmental toxicity study that evaluates immunotoxicity, a potential toxic effect of TPTH to which fetuses and neonates may be especially susceptible, in place of a developmental neurotoxicity study.

At the time of the FQPA Safety Factor Committee Meeting for TPTH, EFED screening models (Tier 1) were used for drinking water risk assessment; the acute dietary assessment was unrefined (TMRC - Tier 1); and the chronic dietary assessment was refined using percent crop treated data from BEAD and anticipated residues from field trial data. Thus, the exposure assessments will not underestimate the potential dietary (food and water) exposures for infants and children from the use of TPTH and currently, no non-dietary (residential) exposures are expected.

The Committee determined that the FQPA Safety Factor can be reduced to 3x for acute dietary risk assessment for the subpopulation, Females 13 years or older, because the increased susceptibility was seen only in the offspring of parental animals receiving *repeated* oral exposures (two-generation reproduction toxicity study) and not seen following *in utero* exposures (developmental studies). For chronic dietary risk assessment, the Committee determined that the 10x Safety Factor should be retained for all populations (including infants and children) because increased susceptibility to the offspring was seen following repeated oral exposures in the two generation reproduction study in rats.

2. Toxicity Doses and Endpoints for Risk Assessment

A summary of the toxicological endpoints used in the human health risk assessment is presented in the table below. A detailed description of the rationale for selection of the selected doses and endpoints can be found in section 3 of the HED chapter.

Summary of Toxicological Endpoints for Use in Human Health Risk Assessment

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	NOAEL = 0.3 mg/kg/day (100 UF) (3x FQPA)	Increased incidents of hyoid body and/or arches unossified in rabbit fetuses.	Oral Developmental toxicity -Rabbit (MRID No.: 40104801)
	Acute PAD = 0.001 mg/kg for Females 13+		
	No acute oral endpoint identified for general population; risk assessment not required.		

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Chronic Dietary	NOAEL = 0.1 mg/kg/day (300 UF)* (10x FQPA)	Decreased white blood cells.	Chronic feeding study - Rat (Accession No.: 099050)
	Chronic PAD = 0.00003 mg/kg/day		
	Risk assessment required for general population including infants and children.		
Carcinogenicity (oral/dermal/ inhalation)	Oral Q1* 1.83 x 10 $(mg/kg/day)^{-1}$	TPTH is classified as a B2 Carcinogen - probable human carcinogen based on pituitary and testicular tumors in rats and liver tumors in mice. A dermal absorption of 10% should be used for this risk assessment. An inhalation absorption of 100% should be used for this risk assessment.	
Short-Term (Dermal)	Dermal NOAEL = 3 mg/kg/day (MOE: 100)[1]	No effects at the highest dose tested.	Dermal Developmental toxicity - Rabbit (MRID No.: 42909101)
Intermediate-Term (Dermal)	Dermal NOAEL = 3 mg/kg/day (MOE: 100)[1]	No effects at the highest dose tested.	Dermal Developmental toxicity - Rabbit (MRID No.: 42909101)
Long-Term Non-cancer (Dermal)	None	Use pattern does not indicate exposure will be for this interval.	
Inhalation (Any Time Period)	0.00034 mg/L (100 UF) (MOE: 100)[1] (NOAEL = 0.092 mg/kg/day)[2]	Lung lesions seen in animals that died at the next highest dose.	Subchronic Inhalation toxicity -Rat (MRID No.: 41017701)

* 10x for intraspecies variability, 10x for interspecies extrapolation, 3x for instability of test material in the diet and potential for increased mortality near the LOAEL.

[1] MOE is only for occupational exposure; there is no residential exposure.

[2] Inhalation dose in mg/L was converted to mg/kg/day using the following equation:
Dose (mg/kg/day) = (NOAEL (0.00034 mg/L) * Respiration rate of a young adult Wistar rat (8.46 L/hr) * Study daily exposure duration (6 hr/day)) / Body weight of a young adult Wistar rat (0.187 kg)

3. Dietary Food Risk Assessment

a. Dietary Exposure Assumptions (*See* section 4.3 of revised HED chapter)

The Reference Dose (RfD) for evaluating dietary risk is derived from an exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control, along with the application of

uncertainty factors. The percent of the RfD is calculated as the ratio of the exposure value to the RfD (exposure/RfD x 100 = % RfD). The population adjusted dose (PAD) is the adjusted RfD reflecting the retention or reduction of the FQPA safety factor for all populations which include infants and children. For TPTH, the population adjusted doses (PAD) pertaining to acute and chronic dietary exposure are 0.001 mg/kg/day (acute PAD) and 0.00003 mg/kg/day (chronic PAD), respectively.

The acute and chronic (non-cancer and cancer) dietary exposure assessments were conducted using the Dietary Exposure and Evaluation Model (DEEM^{TM}) system. DEEM^{TM} can be used to estimate exposure from constituents in foods comprising the diets of the U.S. population, including all population subgroups. The software contains food consumption data generated in USDA's Continuing Survey of Food Intake by Individuals (CFSII) from 1989-1992.

TPTH inputs to the DEEM^{TM} for refined acute and chronic analysis included anticipated residues (ARs) from field trials (based on ½ the sum of LOQs for each metabolite (TPTH and is degradates, di-phenlytin hydroxid and mono-phenyltin hydroxide) for samples with non-detectable residues; all three crops had non-detectable residues); processing factors (where applicable); and percent crop treated (%CT) information for pecans, potatoes, sugar beets, milk and meat. Dietary refinements, such as ARs, are a way to estimate actual exposures, as opposed to high-end estimates (*see* Table 7 in HED chapter). No monitoring data for TPTH were available from USDA's PDP or FDA's Surveillance Monitoring Program.

The Agency has recently conducted revised acute and chronic (non-cancer and cancer) dietary exposure estimates in concurrence with a review and evaluation of the registrants' submission of acute and chronic dietary exposure and risk analyses. In addition, the Agency has revised the Residue Chemistry Chapter (August 25, 1999), in which new acute and chronic ARs, processing factors and %CT information for meat and milk were given.

For purposes of comparing dietary exposure and the associated resulting risks, the Agency conducted analyses of three acute and chronic (non-cancer and cancer) dietary exposure scenarios:

(1) Dietary analyses including all currently registered crops (pecans, sugar beets, potatoes), meat and milk (included because sugar beet tops are the main livestock feed item of the three crops, and sugar beet tops were found to have detectable residues);

(2) Dietary analyses including only meat and milk (i.e., sugar beets, pecans, and potatoes were assumed to have zero residues, in accordance with the TRAC policy paper, "*Assigning Values to Non-detected/Non-quantified Pesticide Residues in Human Health Dietary Exposure Assessments*", 11/7/97); and

(3) Dietary analyses including only pecans and potatoes (i.e., sugar beets, meat, and milk were excluded).

b. Dietary (Food) Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose (aPAD or cPAD) does not exceed the Agency's risk concerns. The Population Adjusted Dose (which is the Reference Dose adjusted to reflect the FQPA Safety Factor) is defined as the dose at which an individual could be exposed on any given day (acute PAD) or over the course of a lifetime (chronic PAD) and no adverse health effects would be expected. The acute PAD for TPTH is 0.001 mg/kg/day, and the chronic PAD is 0.00003 mg/kg/day for all three scenarios. For the cancer endpoint, a dietary risk estimate that is less than 1.0×10^{-6} does not exceed the Agency's level of concern.

The TPTH **acute dietary risk** from food is below the Agency's level of concern for all three scenarios – that is, less than 100% of the aPAD is utilized. For example, at the 99.9th percentile of exposure, for the most highly exposed subgroup within the female 13 + subpopulation – i.e.,. the subpopulation of concern for acute dietary risk (females 20+ years old, not pregnant or nursing) – the % aPAD value is 34% for Scenario 1. Therefore, acute dietary exposure and risk associated with TPTH-treated foods is not of concern. The following table summarizes the acute dietary exposure results of all three scenarios, for the most highly exposed population subgroup.

Subgroups	**99.9th percentile exposure (% aPAD)**	**99.9th percentile exposure (% aPAD)**	**99.9th percentile exposure (% aPAD)**
	Scenario 1[1]	**Scenario 2**[2]	**Scenario 3**[3]
Females (20+ years/not pregnant/not nursing)	0.000339 (33.9 %)	0.000337 (33.7 %)	0.000002 (0.24 %)
Females (13-19 years/not pregnant/not nursing	0.000127 (12.7 %)	0.000126 (12.6 %)	0.000006 (0.61 %)
Females (13+ years/ pregnant/not nursing)	0.000225 (22.5 %)	0.000224 (22.4 %)	0.000001 (0.12 %)
Females (13+ years/nursing)	0.000230 (23.0 %)	0.000230 (23.0 %)	0.000002 (0.16 %)
Females (13-50 years)	0.000194 (19.4 %)	0.000193 (19.3 %)	0.000003 (0.34 %)

[1] Scenario 1: includes all crops (pecans, potatoes, sugar beets), meat and milk.

[2] Scenario 2: includes only meat and milk (pecans, potatoes, sugar beets assumed to have zero residues).

[3] Scenario 3: includes only pecans and potatoes (sugar beets, meat and milk not included).

Similarly, the TPTH **chronic (non-cancer) dietary risk** from food alone is well below the Agency's level of concern. For the U.S. population and all population subgroups, for all three dietary analyses scenarios, the % cPAD values are all less than 5%.

For **chronic cancer dietary risk** from food alone, based on a Q_1* of 1.83x10 $(mg/kg/day)^{-1}$, the carcinogenic risk estimate for Scenario 1 (all registered crops + meat and milk) is 1.1×10^{-6} for the general U.S. population. For Scenario 2 (meat and milk only), the carcinogenic risk estimate is 9.4×10^{-7} for the general U.S. population. For Scenario 3 (pecans + potatoes, no sugar beets or meat and milk), the carcinogenic risk estimate is 8.7×10^{-8} for the general U.S. population.

Although the Agency has assumed that sugar beet tops are fed to livestock in its risk assessment for Scenarios 1 and 2, it should be noted that the TPTH labels carry a legally enforceable feeding restriction, prohibiting the feeding of TPTH treated sugar beet tops to livestock. Despite the feeding restriction on the label, the Agency has determined that such restriction could pose an economic hardship to farmers and that there remains the possibility that sugar beet tops could be fed to livestock. The Agency has thus based its assessment on the possibility that farmers might still feed sugar beet tops, as it cannot ignore the possible worst case scenario. However, feeding of TPTH treated sugar beet tops under labeled conditions would be a violation and the Agency believes that this will deter most farmers from violating the label. Therefore, the Agency's risk estimates that assume TPTH residues in meat and milk are likely to reflect an over-estimate of actual dietary risk, in light of the feeding restriction.

4. Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Drinking water exposure is aggregated with exposures from food and residential uses to determine aggregate risk (*see* Section IIIA6 below), as mandated by FQPA.

Based on environmental fate data, TPTH will partition to a high degree to soils and is not expected to leach to ground water at significant concentrations. The primary means of transport of TPTH to surface water is by spray drift and soil erosion.

To determine the maximum allowable contribution of treated water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food, then determines a "drinking water level of comparison" (DWLOC). The DWLOC is the concentration of TPTH and its metabolites in drinking water which does not exceed a level of concern when considered together with dietary exposure from food alone. The DWLOC value for each dietary assessment (acute, chronic, or cancer) is compared with estimated environmental concentrations (EECs) of TPTH and its metabolites in surface and ground water. If the DWLOC value is greater than the estimated surface and ground water estimated concentrations, then the Agency would believe there is no drinking water concern for aggregate risk assessment purposes.

Water monitoring data for TPTH were not available, so water quality models were used to assess risks from drinking water sources. Ground water modeling with SCI-GROW (Tier I) and

surface water modeling with PRZM-EXAMS (Tier II) were used to calculate drinking water EECs. Inputs for both models are based on the crop with the highest allowed application rate (pecans). SCI-GROW estimates ground water concentrations for pesticides applied at the maximum allowable rate in areas where ground water is vulnerable to contamination, while PRZM-EXAMS estimates surface water concentrations. Surface water EECs represent water concentrations that may result from the maximum allowable aerial application of TPTH to pecans under a standard environmental scenario, because the use pattern for pecans represent the worst-case concentrations. However, the estimated concentrations for water from modeling are conservative and are higher than expected to be actually found in drinking water.

a. Comparison of DWLOC's to EECs in Drinking Water

The estimated environmental concentrations were then compared to the DWLOCs for TPTH. The acute DWLOC for females 20+ not pregnant, not nursing (the most exposed female population subgroup) is 20 ppb. The chronic (non-cancer) DWLOC for children is 0.3 ppb, 0.9 ppb for adult females, and 1.1 ppb for adult males. The cancer DWLOC is 0.002 ppb (based on scenario 2 – meat and milk only, all crops assumed to have zero residues) for the U.S. population. These values are compared to TPTH estimated concentrations in ground water (0.03 ppb) and surface water (13.7 ppb). The following table summarizes these numbers.

Subpopulation of Concern	**Acute DWLOC**	**Chronic DWLOC**	**Cancer DWLOC**	**Ground water EEC (Tier I)**	**Surface water EEC (Tier II)**	
Females 20+	20 ppb	N/A			**Acute**	**Chronic**
Children		0.3 ppb		0.03 ppb	13.7 ppb	3.6 ppb
Adult females		0.9 ppb				
Adult males		1.1 ppb				
U.S. Population			0.002 ppb			

For **acute risk**, potential exposure to drinking water derived from either ground water or surface water (0.03 ppb, or 13.7 ppb, respectively) results in exposure that is below the Agency's level of concern for females (20 ppb), the most exposed population subgroup.

For **chronic (non-cancer) risk**, potential exposure to drinking water derived from ground water (0.03 ppb) results in exposure that is below the Agency's levels of concern for children (0.3 ppb) and adults (0.9 ppb and 1.1 ppb). However, potential exposure derived from surface water (3.6 ppb) would exceed the Agency's levels of concern for children (0.3 ppb) and adults (0.9 ppb and 1.1 ppb).

For **chronic (cancer) risk**, potential exposure to drinking water derived from either ground water or surface water (0.03 ppb, or 3.6 ppb, respectively) results in exposure that exceeds the Agency's level of concern for the U.S. population (0.002 ppb). For informational purposes, even if there were no exposure from residues in food, the cancer DWLOC for the U.S. population would be 0.02 ppb; both ground water and surface water EECs exceed that value. This means that even if there are no exposures from food, total dietary risk (defined to include both food *and* water) could still be of concern, as a result of potential drinking water exposure estimated for the worst case scenario: aerial application to pecans under currently labeled maximum use rates. Generally, for the U.S. population, cancer risk estimates that are less than 1.0×10^{-6} do not represent a risk concern to the Agency – which is essentially the risk estimate for Scenario 1. Any additional exposure through drinking water would lead to risk estimates that further exceed the Agency's level of concern for dietary exposure.

5. Occupational and Residential Risk Assessment (See HED Chapter, 9/21/99)

There are no registered residential uses of TPTH, so only non-dietary, occupational exposures are assessed.

Occupational (or worker) exposure to TPTH residues via dermal and inhalation routes can occur during handling, mixing, loading, applying, and reentry activities. Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for the occupational handler and post-application worker. Because different endpoint effects were selected for the assessment of dermal and inhalation risks, separate risk assessments were conducted for dermal and inhalation exposures. Exposures were evaluated for both commercial applicators and private growers using TPTH. Private growers are expected to have short-term exposure (i.e., it is assumed that they treat only their own field), while commercial applicators are likely to have both short- and intermediate-term exposure to TPTH (i.e., it is assumed that several fields are treated).

The cancer risk assessment for occupational handlers was conducted using the sum of dermal and inhalation exposures combined with an oral Q_1*. Separate cancer risks were calculated, where applicable, for commercial applicators and private growers because, in several cases, the number of days these two types of workers are exposed is significantly different.

The endpoints used in assessing occupational handler risks from TPTH are presented again in the following table.

Endpoints for Assessing Occupational and Residential Risks for TPTH[1]

Exposure Routes	Exposure Duration	Dose (mg/kg/day)	Effect	Study	Uncertainty Factor	Comment
Dermal	Short-term (1-7 days)	NOAEL 3.0	No effect observed at the highest dose tested	Dermal developmental toxicity (rabbit)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Dermal	Intermediate-term (1 week to several mos)	NOAEL 3.0	No effect observed at the highest dose tested	Dermal developmental toxicity (rabbit)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation and intra-species variability(10x)
Inhalation	Any time period	NOAEL 0.092[a]	Lung lesions seen in animals that died at the next highest dose.	Subchronic inhalation study (rat)	100	Route-specific study; MOE based on UF for inter-species (10x) extrapolation, intra-species variability(10x)
Dermal & Inhalation	Any time period	Oral Q_1* 1.83×10 $(mg/kg/day)^{-1}$	Probable human carcinogen (pituitary, testicular, and liver tumors)	Oral Cancer (Rat and mouse)	NA	A dermal absorption of 10% should be used. Based on comparison between rabbit oral and dermal developmental studies. Inhalation absorption assumed to be 100%.

[a] Inhalation dose in mg/L was converted to mg/kg/day using the following equation:
Dose (mg/kg/day) = (NOAEL (0.00034 mg/L) * Respiration rate of a young adult Wistar rat (8.46 L/hr) * Study daily exposure duration (6 hr/day)) / Body weight of a young adult Wistar rat (0.187 kg)

a. Factors Forming the Basis for Occupational & Residential Handler Risk Assessments

Two studies containing chemical-specific data for assessing human exposure during pesticide handling activities, were submitted in support of the reregistration of TPTH. The first study monitored mixers/loaders of the wettable powder formulation (in water soluble bags) of TPTH in three pecan groves. The second study monitored applicators of the liquid formulation by groundboom sprayer, aircraft, and to pecans by airblast sprayer; the Agency determined that only the data for airblast sprayer exposure from enclosed cab application was valid for risk assessment purposes.

It is the policy of EPA to combine submitted chemical-specific data, when possible, with that from the *Pesticide Handlers Exposure Database (PHED)* to assess handler exposures for regulatory action (OPP Science Advisory Council on Exposure, policy paper, "Use of Values from the PHED Surrogate Exposure Guide and from Analyses of Individual PHED Data Sets," March 11, 1999). Accordingly, the data from the exposure study for wettable powder in water-soluble bags were combined with PHED data for that particular handler scenario. Similarly, the airblast sprayer exposure data were combined with PHED data for the enclosed cab application scenario.

For occupational handler scenarios that do not have chemical-specific data, it is the Agency's policy to use data from PHED to assess handler exposures for regulatory action.
PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions, and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

PHED's algorithms (or evaluations of different exposure scenarios to yield unit exposure values) are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying); formulation type (e.g., wettable powders, granulars); application method (e.g., aerial, groundboom); and clothing scenarios (e.g., gloves, double layer of clothing).

In addition to the unit exposure values calculated by PHED, other factors such as standard assumptions about average body weight, work day, daily acres treated, volume of pesticide used, are also used to calculate risk estimates. When available, chemical-specific information about use patterns are incorporated into the assessment. For example, the Agency incorporated information on typical daily acres treated, and typical application rates, into the handler assessments for TPTH.

In addition, occupational handler exposure assessments are conducted by the Agency using different levels of risk mitigation. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE for

non-cancer risk (i.e., an MOE exceeding 100) or cancer risk (i.e., a cancer risk between1.0×10^{-6} and 1.0×10^{-4}; see Section IV below). The lowest tier is represented by the baseline exposure scenario, followed by, if required (e.g., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment (PPE) and engineering controls (EC)). The level of protection at baseline usually involves a handler wearing long pants and a long-sleeved shirt, without chemical resistant-gloves or respiratory protection. Additional PPE may include an additional layer of clothing, chemical-resistant gloves, and/or a dust/mist respirator). Finally, appropriate engineering controls may be employed in an effort to reduce or eliminate the potential for exposure. Examples of engineering controls include closed tractor cabs, closed mixing/loading/transfer systems, and water-soluble packets.

The current label for TPTH requires occupational handlers to wear coveralls over long-sleeved shirt and long pants, water-proof gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear for overhead exposure, and chemical-resistant apron when cleaning equipment or mixing/loading, and a dust/mist respirator. Closed cab is required for ground applications to all three crops. Mechanical transfer systems are required for mixing/loading liquid formulations; in addition, a closed system is required for aerial applications. Flaggers are also required to be in enclosed cabs.

b. Occupational Handler Exposure Scenarios

The Agency has identified 10 major exposure scenarios for which there is potential for occupational handler exposure during mixing, loading, and applying products containing TPTH to pecans, potatoes, and sugar beets. These occupational scenarios reflect mixing/loading and the use of aircraft (for pecans, potatoes, and sugar beets), groundboom sprayer (potatoes and sugar beets), airblast sprayer (pecans only), and chemigation (potatoes only) for application. The scenarios are described below; note that the numbers given to each scenario correlate to the scenarios detailed in the HED chapter and referenced Appendices.

(1a) mixing/loading (M/L) liquids for aerial/chemigation application;
(1b) M/L liquids for groundboom application;
(1c) M/L liquids for orchard airblast sprayer applications;
(2a) M/L wettable powder in water-soluble bags (WSB) for aerial/chemigation application;
(2b) M/L wettable powder in WSB for groundboom application;
(2c) M/L wettable powder in WSB for orchard airblast sprayer application;
(3) applying (A/) sprays with fixed-wing aircraft;
(4) A/ sprays using a groundboom sprayer;
(5) A/ to orchards with an airblast sprayer;
(6) mixing/loading liquid and applying (M/L/A) with a groundboom sprayer;
(7) M/L/A liquid to orchards with an airblast sprayer;
(8) M/L/A wettable powder in WSB with a groundboom sprayer;
(9) M/L/A wettable powder in WSB to orchards with an airblast sprayer;
(10) flagging during aerial spray application.

Seven of these scenarios (1abc, 2abc, 3, 6, 7, 8, 9) required engineering controls by default because unit exposure data for baseline and PPE levels of protection are either not applicable (because engineering controls are required by label) or not available. This occurred for scenarios 1 and 2 because both types of formulations of TPTH have inherent engineering controls for mixing/loading (i.e., the flowable concentrate is to be used with a mechanical transfer or closed system, and the wettable powder is only available in water-soluble bags). Scenarios 6 through 9 are affected for the same reason; unit exposures are not applicable for the mixing/loading portion of the equation. For scenario 3, no data are available for open cockpit during aerial application. The scenarios were classified as short-term (1-7 days) and intermediate-term (1 week to several months) based primarily on the frequency of exposure. A long term exposure duration is not expected.

c. Occupational Handler Risk Characterization

i. Non-Cancer Handler Risk: Summary of Risk Concerns

Generally, **non-cancer handler risk** is measured by a Margin of Exposure (MOE) that determines how close the occupational handler exposure comes to a No Observed Adverse Effect Level (NOAEL). Both short-term and intermediate-term MOEs for occupational handlers were derived based upon comparison of dermal exposure estimates against a NOAEL of 3.0 mg/kg/day; inhalation MOEs were derived based upon comparison of inhalation exposure estimates against a NOAEL of 0.092 mg/kg/day. Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

For short- and intermediate-term **dermal risks** at baseline, MOEs are greater than 100 for all the assessed exposure scenarios **except** scenario (5) application of sprays to pecan orchards with an airblast sprayer at maximum and typical rates (MOEs = 33 at max rate; 50 at typical rate). When additional PPE (personal protective equipment) is applied, the dermal MOEs are still less than 100 for this scenario (MOEs = 55 and 82). Using engineering controls (i.e., enclosed cab) mitigates dermal risks to MOEs of greater than 100 (MOEs = 630 and 950).

Assessments for scenarios 1abc, 2abc, 3, 6, 7, 8, and 9 incorporated engineering controls. Dermal MOEs are more than 100 for all scenarios **except** two scenarios. The engineering control scenario (2a) mixing/loading wettable powder in WSB for aerial/chemigation application to all crops yielded MOEs that range from 65 to 82 even when typical application rates, rather than maximum rates, were used. The engineering control scenario (1a) mixing/loading liquids for aerial application to sugar beets has an MOE of 84 when the maximum application rate is used. This MOE is mitigated to 170 with the use of the typical application rate.

However, for scenario (2a), engineering controls (and chemical-resistant gloves) in conjunction with the use of typical application rates, rather than maximum rates, are not adequate to mitigate dermal risks to an MOE of 100 or more. Therefore, this scenario remains a concern to the Agency.

Summary of Dermal Risks that Remain a Concern

Scenario	**Crop**	**Rate** (max or typical) lb ai/acre	**Baseline MOE**	**w/ PPE**[1]	**w/ Engineering Controls**[2]
(5) Applying sprays to orchards with airblast sprayer	pecans	max = 0.375 typ = 0.25	max = 33 typ = 50	max = 55 typ = 82	max = 630 typ = 950
Engineering Control Scenarios	**Crop**	**Rate**	**N/A**	**N/A**	**Engineering Controls**
(1a) M/L liquids for aerial application	sugar beets	max = 0.25 typ = 0.125	N/A	N/A	max = 84 typ = 170
(2a) M/L wettable powder (WSB) for aerial/chemigation application	pecans	max = 0.375 typ = 0.25	N/A	N/A	max = 55 typ = 82
	potatoes	max =0.1875 typ = 0.125	N/A	N/A	max = 44 typ = 65
	sugar beets	max = 0.25 typ = 0.125	N/A	N/A	max = 33 typ = 65

[1]PPE includes double layer of clothing and chemical resistant gloves.

[2]Engineering controls include closed mixing/loading or water-soluble bag, single layer of clothing, chemical resistant gloves, enclosed cab, enclosed cockpit, or enclosed truck.

Gray, shaded areas indicate mitigation measures that would reduce risks to a level that would not represent a concern to the Agency (i.e., MOE of above 100). E.g., for scenario (1a), using the typical rate (*) would mitigate risks to an MOE of 170.

For short- and intermediate-term **inhalation risks**, MOEs are greater than 100 at baseline for all the assessed exposure scenarios **except** scenario (5) applying sprays to pecan orchards with an airblast sprayer at the maximum application rate (MOE = 95). This risk estimate is mitigated to an MOE of 140 with the use of the typical application rate, and an MOE of 480 with PPE.

For the assessments incorporating engineering controls, scenarios 1abc, 2abc, 3, and 6 through 9, all inhalation MOEs are greater than 100.

Summary of Inhalation Risks that Remain a Concern

Scenario	**Crop**	**Rate** (max or typical) lb ai/acre	**Baseline MOE**	**w/ PPE**[1]	**w/ Engineering Controls**[2]
(5) Applying sprays to orchards with airblast sprayer	pecans	max = 0.375 typ = 0.25	max = 95 typ = 140	max = 480 typ = 720	max = 950 typ = 1,400

[1]PPE: dust/mist respirator.

[2]Engineering controls: enclosed cab.

Gray, shaded areas indicate mitigation measures that would reduce risks to a level that would not represent a concern to the Agency (i.e., MOE of above 100).

ii. Cancer Handler Risk: Summary of Risk Concerns

The cancer risk assessment used an oral Q_1*; a 10 percent dermal absorption value; and a 100 percent inhalation absorption value. The dermal and inhalation exposures were summed to calculate a total exposure, which was combined with the Q_1* to estimate cancer risk. Generally, cancer risk estimates greater than 1.0×10^{-4} would represent a risk concern for the Agency. As well, cancer risk estimates that are less than 1.0×10^{-4} but greater than 1.0×10^{-6} would raise concerns that may require further mitigation and risk-benefit balancing for risk management purposes (see Section IV below).

Risk estimates indicate that cancer risks at baseline are greater than 1.0×10^{-4} for scenario (4) commercial application of sprays with a groundboom sprayer to potatoes (1.4×10^{-4}). For the private grower, the cancer risk is 4.3×10^{-6}. With PPE, risks are 8.1×10^{-5} for commercial applicators, and 2.5×10^{-6} for private growers. As mentioned previously, seven scenarios (1abc, 2abc, 3, 6, 7, 8, 9) incorporated engineering controls. Of these, scenarios (2ab) mixing/loading wettable powder in WSB for aerial/chemigation application and for groundboom application, yielded cancer risk estimates ranging from 8.1×10^{-6} (pecans; not captured in table below because not a concern) to 1.5×10^{-4} (potatoes) for the commercial applicator. For the private grower, the cancer risk estimates for these same scenarios ranged from 3.6×10^{-6} to 9.1×10^{-5}.

For scenario (2ab), engineering controls (and chemical-resistant gloves) in conjunction with the use of typical application rates are not adequate to mitigate cancer risk estimates to below 1.0×10^{-4} for commercial treatment of potatoes.

Risk estimates incorporating engineering controls are in the range of 1.0×10^{-4} to 1.0×10^{-6} for all other scenarios, except the flagging scenario, which has risks that are less than 1.0×10^{-6}:

Summary of Cancer Risks Exceeding 1.0 x 10^{-4} (all scenarios used typical rates & typical number of applications per year)

Scenario	**Crop**	**Rate** (typical only) lb ai/acre	**Baseline**	**w/ PPE**	**w/ Engineering Controls**
(4) A/ sprays with a groundboom sprayer*	potatoes	0.125	1.4 x 10^{-4}	8.1 x 10^{-5}	3.5 x 10^{-5}
Engineering Control Scenarios	**Crop**	**Rate**	**N/A**	**N/A**	**Engineering Controls**
(2a) M/L wettable powder (WSB) for aerial/chemigation*	potatoes	0.125	N/A	N/A	1.5 x 10^{-4}
(2b) M/L wettable powder (WSB) for groundboom*	potatoes	0.125	N/A	N/A	1.5 x 10^{-4}

* commercial applications only

Summary of Cancer Risks in the 1.0 x 10^{-6} to 1.0 x 10^{-4} Range (all scenarios used typical application rates & typical number of applications per year)

Scenario	**Crop**	**Baseline**	**w/ PPE**	**w/ Engineering Controls**
(4) A/ sprays with a groundboom sprayer*	sugar beets	8.3 x 10^{-5}	4.9 x 10^{-5}	2.1 x 10^{-5}
(5) A/ sprays to orchards with airblast sprayer	pecans	4.4 x 10^{-5}	2.5 x 10^{-5}	2.5 x 10^{-6}
(10) Flagging spray applications	potatoes	3.4 x 10^{-5}	2.5 x 10^{-5}	6.8 x 10^{-7}
	sugar beets	2.0 x 10^{-5}	1.5 x 10^{-5}	4.1 x 10^{-7}
Engineering Control Scenarios	**Crop**	**N/A**	**N/A**	**Engineering Controls**
(1a) M/L liquids for aerial/chemigation*	potatoes	N/A	N/A	6.3 x 10^{-5}
	sugar beets	N/A	N/A	3.8 x 10^{-5}
(1b) M/L liquids for groundboom application*	potatoes	N/A	N/A	6.1 x 10^{-5}
	sugar beets	N/A	N/A	3.7 x 10^{-5}
(2a) M/L wettable powder (WSB) for aerial/chemigation application	sugar beets	N/A	N/A	9.1 x 10^{-5}

Scenario	Crop	Baseline	w/ PPE	w/ Engineering Controls
(2b) M/L wettable powder (WSB) for groundboom*	sugar beets	N/A	N/A	8.8×10^{-5}
(3) A/ sprays w/ fixed wing aircraft	potatoes	N/A	N/A	3.8×10^{-5}
	sugar beets	N/A	N/A	2.3×10^{-5}

*commercial applications only

d. Incident Reports

The Agency has reviewed the OPP Incident Data Systems (IDS), the Poison Control Center (PCC), the California Department of Pesticide Regulation (CA-DPR), and the National Pesticide Telecommunications Network (NPTN) databases for reported incident information for TPTH. No data were reported from PCC or CA-DPR. From the NPTN, TPTH was not reported to be involved in human incidents out of the list of the top 200 chemicals for which NPTN received calls from 1984 to 1991. Seven cases were submitted to the IDS; however, the cases from the IDS do not have documentation confirming exposure or health effects unless otherwise noted. The Agency concludes that relatively few incidents of illness from exposure to TPTH have been reported. No recommendations can be made based on the few incident reports available.

e. Occupational Post-Application Exposure

EPA has determined that there are potential post-application exposures to individuals entering treated areas for purposes of:

- harvesting pecans (although this is done mechanically, it is a very dusty operation);

- scouting and moving hand-set irrigation pipes for potatoes and sugar beets; and

- harvesting, sorting/packing, and brushing/washing potatoes and sugar beets. Although this is usually done mechanically for potatoes, there may be some farms at which these activities are performed by hand. For sugar beets, these activities are done almost exclusively by mechanical means and, therefore, were not assessed. However, in the case that hand methods are used for sugar beet harvesting, the exposures are not expected to exceed those encountered during potato-harvesting activities.

None of these crop activities have been identified as scenarios yielding potential chronic exposure (i.e., greater than or equal to 180 days of exposure/year) concern.

i. Data and Assumptions for Post-application Exposure Assessment

The TPTH Taskforce submitted a reentry study of pecan workers operating windrowing equipment as part of pecan harvesting activities in Georgia and Texas. Both dermal and inhalation exposure monitoring were conducted. In addition, soil and thatch samples were collected from the dripline beneath the pecan trees. The Agency used both the monitoring data and the soil/thatch residue levels in assessing post-application risk.

The Taskforce also submitted soil and foliar dissipation data collected following applications of TPTH to potatoes and peanuts (although peanuts is no longer a registered use, so only potato data were used). The Agency determined the data acceptable and found the potato data also useful for the sugar beets assessment because both crops have similar application rates and cultural practices.

Agency assumptions about application rates, transfer coefficients (where applicable), work day, average body weight, exposure duration and frequency factored into the calculations of post-application risk. Otherwise, the chemical-specific and transferable residue data described above were used to complete this assessment. For assessing maintenance activities, the non-cancer calculations were completed using the maximum application rates for specific crops recommended by TPTH labels. Typical application rates were used in calculations for the cancer assessment.

ii. Occupational Post-application Risk Characterization (*see* Appendices 5 through 7 of revised HED chapter for more detail.)

Post-application risk estimates indicate that for pecan harvesting, MOEs exceed 100 (i.e., are not a concern) on day zero after application. **Cancer risk estimates** are greater than 1.0×10^{-4} (i.e., are a concern), however, until 7 days after the last application at the Georgia site, and are greater than 1.0×10^{-4} until some time between 21 and 30 days after the last application at the Texas site. MOEs for potato maintenance activities are greater than or equal to 100 on day zero after application; MOEs for sugar beet maintenance activities are greater than or equal to 100 on the second day after application. The cancer risk estimate for maintenance activities are less than 1.0×10^{-4} on the second day after application for both potatoes and sugar beets. The MOE and cancer risk estimate for potato harvesting are below the Agency's levels of concern on any day after application.

The current reentry interval (REI) is 48 hours for all crops. TPTH has the potential to be a primary eye irritant (toxicity category I), which triggers the worker protection standard's (WPS) default REI of 48 hours.

6. Aggregate Risk Assessment and Risk Characterization

In establishing or reassessing tolerances, the Food Quality Protection Act (FQPA) requires EPA to consider aggregate exposures to pesticide residues, including all anticipated dietary exposures and

other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. Dietary exposures include those from food and drinking water sources. Exposures from residential or other non-occupational uses are also aggregated; however, for TPTH, there are no registered residential uses, so these types of exposures are not expected. For the risk assessment of TPTH, the Agency has not assumed that TPTH has a common mechanism of toxicity with any other chemicals. Therefore, for assessing aggregate risk from TPTH use, the Agency has evaluated only dietary exposure through food and drinking water.

a. Acute Aggregate Risk

The acute aggregate risk assessment for TPTH is defined to include risk estimates associated with dietary exposure through food and drinking water only. As previously described, based on a refined analysis using exposure data that incorporated anticipated residues, percent crop treated data, and processing factors, acute dietary risk estimates for food alone are all below the Agency's level of concern (i.e., less than 100% of aPAD is consumed). For the most highly exposed female population subgroup, females 20+ years old, not pregnant, not nursing, 34% of the acute PAD is occupied at the 99.9th percentile of exposure. In addition, drinking water EECs for both ground and surface water (acute EEC = 13.7) do not exceed the acute DWLOC value. Therefore, acute aggregate risk from food and drinking water exposures do not represent a concern to the Agency.

b. Short- and Intermediate-term Aggregate Risk

Short- and Intermediate-term aggregate risk estimates, defined to include exposures from food, water, and residential uses, are not required for TPTH because there are no residential uses.

c. Chronic (Non-Cancer) Aggregate Risk

The chronic aggregate risk assessment for TPTH includes risk estimates associated with chronic dietary exposure through food and water. As previously described, refined chronic dietary risk estimates for food alone are below the Agency's level of concern (i.e., less than 100% of the cPAD is consumed). For the most highly exposed population, children 1-6 years old, 4% of the chronic PAD is occupied. However, potential exposure derived from surface water (chronic EEC = 3.6 ppb) would exceed the Agency's level of concern for children (0.3 ppb) and adults (0.9 ppb for females, 1.1 ppb for males) – therefore, chronic aggregate risk from dietary exposure could exceed the Agency's level of concern (i.e., could exceed 100% of cPAD).

d. Chronic (Cancer) Aggregate Risk

The cancer aggregate risk assessment for TPTH includes risk estimates associated with dietary exposure through food and water only, as there are no registered residential uses of TPTH. As previously described, exposure to TPTH from food sources alone exceed the Agency's level of concern for cancer dietary risk estimates. Based on a Q_1* approach for cancer risk estimate, the cancer dietary

risk estimate for Scenario 1 (all crops + meat and milk), which comprises only food exposure, is 1.1 x 10^{-6} – this risk estimate contributes to the entire allocation of risk for dietary exposure (which includes food *and* drinking water). Generally, for the U.S. population, cancer risk estimates that are less than 1.0 x 10^{-6} do not represent a risk concern to the Agency – the risk estimate for Scenario 1 slightly exceeds that allocation. Therefore, any additional exposure through drinking water would lead to risk estimates that further exceed the Agency's level of concern for dietary exposure.

With dietary exposure refinements reflected in Scenarios 2 (only meat and milk; all crops assumed to have zero residues) and 3 (pecans + potatoes only; sugar beets, meat and milk excluded), risk estimates for food exposure alone are less than 1.0 x 10^{-6} – risk estimates are lowered to 9.4 x 10^{-7} and 8.7 x 10^{-8}, respectively. However, as related above, cancer risk estimates for potential exposure to drinking water derived from either ground water or surface water (0.03 ppb, or 13.7 and 3.6 ppb, respectively) exceed the Agency's level of concern for the U.S. population (0.002 ppb). Also, even if there are no residues from food, the cancer DWLOC value for the U.S. population is 0.02 ppb, and estimated concentrations in water would still exceed that DWLOC. Therefore, cancer risk from drinking water exposures based on water modeling causes dietary risk estimates (defined to include food *and* drinking water) for all three dietary scenarios to exceed the Agency's level of concern for dietary exposure.

B. Environmental Fate and Effects Risk Assessment (for details on risk assessment, see EFED chapter, June 8, 1999)

1. Environmental Risk Assessment

Risk assessment of a pesticide's ecological effects integrates the results of exposure and eco toxicity data to evaluate the likelihood of adverse ecological effects on a non-target species. The means of integrating these exposure factors is the risk quotient (RQ) method. Risk quotients are calculated by dividing estimated environmental concentrations (EECs) of the pesticide by acute and chronic eco toxicity values. EECs are based on the maximum application rates for that pesticide.

Risk quotients are then compared to the Agency's levels of concern (LOCs). These LOCs are used to analyze potential risk to non-target organisms and the need to consider regulatory action. The criteria are used to indicate when a pesticide used as directed has the potential to cause adverse effects on non-target organisms. LOCs currently address the following risk presumption categories: (1) acute high: potential for acute risk is high and regulatory action may be warranted in addition to restricted use classification; (2) acute restricted use: the potential for acute risk is high, but may be mitigated through restricted use classification; (3) acute endangered species: endangered species may be adversely affected by use; and (4) chronic risk: the potential for chronic risk is high, regulatory action may be warranted. Currently, the Agency does not perform assessments for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to birds or mammals.

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below.

Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Avian		
Acute High Risk	EEC1/LC50 or LD50/sqft2 or LD50/day3	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

1 abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

2 mg/ft2 = LD50 * wt. of bird

3 mg of toxicant consumed/day = LD50 * wt. of bird

Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC1/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1

1 EEC = (ppm or ppb) in water

Risk Presumptions for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC1/EC25	1
Acute Endangered Species	EEC/EC05 or NOEC	1
Aquatic Plants		
Acute High Risk	EEC2/EC50	1
Acute Endangered Species	EEC/EC05 or NOEC	1

1 EEC = lbs ai/A

2 EEC = (ppb/ppm) in water

In addition, the Agency considers any incident data that is submitted concerning adverse effects on non-target species; for TPTH, no incident data have been submitted.

a. Risk to Nontarget Terrestrial Organisms

TPTH is moderately toxic to avian and mammalian species and exceeds acute and chronic LOCs. For a single application of TPTH, acute avian LOCs were exceeded for endangered species for all crops (RQ range 0.01 - 0.40). In addition, the restricted use LOC is exceeded for pecans (short range grass) and beets (short range grass) (RQ range 0.20 - 0.40). The avian chronic level of concern is exceeded at all registered maximum application rates (RQ range 1.3 - 30).

For multiple applications avian acute high levels of concern are exceeded for short range grass at the maximum allowable application rate for all uses (RQs = 0.6) and in pecans for all feed items except seeds (RQ range 0.7 - 1.24). Restricted use and endangered species levels of concern are exceeded for all maximum application rates except seeds (RQ range 0.3 - 0.60). Avian chronic LOCs are exceeded for all food items at all registered maximum application rates (RQ range 3.0 - 104).

For multiple broadcast applications of liquid products, mammalian acute levels of concern are not exceeded at maximum application rates for any crop. However, the mammalian chronic LOC is exceeded at all registered maximum application rates for all food uses (RQ range 2.0 - 63).

The tables below summarize the avian and mammalian exposure assessments.

Avian exposure assessment for TPTH use. "X" indicates that the RQ exceeds the LOC.

Crop	Food Item	Single Application						Multiple Applications					
		acute RQ	chronic RQ	acute high risk	acute restricted use	endangered species	chronic risk	acute RQ	chronic RQ	acute high risk	acute restricted use	endangered species	chronic risk
Potatoes	Short grass	0.18	15			X	X	0.60	48	X	X	X	X
	Tall grass	0.08	7			X	X	0.30	22		X	X	X
	Broadleaf plants/Insects	0.1	8.3			X	X	0.30	27		X	X	X
	Seeds	0.01	1					0.04	3.				X
Pecans	Short grass	0.4	30		X	X	X	1.24	104	X	X	X	X
	Tall grass	0.16	13.7			X	X	0.60	48	X	X	X	X
	Broadleaf plants/Insects	0.2	17			X	X	0.70	59	X	X	X	X
	Seeds	0.02	2			X	X	0.08	7				X
Sugar beets	Short grass	0.24	20		X	X	X	0.60	48	X	X	X	X
	Tall grass	0.11	9.3			X	X	0.30	22		X	X	X
	Broadleaf plants/Insects	0.13	11.3			X	X	0.32	27		X	X	X
	Seeds	0.02	1.3			X	X	0.04	3				X

Mammalian exposure assessment for TPTH use. "X" indicates that the RQ exceeds the LOC.

Crop	Food Item	Single Application						Multiple Applications					
		acute RQ	chronic RQ	acute high risk	acute restricted use	endangered species	chronic risk	acute RQ	chronic RQ	acute high risk	acute restricted use	endangered species	chronic risk
Potatoes	Short grass	0.01	9.0				X	0.04	29				X
	Tall grass	0.00	4.2				X	0.02	13				X
	Broadleaf plants/Insects	0.00	5.0				X	0.03	16				X
	Seeds	0.00	0.6					0.00	2.0				X
Pecans	Short grass	0.03	18				X	0.10	63				X
	Tall grass	0.01	8.2				X	0.04	29				X
	Broadleaf plants/Insects	0.02	10				X	0.05	35				X
	Seeds	0.00	1.2				X	0.00	4.0				X

Crop	Food Item	Single Application						Multiple Applications					
		acute RQ	chronic RQ	acute high risk	acute restricted use	endangered species	chronic risk	acute RQ	chronic RQ	acute high risk	acute restricted use	endangered species	chronic risk
Sugar beets	Short grass	0.02	12				**X**	0.05	29				**X**
	Tall grass	0.00	5.6				**X**	0.02	13				**X**
	Broadleaf plants/Insects	0.01	6.8				**X**	0.03	16				**X**
	Seeds	0.00	0.80					0.00	2.0				**X**

b. Risk to Nontarget Freshwater and Marine Aquatic Organisms

TPTH is very highly toxic to freshwater and marine/estuarine organisms. Exposure assessments were conducted using Tier II level modeling with PRZM/EXAMS. The RQs calculated from the modeling results show that acute and chronic LOCs for freshwater fish are exceeded (RQs range 0.07 - 0.7_{acute} and 9.2 - $102_{chronic}$).

High acute and chronic LOCs for freshwater invertebrates are exceeded for the pecan use pattern (RQs 1.4_{acute} and $10.8_{chronic}$). Also, acute restricted use, endangered species (RQs 0.14 - 0.20) and chronic (RQs 1.2 and 1.3) LOCs for freshwater invertebrates were exceeded for the potato and sugar beet use patterns.

High acute risk LOCs for estuarine/marine fish are exceeded for the pecan use pattern (RQ 0.54). Also, endangered species LOCs for estuarine/marine fish were exceeded for the potato and sugar beet use patterns (RQs 0.05 - 0.06). No data were submitted to assess chronic risk. Also high acute, restricted use and endangered species LOCs for estuarine/marine invertebrates are exceeded for all use patterns (RQs range 4.8 - 47.2). No data were submitted to assess chronic risk. These data will be required (*see* Section V).

The table below summarizes the aquatic exposure assessment.

Aquatic exposure assessment for TPTH use. "X" indicates that the RQ exceeds the LOC.

Organism	Scenario	acute RQ	chronic RQ	acute high risk	acute restricted use	acute endangered species	chronic risk
Freshwater Fish	potato	0.07	9.2			X	X
	pecan	0.7	102	X	X	X	X
	sugar beets	0.08	10.8			X	
Freshwater Invertebrates	potato	0.14	1.17		X	X	X
	pecan	1.37	10.8	X	X	X	X
	sugar beets	0.2	1.3			X	X
Estuarine and Marine Fish	potato	0.05	no data				X
	pecan	0.06	no data			X	X
	sugar beets	0.54	no data	X	X	X	

c. Risk to Endangered Species

Endangered and threatened avian species may be at acute and chronic risk from applications of TPTH. There were no acute risks to endangered and threatened mammalian species associated with single applications of TPTH but risks from multiple applications were associated with the pecan use. Endangered and threatened mammalian species may be at chronic risk from most single and all multiple applications of TPTH. Endangered and threatened freshwater fish, freshwater invertebrates, estuarine/marine fish and especially mollusks may be at acute risk from TPTH. Also, endangered and threatened freshwater fish and invertebrates may be at chronic risk from TPTH. Chronic risk to endangered and threatened estuarine/marine fish and invertebrates is unknown due to a lack of data, although risk would likely be present due to high toxicity of the compound to aquatic organisms in general and extrapolation from freshwater data.

2. Environmental Fate Assessment

TPTH is hydrophobic (log K_{ow} = 3.1), and although there is some uncertainty with regard to measured values of K_{oc} values, indications are that TPTH partitions very strongly to soils, with K_{oc} possibly ranging from 1900 mL/g to greater than 54000 mL/g. Based on submitted data, TPTH is resistant to photo degradation and hydrolysis. Data also indicate that TPTH degrades in aerobic soil with a half life of 21 days, although open literature indicates that the half life may be as high as 140 days. TPTH half life under anaerobic soil conditions is 36 days, according to submitted reports. Based on its high K_{oc} and comparatively short soil half life (from submitted data), TPTH is not expected to reach groundwater at significant concentrations. However, if the half-life of TPTH is closer to reported literature values, TPTH could reach groundwater in concentrations higher than previously predicted. TPTH that reaches the ground after field application will be strongly sorbed; thus the major transport mechanism to surface water bodies will be by spray drift and soil erosion. Once in surface water bodies,

studies indicate that TPTH will accumulate in tissues of fish by factors of 2900, 4900, 3700X for the edible tissue, nonedible tissue, and in the whole fish, respectively.

There remains uncertainty, however, about the persistence of TPTH in water and the possible toxicity to aquatic invertebrates. This uncertainty is compounded by a lack of appropriate data (e.g., aerobic and anaerobic aquatic metabolism studies). Also, more data is needed to characterize the fate of TPTH degradates of toxicological concern, mono-phenyltin and di-phenyltin, in soil and aquatic systems.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions 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., an active ingredient specific) data required to support reregistration of products containing triphenyltin hydroxide or TPTH 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 TPTH for use on pecans, potatoes, and sugar beets. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of TPTH, 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 TPTH. The Agency determined that TPTH products, when used as specified in this document (i.e., with the mitigation measures outlined in this section), can be used on currently registered crop sites without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing TPTH as the active ingredient, for use on pecans, potatoes, and sugar beets 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 TPTH 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 TPTH, 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 ingredient TPTH, the Agency has sufficient information on the health effects of TPTH and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that TPTH products, labeled and used as specified in this Reregistration Eligibility Decision, will not cause unreasonable adverse effects to humans or the environment. Therefore, the Agency concludes that products containing TPTH for use on pecans, potatoes, and sugar beets are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that use of TPTH on all currently registered crop sites (pecans, potatoes, sugar beets) are eligible for reregistration under the conditions specified in this Reregistration Eligibility Decision.

B. Regulatory Position

The registrants of TPTH have agreed to amend current labels to prevent TPTH from reaching drinking water sources, add protective measures for pecan harvesters, mitigate risks to non-target species and aquatic ecosystems, and conduct confirmatory studies to refine the Agency's worker, drinking water, and aggregate risk assessments. The Agency has determined that these measures will reduce risks such that the benefits of TPTH use presently outweigh the risks, and that unreasonable adverse effects will not result from such use. The Agency thus finds that all currently registered uses of TPTH are eligible for reregistration, with the following risk mitigation measures incorporated into amended labels for TPTH-containing products in the 2000 use season.

For all crops:
– A buffer zone of 100 feet from water bodies for ground applications.
– A buffer zone of 300 feet from water bodies for aerial applications.
– Enclosed cabs for all applicators and flaggers.
– Conduct a new worker exposure study on mixing and loading of wettable powder in water soluble packaging for groundboom and aerial/chemigation application.

For pecans:
– In areas and states that are west of Interstate 35 (e.g., Arizona, New Mexico, and some areas of Oklahoma and Texas), the maximum seasonal use will not exceed 24 ounces ai/acre.
– In all other areas and states (east of Interstate 35) the maximum seasonal use will not exceed 36 ounces ai/acre.
– A pre-harvest interval (PHI) of 30 days after the last application.

For potatoes:
– The maximum seasonal use will not exceed 9 ounces ai/acre.

For sugar beets:
– In all states EXCEPT Minnesota, North Dakota, and Michigan (where the maximum seasonal use will remain unchanged), the maximum seasonal use will not exceed 8 ounces ai/acre.

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

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for TPTH, with the amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered the available information on the toxicity, use practices and scenarios, and the environmental behavior of TPTH.

There are no TPTH products registered for home or other non-occupational use; therefore there is no residential exposure considered in the aggregate risk assessment. The Agency has concluded that for acute non-cancer dietary risk from food, estimates for the subpopulation of concern, females 13+ years, are less than 34% of the aPAD, and therefore is below the Agency's level of concern. For chronic non-cancer dietary risk from food, estimates for all U.S. populations are less than 5% of the cPAD, and therefore is below the Agency's level of concern. For chronic cancer dietary risk from food, based on Scenario 1 (all registered crops, meat and milk), the estimate for the U.S. population, including infants and children, is essentially 1.0×10^{-6} (1.1×10^{-6}). Thus, exposure from food alone exhausts the entire allocation for dietary risk, such that if drinking water exposures occur, this could result in potential dietary risk.

Based on the Agency's water modeling assessment, chronic (non-cancer and cancer) drinking water levels of concern are exceeded. Water modeling estimates indicate that potential drinking water contributions from surface water sources result in chronic (non-cancer and cancer) dietary risk that exceeds the Agency's level of concern, when combined with food exposures. The Agency's modeling estimates are expected to be higher than actual concentrations, due to assumptions built into the model, and the Agency would normally require a water monitoring study to better refine the expected dietary contribution from water. However, given that available information indicates that TPTH binds strongly to soil, and that the registrants have agreed to impose buffer zones to prevent run-off and spray drift, through which TPTH could otherwise reach surface water, at this time EPA believes that water monitoring in not necessary. If TPTH does reach aquatic systems, it will partition to the sediment, thereby reducing TPTH concentrations in overlying water. In the present case, since the Agency has only limited data on the fate of TPTH's degradates in the environment, rather than requiring a water monitoring study, the Agency is requiring a field dissipation study, aerobic and anaerobic aquatic metabolism, and

aerobic soil metabolism studies to verify its conclusion that TPTH and its degradates will not be present in water at levels of concern. The Agency's requirement of additional data will allow it to better evaluate the fate characteristics of TPTH and its degradates in water and soil. Based on these studies, the Agency will determine whether water monitoring is warranted.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for TPTH, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of TPTH residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from TPTH residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on the current data requirements, TPTH has a substantially complete database for developmental and reproductive toxicity. Studies cited earlier in this document indicate evidence of increased susceptibility of offspring following pre- and post-natal exposure in a two-generation reproduction study in rats. Based on these and other findings (see section III above), the Agency retained the FQPA 10x Safety Factor for **chronic** dietary risk assessment of all populations, including infants and children.

All doses for risk assessment purposes were assessed using the conventional safety factors of 10x for interspecies extrapolation and 10x for intraspecies variability. In addition, the FQPA 10x Safety Factor was retained for **chronic** dietary risk assessment of all populations, including infants and children, because increased susceptibility of the offspring was seen following repeated oral exposures in a two-generation reproduction toxicity study. For **acute** dietary risk assessment, the FQPA Safety Factor was reduced to 3x for the subpopulation Females 13+ (13-50 years, i.e., females of childbearing age). Although increased susceptibility was not seen following *in utero* exposures (developmental studies), the Agency is concerned about potential immunotoxic effects, and is requiring developmental neurotoxicity studies, including one that tests for immunotoxicity (*see* Section V).

As discussed earlier, the chronic non-cancer dietary risk estimates for food alone is less than 5% of the cPAD for the U.S. population, including infants and children. Acute dietary risk from food alone occupies 34% of the aPAD for all females 13+, the subpopulation of concern for acute dietary risk assessment. At these levels of contribution from food, the Agency is generally not concerned about potential drinking water dietary contribution from ground water sources, because EECs do not exceed

the DWLOC values for these risk assessments, and fate data suggests that TPTH will not reach ground water at significant concentrations.

However, potential contribution from surface water sources may pose concerns. The chronic cancer dietary risk estimate for food exposure alone is 1.0×10^{-6}, and potential drinking water contributions from surface water sources, based on modeling data, would exceed the Agency's level of concern. At this time, however, as explained above, the Agency believes the buffer zones and TPTH's soil binding properties will prevent TPTH from reaching surface water and is requiring additional confirmatory fate studies to demonstrate that TPTH will not reach drinking water sources at significant concentrations.

c. Endocrine Disruptor Effects

FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disruptor Screening Program was published in the *Federal Register* of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of TPTH and end-use products for endocrine effects may be required.

2. Tolerance Reassessment Summary

Tolerances for residues of TPTH are currently expressed in terms of TPTH *per se* (40 CFR §180.236). TPTH residues of concern in plant and animal commodities have been determined to include TPTH and its metabolites, MPTH and DPTH. Accordingly, the tolerance definition for TPTH residues should also be changed to read as follows:

> "Tolerances are established for the combined residues of the fungicide triphenyltin hydroxide and its monophenyltin (MPTH) and diphenyltin (DPTH) hydroxide and oxide metabolites, expressed in terms of parent TPTH, in/on the following raw agricultural commodities:"

A summary of the TPTH tolerance reassessment for the animal and crop commodities and recommended modifications in commodity definitions are presented in Table 6 of the HED chapter (replicated below).

Tolerances Listed Under 40 CFR §180.236:

Sufficient data are available to reassess tolerances for the combined residues of TPTH in/on pecans, potatoes, sugar beets, and livestock commodities.

The available residue data indicate that the established tolerances for TPTH residues in/on pecans, potatoes and sugar beet roots are adequate provided that use directions are amended as required, and the storage stability data are provided for residues in pecans and confirmatory storage stability data for sugar beet tops. The existing tolerance for sugar beet root is adequate to cover residues in refined sugar, molasses, and dehydrated pulp from sugar beet processing. The existing tolerance for potato is adequate to cover residues in potato processed commodities.

The available data indicate that the established tolerances for residues of TPTH in the kidney and liver of cattle, goats, horses, and sheep (0.05 ppm each) are lower than necessary to protect human health and the environment. These tolerances should be revised, in terms of the combined residues of TPTH, to 4.0 ppm in liver and 2.0 ppm in kidney of cattle, goats, horses, and sheep.

Residue data indicate that tolerances for residues of TPTH in hog kidney and liver should be reassigned by establishing a separate tolerance of 0.3 ppm for residues in hog meat byproducts.

Tolerances to be Established Under 40 CFR §180.236:

Based on the available residue data, a tolerance of 10.0 ppm should be established for TPTH residues in/on sugar beet tops.

For livestock commodities, new tolerances for the combined residues of TPTH in cattle, goat, horse, and sheep commodities should be established at 0.5 ppm in meat, 0.2 ppm in fat, and 0.06 ppm in milk. New tolerances are needed for residues in hog meat and fat (at 0.06 and 0.3 ppm, respectively). In addition, the separate tolerances for residues in hog kidney and liver should be reassigned by establishing a separate tolerance for residues in hog meat byproducts at 0.3 ppm..

Tolerance Reassessment Summary for Triphenyltin Hydroxide (TPTH) (Table 6 from HED chapter).

Commodity	Current Tolerance (ppm) [a]	Tolerance Reassessment (ppm) [b]	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.236:			
Pecans	0.05	0.05	*Pecan*
Potatoes	0.05	0.05	*Potato*
Sugar beet, roots	0.05	0.05	*Beets, sugar, roots*

Commodity	Current Tolerance (ppm) [a]	Tolerance Reassessment (ppm) [b]	Comment/*Correct Commodity Definition*
Liver and kidney of cattle, goats, horses, and sheep	0.05	4.0	The available data from the ruminant feeding study support increasing the tolerance on liver.
		2.0	The available data from the ruminant feeding study support increasing the tolerance on kidney.
Liver and kidney of hogs		Reassigned	The tolerance should be reassigned by establishing a separate 0.3 ppm tolerance for residues in *meat byproducts* of hogs.
Tolerances to be established under 40 CFR §180.236:			
Beets, sugar, tops (leaves)	None	10.0	Based on the available field trial data on sugar beet tops.
Meat of cattle, goats, horses, and sheep	None	0.5	Based on data from the ruminant feeding study.
Fat of cattle, goats, horses, and sheep	None	0.2	
Hog, fat	None	0.3	
Hog, meat	None	0.06	
Hog, meat byproducts	None	0.3	A tolerance of 0.3 ppm for residues in mbyp should be established to replace separate tolerances for residues in kidney and liver.
Milk	None	0.06	Based on non-detectable residues and a LOQ of 0.02 ppm for each metabolite.

[a] Expressed in terms of TPTH *per se*.

[b] Expressed in terms of the combined residues of TPTH, and its metabolites MPTH and DPTH.

CODEX HARMONIZATION

There are currently no Codex Maximum Residue Limits (MRLs) established for residues of TPTH in/on plant or animal commodities.

3. Human Health Risk Mitigation

a. Acute Dietary Risk Mitigation

Acute dietary exposure is below the Agency's level of concern for the subpopulation of concern (females 13+ years old). The 99.9th percentile of acute exposure through food to this subpopulation occupies 34% of the acute PAD. As noted above, potential drinking water exposure from either ground or surface water sources (i.e., EECs) do not exceed the acute DWLOC value, and would not be a

concern to the Agency. Therefore, no mitigation measures are necessary to address acute dietary risks from food and water.

b. Chronic (Non-Cancer) Dietary Risk Mitigation

Chronic non-cancer dietary risk from TPTH treated food is below the Agency's level of concern. For the U.S. population and all population subgroups, the % cPAD values are all less than 5%. Therefore, no mitigation measures are necessary to address chronic (non-cancer) dietary risks from food. As noted above, potential drinking water exposure from ground water sources (i.e., EECs) do not exceed the chronic DWLOC value, and would not be a concern to the Agency. However, potential exposure from surface water sources would exceed the Agency's level of concern. Therefore, mitigation measures and confirmatory data are necessary to resolve potential chronic risk from surface water source drinking water exposure – these are discussed in conjunction with remaining chronic cancer dietary risks below.

c. Chronic (Cancer) Dietary Risk Mitigation

Generally, for the U.S. population, cancer dietary (food *and* water) risk estimates that are less than 1.0×10^{-6} do not represent a risk concern to the Agency. The carcinogenic risk estimate for all three crops plus meat and milk (i.e., Scenario 1), is 1.1×10^{-6}. This risk estimate contributes to the entire allocation of risk for dietary exposure, which includes exposures from food *and* drinking water.

When aggregated with estimated concentrations of TPTH in drinking water sources (based on modeling), the carcinogenic risk from dietary exposures exceeds the Agency's level of concern. As noted above in the aggregate risk discussion, even if there are no residues from food, the cancer DWLOC value for the U.S. population is 0.02 ppb, and drinking water EECs would still exceed that DWLOC.

Under the Agency's 1997 policy, *"Interim Approach for Addressing Drinking Water Exposure"* (S. Johnson memo, 11/17/97), EPA believes it is not appropriate to require elimination of uses/crops based on dietary exceedence from water modeling alone. Instead, the Agency's policy is to require surface water monitoring to refine the water residue estimates calculated by the PRZM/EXAMS model. At this time, however, EPA will not require surface water monitoring because the Agency believes the following measures will mitigate potential drinking water and food exposures from TPTH:

• Labels will be revised to establish 100 foot (ground) and 300 foot (aerial) buffer zones from water (outlined in the ecological risk mitigation section). These buffer zones will reduce the potential for TPTH residues to reach surface water resources.

• The registrants will conduct a field dissipation study (of pecans and sugar beets); anaerobic and aerobic aquatic metabolism studies; an aerobic soil metabolism study; and batch equilibrium studies. These studies are being conducted so that the Agency can confirm that the TPTH parent compound and

its degradates are unlikely to reach drinking water sources at significant concentrations or at levels that will pose dietary risk. Based on available but limited fate data, TPTH binds strongly to soil, and is expected to partition to the sediment in aquatic systems. These studies will confirm the fate of both the parent compound and degradates in soil and aquatic systems, allowing the Agency to refine its environmental fate assessment of TPTH.

• Lower seasonal use rates (as outlined in ecological risk mitigation section) may further reduce the likelihood that residues of TPTH and its degradates will reach surface water resources.

d. Occupational Risk Mitigation

Non-cancer Occupational Risks

To address dermal and inhalation risk from airblast spray applications (scenario 5), **enclosed cabs for applicators are required**. Dermal and inhalation MOEs are mitigated to greater than 600 with such engineering controls as enclosed cab application. Enclosed cabs are currently required for ground applications; amended labels will require enclosed cab for all applicators using ground or aerial equipment.

MOEs for mixing/loading wettable powder (WSB) for aerial/chemigation application (scenario 2a) remain of concern: MOEs for pecans range from 55 (maximum application rate) to 82 (typical rate); MOEs for potatoes range from 44 to 65; MOEs for sugar beets range from 33 to 65. Based on this assessment, the wettable powder (WSB) formulation for aerial/chemigation application poses unreasonable risk. However, based on a number of factors, the Agency believes that the MOEs for the water soluble bag formulation are acceptable. First, the results of the Agency's non-cancer occupational risk assessment for this formulation, and similar results in the occupational cancer risk assessment (discussed below), are not consistent with the Agency's experience that water soluble packaging results in exposures comparable to the use of other engineering controls such as closed mixing/loading systems for liquid formulations, and is therefore a protective measure the Agency generally promotes. Second, the Agency believes that the significant discrepancy observed between exposure from liquid formulations in closed systems and water soluble bags for this chemical are due to the failure of the TPTH water soluble bag study to replicate actual use patterns on all three registered crop sites – i.e., the study monitored workers who handled only enough active ingredient to treat 5 acres, modeling an airblast application scenario for pecan orchards which are 40 acres, rather than the 1,200 acres for aerial application to sugar beets and potatoes. Results of the worker exposure study were thus, of necessity, extrapolated to calculate risks from handling enough active ingredient to evaluate larger acreages, resulting in potential overestimates of worker exposure, since the Agency does not believe, under the circumstances present, that a linear extrapolation of exposure from 5 acres to 1,200 acres is appropriate. Consequently, although the Agency believes that the study is appropriate to estimate exposures based on treatment of 40 acres, it does not believe that it is appropriate to use this same study to estimate exposures based on treatment of 1,200 acres. Based on the above, the Agency believes that a new exposure study based on a larger treated acreage will demonstrate that the MOEs for the water soluble

bag formulation are acceptable. The Agency believes an eligibility finding is supported in this instance since it is reasonable to expect that a two- to three-fold reduction in exposure can be demonstrated in a new study, based on the level of exposure reduction expected through water soluble bag technologies, which would be sufficient to bring MOEs to an acceptable level. Furthermore, the regulatory endpoint for non-cancer occupational risk was based on no-observable adverse effects at the highest dose tested, which may thereby provide an additional margin of protection and/or be a potential source of overestimating risk.

Therefore, to support this formulation and to refine the risk estimates for wettable powder in water soluble bags for groundboom and aerial/chemigation application on the larger acreages representative of actual use, the Agency will call in a **new, confirmatory exposure study on the wettable powder formulation**. If this study does not confirm the Agency's belief that the MOEs are acceptable, the Agency would consider appropriate regulatory action. Alternatively, the registrants may cancel this use rather than generate the data.

Cancer Occupational Risks

Risks below 10^{-6}. Generally, EPA considers worker cancer risks of 10^{-6} and below not of concern for risk management purposes, and would not typically pursue risk reduction measures for such risks.

None of the occupational handler scenarios assessed for TPTH have risk estimates that are less than 1.0×10^{-6} at baseline. However, for scenario (10) flagging spray applications, engineering controls reduce risks to below10^{-6}. Current labels require human flaggers to be in enclosed cabs, so further mitigation is not necessary.

Risks greater than 10^{-4}. Generally, EPA will not allow the continued registrations of existing uses that have worker cancer risks greater than 10^{-4}, because such risks typically outweigh the benefits of use, and thus will cause unreasonable adverse effects. If risk reduction measures do not reduce the risk below the Agency's level of concern, EPA may take regulatory action.

Mixing/loading of wettable powder uses: As described in section III, based on this assessment both the engineering control scenarios (2a) and (2b), mixing/loading wettable powder (WSB) for aerial/chemigation or groundboom sprayer commercial application to potatoes result in cancer risk estimates greater than 10^{-4}; furthermore, MOEs for these scenarios are also of concern. Even though these scenarios have incorporated engineering controls (i.e., water soluble bags), and the Agency incorporated results from a chemical-specific worker exposures study, cancer risk estimates continue to exceed 1.0×10^{-4}, and MOEs are below 60. EPA believes that these results are related to flaws in the TPTH water soluble bag study such that worker exposure from these handling scenarios were not adequately replicated. As discussed above, the Agency believes that the results of the new worker exposure study for the wettable powder (WSB) formulation will demonstrate that worker exposures have been overestimated for these use scenarios and that worker risks are below 1.0×10^{-4}. Therefore, the

Agency is requiring a new exposure study for aerial application of the water soluble bag formulation to support this use.

Application with groundboom sprayer: The cancer risk estimate for applying sprays with a groundboom sprayer for commercial application to potatoes (scenario 4) is greater than 10^{-4} at baseline. An **enclosed cab requirement for applicators on all crop sites** mitigates risks to the 10^{-5} range. Current TPTH labels require all ground applicators to be in enclosed cabs; however labels must be amended to require enclosed cabs for all application methods, including ground and aerial applications.

Risks between 10^{-6} and 10^{-4}. The Agency's goal is to reduce worker cancer risks to 10^{-6} or less, although risks somewhat higher than 10^{-6} will be considered acceptable if measures to mitigate these risks are not available and benefits of continuing use are demonstrated. Thus, for risks that are greater than 10^{-6} and less than 10^{-4} the Agency carefully examines risks in this range including the benefits of use, availability of alternatives, number of workers at risk, and will seek ways to further mitigate these risks. Since the majority of the worker scenarios described in Section III have cancer risk estimates in the range of 10^{-6} to10^{-4}, EPA considered whether additional worker mitigation measures were available, and examined the benefits of TPTH use on pecans, sugar beets, and potatoes.

Based on a benefits assessment developed as part of the TPTH Special Review (updated in August, 1999, attached), and recent Agency discussions with and submissions by pecan, potato, and sugar beet growers (*see* revised benefits assessment, October, 1999), the Agency found that there are several effective, registered alternatives available to control disease on all three crops, as well as pending registration applications for several alternatives, including reduced risk pesticides. EPA has determined that TPTH plays an important role in managing resistance within an Integrated Pest Management (IPM) program. The benefits of TPTH in resistance management programs are highest for pecans, followed by sugar beets, and are lowest for potatoes.

On **pecans**, TPTH controls scab disease, the most significant fungal disease, as well as a broad spectrum of other diseases (e.g., brown leaf spot, downy spot, liver spot, powdery mildew, sooty mold, leaf blotch). Although several alternative fungicides are registered for pecans, none of the alternative fungicides control all of the diseases controlled by TPTH. Also, the alternatives fenbuconazole and propiconazole are more expensive, which will increase the economic burden on many small pecan growers. More importantly, because these alternatives have similar modes of action, if TPTH were not available for use with these alternatives, this could lead to earlier development of resistance in the pest to fenbuconazole and propiconazole (if used exclusively for two to three years).

On **sugar beets**, TPTH controls Cercospora leaf spot disease. Several registered alternatives to TPTH are available (copper fungicides, mancozeb, benomyl, thiabendazole, thiophanate-methyl and tetraconazole (under a section 18 to Minnesota and North Dakota)). Copper fungicides, however, have lost their efficacy in controlling the disease, and the pest has developed resistance against the benzimidazole fungicides in most states. Sugar beet growers minimize their use of mancozeb, a B2 carcinogen, because of its lower efficacy and need for more frequent application timings relative to TPTH

(7-10 day intervals for mancozeb, 12-16 day intervals for TPTH), resulting in a higher level of environmental loading of pesticides for similar levels of control. Although the pest has developed tolerance against TPTH in Minnesota and North Dakota, it is still effective in controlling disease at maximum labeled application rates. Minnesota and North Dakota growers currently use TPTH (at maximum labeled rate) and tetraconazole in alternation to control leaf spot disease. Growers in these states believe that the pathogen may soon develop resistance against tetraconazole if it is not applied in alternation with a protectant fungicide like TPTH. Sugar beet growers in other states can still use benzimidazole and TPTH at moderate labeled rates to control the disease because the resistance to benzimidazole and tolerance to TPTH is not as severe as in Minnesota and North Dakota. Therefore, TPTH still plays an important role in pest resistance management programs for sugar beets.

On **potatoes**, TPTH controls early and late blight. There are at least six registered alternative fungicides, with different modes of action, available for use on potatoes to control these blights. These alternatives effectively control these diseases. However, TPTH remains an important tool in preventing development of resistance, particularly for early and late blight, which have become more problematic in the past year.

EPA has determined that further viable mitigation measures to mitigate worker cancer risks to 10^{-6} were not available short of cancellation of the current uses. Because of its continuing role as a resistance management tool for all three crop uses, the benefits of TPTH warrant continued availability of the fungicide, but only to the extent consistent with the minimum amount required to manage resistance within an IPM program. The Agency believes that the reduction in the total amount of TPTH that can be used in a given use season (described below for ecological risk mitigation) will allow farmers to manage resistance within an IPM program, until more effective and reduced risk alternatives become available. EPA recognizes that the benefit of TPTH for resistance management may decrease for particular crops as more alternatives become available.

Additionally, these use reductions will help ensure that worker cancer and non-cancer risks will not increase. The Agency assessed worker cancer risks using typical rates and typical numbers of applications for each handler scenario. By limiting the amount of seasonal use on all three crops, the Agency ensures that worker exposures will not increase beyond these current levels, particularly as tolerance to TPTH develops (e.g., on sugar beets), requiring growers to apply higher rates to achieve similar levels of control if they choose to rely on TPTH rather than other alternatives.

Post-Application Worker Risk to Pecan Harvesters

Based on a study that monitored exposure from TPTH use on pecans at maximum labeled rates and numbers of applications, post-application cancer risk estimates for pecan harvesters are greater than 1.0×10^{-4} until 7 days after the last application at the Georgia site, and are greater than 1.0×10^{-4} until some time between 21 and 30 days after the last application at the Texas site. To address pecan harvester worker risk, registrants will amend labels to require a **pre-harvest interval (PHI) for pecans of 30 days**. Since harvesting activities do not generally begin until at least 21 days after the last pesticide application, this PHI will have minimal impact on a farmer's ability to harvest pecans. EPA has

determined that further mitigation of pecan harvester risks are not feasible short of cancellation of this use. Given the benefits of TPTH for pecan use, however, and the lower exposures that will result from reduced seasonal use rates, the Agency has determined that the pecan harvester risks are acceptable.

Although cancer risk estimates for pecan harvesters remain greater than 10^{-6} (i.e., are in the 10^{-5} range) after 30 days after the last application, these risks cannot be mitigated to the Agency's goal of 10^{-6} – however, as the Agency has determined that the benefits of use outweigh remaining worker and handler risks, the Agency is accepting the 30-day PHI as the best mitigation measure available.

4. Ecological Risk Mitigation

Mammalian and Avian Risk Mitigation

Risk to terrestrial ecosystems is expected based on both acute and chronic effects to birds and mammals, especially from use of maximum application rates, and multiple applications of TPTH. For example, at currently labeled use, the avian acute RQ exceeds the LOC value by a factor of 2.5, and it exceeds the restricted use LOC by a factor of up to six. Also, for avian species, chronic RQs are as high as 104, and endangered species LOCs are exceeded by factors as high as 12.4. For mammalian species, acute LOCs are not exceeded, but chronic LOCs are exceeded by factors as high as 63. The pecan use, because of its higher application rates and frequency of applications relative to potatoes and sugar beets, poses the greatest risk to these non-target species.

To address mammalian and avian risk concerns, the registrants have agreed to amend current labels to **limit the maximum seasonal use on all three crop sites in the following manner:**

(1) On **pecans**, the current label allows a maximum seasonal use of 60 ounces ai/acre in all states.

The maximum seasonal use on pecans will be revised to 24 ounces ai/acre in areas and states that are west of Interstate 35 (e.g., Arizona, New Mexico, Oklahoma and some areas of Texas). In all other areas and states (east of Interstate 35) the maximum seasonal use on pecans will not exceed 36 ounces ai/acre. These new limits reflect a 40 and 60% reduction in use in areas east and west of Interstate 35, respectively. Of the total national pecan acreage, 30% of the acreage will be limited to the lower seasonal rate (24 ounces ai/acre) and 70% will be limited to the higher rate (36 ounces ai/acre). The total reduction is 46% overall. High humidity, east of Interstate 35, favors disease development, requiring higher numbers of sprays to control the disease. These reductions also address the higher risks associated with pecan use due to the higher application rates and frequency of applications for pecans relative to potatoes and sugar beets.

(2) On **potatoes**, the current label allows a maximum seasonal use of 12 ounces ai/acre.

The maximum seasonal use on potatoes will be revised to 9 ounces ai/acre in all states.

The new limit reflects a 25% reduction in use in all potato growing areas. This limit will be sufficient to control the disease in areas with high disease pressure because many other registered alternatives are available.

(3) On **sugar beets**, the current label allows a maximum seasonal use of 12 ounces ai/acre in all states.

The maximum seasonal use on sugar beets will be revised to 8 ounces ai/acre in all states EXCEPT Minnesota, North Dakota, and Michigan. The new limit reflects a 33% reduction in use in all states except Minnesota, North Dakota and Michigan. These states need to retain the current labeled limit for effective disease suppression. The pest has developed tolerance to TPTH and lower numbers of sprays or lower use rates may not provide adequate disease control. Sixty percent of the total U.S. sugar beet acreage are in these three states.

Aquatic Risk Mitigation

Chronic and acute LOCs are exceeded for all freshwater fish and invertebrates, and are especially high for freshwater fish at the maximum application rate for pecans. Chronic LOCs are as high as 102 for the pecan use. Acute high risk, restricted use, and endangered species LOCs are exceeded by factors as high as 2.7, 13.7, and 27, respectively.

Reductions in seasonal use rates on the three crops will help mitigate aquatic risks. Also, since risk to aquatic ecosystems results primarily from ground and aerial spray drift and from runoff, buffer zones will reduce the potential for exposure to aquatic ecosystems. Therefore, the registrants have agreed to amend product labels to require a **buffer zone of 100 feet from water bodies for ground applications, and 300 from water bodies for aerial applications**.

Although the mitigation measures developed to address ecological risks do not reduce all RQs to an acceptable level, based on a qualitative examination of benefits, the Agency has determined that unreasonable adverse effects on the environment will not result from TPTH use as amended by the above use reductions and addition of buffer zones.

5. Occupational (Worker Protection Standard) Labeling Rationale

During the reregistration process, EPA considers all relevant generic and product-specific information to decide what protections and risk mitigation is needed for all products. Products may contain various types of occupational uses, which may or may not be covered by the Worker Protection Standard (WPS).

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses covered by the WPS. Uses covered by the WPS include all commercial and research uses on farms, forests, nurseries, and in greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals,

and seedlings). The WPS covers not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes.

At this time, all products containing TPTH are intended primarily for occupational use (i.e. mixed, loaded, and applied by commercial applicators. All of these uses are covered by the WPS.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

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

For each end-use product, PPE requirements for pesticide handlers will be determined by comparing the PPE requirements based on the toxicity of the active ingredient, as listed earlier, with the PPE required based on the acute toxicity of the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) would apply to the end-use product. As discussed in the risk mitigation section above, the additional PPE is needed due to TPTH's high acute toxicity, developmental, cancer, dermal and inhalation effects.

Post-Application/Entry Restrictions

Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REIs) for all uses covered by the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

For TPTH, EPA has determined that no regulatory action is needed as the result of acute or other adverse effects of the active ingredient. The early-entry PPE requirements will be established on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the end-use products.

C. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing TPTH. For the specific labeling statements, refer to Section V of this document.

1. 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.

In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has completed and distributed over 300 county bulletins.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling as specified in section V . The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, the following spray drift related language is required on product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method:

"Do not allow this product to drift"

V. ACTIONS REQUIRED OF REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of TPTH for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain and data are still required for confirmatory purposes:

Guideline #	**Study**
830.7050	UV/Visible Absorption
870.6200 (81-8)	Acute neurotoxicity/rat
870.6200 (82-7)	Subchronic neurotoxicity/rat
Special Study	Developmental immunotoxicology neurotoxicity study (consult with Agency on protocol)
860.1340 (171-4c and d)	Independent laboratory validation (for animal method) and radio validation (plant and animal methods)
860.1360 (171-4m)	Multiresidue testing
860.1380 (171-4e)	Storage stability
860.1500 (171-4k)	Crop field trials–beets, sugar
231 and 232	Worker exposure, wettable powder in water soluble bag, mixing/loading enough quantities to treat large acreages with groundboom (150 acres) or aerial/chemigation (1,000 acres) equipment
72-4a	Fish early life stage toxicity test (sheepshead minnow)
72-4b	Aquatic invertebrate life cycle (mysid)
850.4400 (122-2)	Aquatic plant growth
835.1230 (163-1)	Sediment and soil absorption/desorption for parent and degradates
835.6100 (164-1)	Field dissipation study
835.4100 (162-1)	Aerobic soil metabolism
835.4300 (162-4)	Aerobic aquatic metabolism
835.4400 (162-3)	Anaerobic aquatic metabolism

Specific product and residue chemistry data requirements remain unfulfilled for the following registered 96% T/TGAIs

830.1550, 1700, 1750, 1800, 6314, 6316, and 7370.	Elf Atochem 96% Technical
830.1550	AgrEvo 96% Technical
830.1550, 1750, 6314, 6316, 6317, and 6320.	Agtrol 96% Technical

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the labeling contained Table 5 at the end of this section.

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. 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.

2. Labeling Requirements for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to implement these changes is specified in Table 5 at the end of this section.

C. Required Labeling Changes Summary Table

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
Manufacturing Use Products		
Required on all MUPS	"Only for formulation into fungicide products intended for the following use(s):" [*registrants insert uses that are being supported by MP registrant*]. "This product may only be used to formulate liquid end-use products labeled for use in closed systems only, and wettable powder end-use products that are packaged in water-soluble packets."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to fish and wildlife. 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 (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards
End Use Products Intended for Occupational Use (WPS)		
Restricted Use Pesticide Statement	"RESTRICTED USE PESTICIDE due to carcinogenicity, potential for affecting fetal development, and high acute toxicity to humans. For retail sale to and use by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicators certification. "	Top of front panel and beginning of Directions for Use

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
PPE Requirements established by the RED based on the active ingredient.[1]	**"Personal Protective Equipment (PPE)** Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, flaggers, and other handlers using engineering controls (see requirements below) must wear: --long-sleeve shirt and long pants, --shoes plus socks, and --chemical-resistant gloves and chemical-resistant apron when mixing and loading**."** "Handlers for which use of an engineering control is not possible, such as cleaning up a spill or leak and cleaning or repairing contaminated equipment must wear: --long-sleeve shirt and long pants, --chemical-resistant gloves, --chemical-resistant footwear plus socks, --chemical-resistant apron, --chemical-resistant headgear if overhead exposure, In addition, handlers exposed to the concentrate must wear coveralls (over the long-sleeve shirt and long pants) and a NIOSH-approved dust/mist respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N^2, R, P, or HE."	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
Engineering Controls for liquid/flowable products	**"Engineering Controls"** "Mixers and loaders supporting aerial and chemigation applications must use a closed mixing and loading system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for providing both dermal and inhalation protection. The system must include a mechanism for removing the pesticide from the shipping container, rinsing the container, and transferring the pesticide and rinsate into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-of device that is warranted by the manufacturer to minimize drippage to not more than 2 ml. per disconnect point. Mixers and loaders supporting ground applications must use a mechanical transfer system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for providing dermal protection. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-of device that is warranted by the manufacturer to minimize drippage to not more than 2 ml. per disconnect point. Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. Ground-equipment applicators and flaggers must use an enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(5)]. All mixers, loaders, applicators, and flaggers must wear the personal protective equipment specified above for the task they are performing and all (except aerial applicators) must be provided and must have immediately available for use in an emergency, such as a spill or equipment failure, the PPE specified above for handlers not using engineering controls."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
Engineering Controls for wettable powders (*packaged in water soluble packages*)	**"Engineering Controls"** "Mixers and loaders using intact water-soluble packaging are using a closed mixing and loading system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)]. Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. Ground-equipment applicators and flaggers must use an enclosed cab that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(5)]. All mixers, loaders, applicators, and flaggers must wear the personal protective equipment specified above for the task they are performing and all (except aerial applicators) must be provided and must have immediately available for use in an emergency, such as a spill or equipment failure, the PPE specified above for handlers not using engineering controls."	Precautionary Statements immediately following the User Safety Requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
Environmental Hazards	**"Environmental Hazards:** This pesticide is toxic to fish and wildlife. Do not apply directly to water, or to area where surface water is present, or to intertidal areas below the mean high water mark. Do not allow this product to drift. Do not apply with aircraft within 300 feet of any waterbed including, but not limited to rivers, streams, ponds, lakes and reservoirs. Do not apply with aircraft when wind speed is greater than 10 mph. Do not apply with groundboom equipment within 100 feet of any waterbed including, but not limited to rivers, streams, ponds, lakes and reservoirs. Apply this pesticide only as specified on this label. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements under Environmental Hazards. Buffer zones and drift statement should be repeated in the Directions for Use under General Precautions and Restrictions
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours for all crops."	Directions for Use, Agricultural Use Requirements Box and also put in Directions for Use under Applications Instructions for the specific crop.
Early Re-entry Personal Protective Equipment	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: - coveralls - chemical resistant gloves such as any waterproof material - shoes and socks - protective eyewear"	
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "Do not allow this product to drift."	For WPS Products place in the Direction for Use directly above the Agricultural Use Box. For non-WPS Products, place in Directions for Use in General Precautions and Restrictions

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
Application Restrictions	"Do not allow this product to drift."	Directions for Use
Other Application Restrictions	**Pecans** In areas and states west of Interstate 35 (e.g., Arizona, New Mexico, Oklahoma and Texas) the maximum amount of active ingredient that can be applied per season must be revised to 24 ounces ai/acre. In all other areas and states (east of Interstate 35), the maximum amount of active ingredient that can be applied per season must be revised to 36 ounces ai/acre. The pre-harvest interval (PHI) must be revised to 30 days. **Potatoes** The maximum amount of active ingredient that can be applied per season must be revised to 9 ounces ai/acre. **Sugar beets** In all states EXCEPT Minnesota, North Dakota, and Michigan, the maximum amount of active ingredient that can be applied per season must be revised to 8 ounces ai/acre.	Directions for Use
Spray Drift language that must be placed on each product that can be applied aerially:	"Aerial Spray Drift Management" "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."	Directions for Use

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	"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."	Directions for Use
The following language must be placed on each product that can be applied aerially:	"Aerial Drift Reduction Advisory" "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)."	Directions for Use

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	**"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."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"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."	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"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."	

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	**"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.)"	Directions for Use
The following language must be placed on each product that can be applied aerially:	**"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."	
The following language must be placed on each product that can be applied aerially:	**"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."	
The following language must be placed on each product that can be applied aerially:	**"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."	Directions for Use

Table 5: Summary of Required Labeling Changes for Triphenyltin Hydroxide (TPTH)		
Description	**Required Labeling**	**Placement on Label**
The following language must be placed on each product that can be applied aerially:	**"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)."	Directions for Use

VI. APPENDICES

Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/A)	Max.# Apps	Max. Seasonal Total	Min Interval	Pre-Harvest Interval (PHI)	Restrictions/Comments[1]
Food/Feed Uses							
Pecans							
Broadcast foliar applications Aerial or ground equipment	4 lb/gal FlC	0.38	10	Do not exceed 24 oz ai/A in Arizona and New Mexico, and all areas west of Interstate 35, including those parts of Oklahoma and Texas west of I-35. Do not exceed 36 oz. ai/A in all other states east of I-35	14 Days	30 days	Minimum volume for aerial applications is 20 gal/A. Minimum buffer zone for aerial and ground applications near lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, or commercial fish ponds is 300 feet and 100 feet, respectively. Enclosed cabs are required for applicators and flaggers. Labels prohibit application after shucks have started to open.
	80% WP	0.38	10	Same	14 Days	30 days	
	47.5% WP	0.38	10	Same	14 Days	30 days	

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/A)	Max.# Apps	Max. Seasonal Total	Min Interval	Pre-Harvest Interval (PHI)	Restrictions/Comments[1]
Sugar Beets							
Broadcast foliar applications Aerial or ground equipment	4 lb/gal FlC	0.25	Not Specified	Do not exceed 8 oz. ai/A in all states except Minnesota, North Dakota, and Michigan, where the maximum seasonal use allowed will be 12 oz. ai/acre.	10 Days	21 days	Minimum volume for aerial and ground applications is 5 gal/A and 15 gal/A, respectively. Minimum buffer zone for aerial and ground applications near lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, or commercial fish ponds is 300 feet and 100 feet, respectively. Enclosed cabs are required for applicators and flaggers. The labels prohibit grazing or feeding of sugar beet tops to livestock.
	80% WP	0.25	Not Specified	Do not exceed 10 oz. formulated 80% WP in all states except Minnesota, North Dakota, and Michigan, where the maximum seasonal use allowed will be 15 oz. formulated 80% WP.	10 Days	21 Days	
	0.5 lb/gal EC	0.25	Not Specified	Same as 4 lb/gal formulation.	10 Days	21 Days	
	47.5% WP	0.25	Not Specified	Same as 4 lb/gal formulation.	10 Days	14 Days	

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/A)	Max.# Apps	Max. Seasonal Total	Min Interval	Pre-Harvest Interval (PHI)	Restrictions/Comments[1]
Potatoes							
Broadcast foliar application Aerial, ground, or chemigation equipment	4 lb/gal FlC	0.19	Not Specified	Do not exceed 9 oz. ai/A/season	Not Specified	7 Days	Labels specify a minimum volume for aerial and ground applications of 3 gal/A and 15 gal/A, respectively. Minimum buffer zone for aerial and ground applications near lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, estuaries, or commercial fish ponds is 300 feet and 100 feet, respectively. Enclosed cabs are required for applicators and flaggers.
	80% WP	0.19	Not Specified	Same	7 Days	7 Days	
	0.5 lb/gal EC	0.19	Not Specified	Same	7 Days	7/14 Days[2]	
	47.5% WP	0.24	Not Specified	Same	7 Days	7 Days	

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/A)	Max.# Apps	Max. Seasonal Total	Min Interval	Pre-Harvest Interval (PHI)	Restrictions/Comments[1]
Residential Uses							
There are no approved residential uses for TPTH.							

1. Restricted Entry interval is 48 hours for all crops.
2. Seven Days in Connecticut, Delaware, Florida, Maine, Michigan, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, Vermont, and Wisconsin. Fourteen Days in all other states.

Appendix B. TABLE OF GENERIC DATA REQUIREMENTS AND STUDIES USED TO MAKE THE REREGISTRATION DECISION

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within case 0099 (TPTH) covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to TPTH 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) 605-6000.

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 Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	Old Guideline Number			
830.1550	61-1	Product Identity and Composition	All	(DATA GAP-Elf Atochem 96% T, AgrEvo 96% T, Agtrol 96% T)
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	00137668, 00142930, 00145053, 00147329, 42642201, 42852201, 43557401
830.1670	61-2B	Formation of Impurities	All	00137668, 00142930, 00147329, 00150573, 42642201, 42852201
830.1700	62-1	Preliminary Analysis	All	(DATA GAP-Elf Atochem 96% T) 00142930, 00150573, 00161669, 40802501, 42640901, 42725201, 42965601, 43125101, 43125201
830.1750	62-2	Certification of limits	All	(DATA GAP-Elf Atochem 96% T, Agtrol 96% T) 00142930, 00150573, 00161669, 40802501, 42585401, 43125101
830.1800	62-3	Analytical Method	All	(DATA GAP-Elf Atochem 96% T) 00142930, 00150573, 00161669, 40802501, 42365503, 42578902, 42578904, 42585401, 42725201
830.7300	63-7	Density	All	00142930, 00147329, 00150573, 42640901, 42725201

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
830.7840	63-8	Solubility	All	42049501, 42578901, 42640901, 42678903, 42725201
830.7950	63-9	Vapor Pressure	All	00142930, 00147329, 00150573, 42578901, 42640901, 42725201
830.7370	63-10	Dissociation Constant	All	(DATA GAP-Elf Atochem 96% T) 00142930, 00147329, 00150573, 42578901, 42578904, 42640901
	63-11	Octanol/Water Partition Coefficient	All	00147329, 42578901, 42578903, 42640901
830.7000	63-12	pH	All	00147329, 42640901
830.6313	63-13	Stability	All	00147329, 42640901
830.6314	63-14	Oxidizing/Reducing Action	All	(DATA GAP-Elf Atochem 96% T, Agtrol 96% T) 42640901, 43102201
830.6316	63-16	Explodability	All	(DATA GAP-Elf Atochem 96% T Agtrol 96% T) 42640901, 43102201
830.6317	63-17	Storage stability	All	(DATA GAP Agtrol 96% T) 42640901, 43125101, 43218701, 43324201
830.6320	63-20	Corrosion characteristics	All	(DATA GAP Agtrol 96% T) 42640901, 43125101, 43187801, 43218701

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	A,B	00125275, 00125276
850.2200	71-2A	Avian Dietary Toxicity - Quail	A,B	00142758
850.2200	71-2B	Avian Dietary Toxicity - Duck	A,B	00142759, 00162016, 40173301
850.2300	71-4A	Avian Reproduction - Quail	A,B	00160091, 00161680, 43178501, 43178502
850.2300	71-4B	Avian Reproduction - Duck	A,B	00160092, 00161655, 43178502
850.1075	72-1C	Fish Toxicity Rainbow Trout	A,B	00142885, 40098001
850.1010	72-2	Freshwater Invertebrate-Acute	A,B	00125267, 40098001
	72-3A	Estuarine/Marine Toxicity - Fish	A,B	43212702
	72-3B	Estuarine/Marine Toxicity - Mollusk	A,B	40228401, 43212703, 44023901
	72-3C	Estuarine/Marine Toxicity - Shrimp	A,B	43212701
	72-4(a)	Fish- Early Life Stage	A,B	(DATA GAP) 00125273, 43490101
	72-4(b)	Estuarine/Marine Invertebrate Life Cycle	A,B	(DATA GAP) 00125270, 00125273, 43490101
850.1500	72-5	Life Cycle Fish	A,B	43490101

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	A,B	00071364, 00139027, 00139028, 00139029, 00139030, 00139031, 00139032, 00139033, 00139034, 00139035, 00139036
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A,B	00071364
870.1300	81-3	Acute Inhalation Toxicity-Rat	A,B	00071364
870.2400	81-4	Primary Eye Irritation-Rabbit	A,B	00071364
870.2500	81-5	Primary Skin Irritation	A,B	00071364
870.2600	81-6	Dermal Sensitization	A,B	00071364, 00124212, 00139027, 00139028, 00139029, 00139030, 00139031, 00139032, 00139033, 00139034, 00139035, 00139036, 40318001, 41429501
870.6200	81-8	Acute Neurotoxicity Screen	A,B	(DATA GAP)
870.3100	82-1A	90-Day Feeding - Rodent	A,B	00157771, 00157952, 41085702
870.3150	82-1B	90-Day Feeding - Non-rodent	A,B	0155630, 00155631, 40285501
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A,B	00142880
870.3465	82-4	90-Day Inhalation - Rat	A,B	40029403, 40028404, 41017701
870.6200	82-7	Subchronic Neurotoxicity Screen	A,B	(DATA GAP)
	83-1A	Chronic Feeding Toxicity - Rodent	A,B	41085702

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
	83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B	40285501
	83-2A	Oncogenicity - Rat	A,B	41085702
	83-2B	Oncogenicity - Mouse	A,B	41085701
870.3700	83-3A	Developmental Toxicity - Rat	A,B	00142877, 00142878, 00144489, 00148907
870.3700	83-3B	Developmental Toxicity - Rabbit	A,B	40104801, 42909101
870.3800	83-4	2-Generation Reproduction - Rat	A,B	00162655
870.5140	84-2A	Gene Mutation (Ames Test)	A,B	00152223, 00152226, 00155521
	84-2B	Structural Chromosomal Aberration	A,B	00152223, 00155630, 00155631, 40371102
	84-4	Other Genotoxic Effects	A,B	00155522, 00152224, 00152225
870.7485	85-1	General Metabolism	A,B	00166535, 40029405, 40029406, 40029407, 41309102
870.7600	85-2	Dermal Penetration	A,B	00142281, 00156325, 00156684, 40073001, 40198301
	85-A-SS	Imunotoxicity Studies	A,B	00157952, 00157771, 00261753, 00261754, 40303701, 41518201, 41518202
	Special Study	Developmental Immunotoxicity Screen	A,B	(DATA GAP)

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	A,B	42507801, 43218701, 43557401
875.2200	132-1B	Soil Residue Dissipation	A,B	43557401
875.2400	133-3	Dermal Passive Dosimetry Exposure	A,B	43557401
875.2500	133-4	Inhalation Passive Dosimetry Exposure	A,B	43557401
	133-A-SS	Reentry Protection	A,B	00157160, 40816901, 43557401
	231	Estimation of Dermal Exposure at Outdoor Sites	A,B	(DATA GAP FOR WATER SOLUBLE FORMULATION) 40816901, 43599401, 44105701
	232	Estimation of Inhalation Exposure at Outdoor Sites	A,B	(DATA GAP FOR WATER SOLUBLE FORMULATION) 40816902, 43599401, 44105701
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A,B	00093874, 00093875
835.2240	161-2	Photodegradation - Water	A,B	00156003, 42049502
835.2410	161-3	Photodegradation - Soil	A,B	00156002, 42119801, 42449801
835.4100	162-1	Aerobic Soil Metabolism	A,B	(DATA GAP) 00156004
835.4200	162-2	Anaerobic Soil Metabolism	A,B	00143246, 00156005
835-4400	162-3	Anaerobic Aquatic Metabolism	A,B	(DATA GAP)

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
835-4300	162-4	Aerobic Aquatic Metabolism	A,B	(DATA GAP)
835.1230	163-1	Leaching/Adsorption/Desorption	A,B	(DATA GAP) 00156006
835.6100	164-1	Terrestrial Field Dissipation	A,B	(DATA GAP) 00155453, 40106501, 40106502, 42063501
835.1850	165-1	Confined Rotational Crop	A,B	00156007, 00161670, 41512701
	165-4	Bioaccumulation in Fish	A,B	40185901, 40185902, 42995601
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	A,B	Registration Standard 00030252, 00030253, 00030254, 00030309, 00030310, 00030311, 00086459, 00086493, 00086494, 00124220
860.1300	171-4B	Nature of Residue - Livestock	A,B	Registration Standard 00030250, 00030251, 00030313, 00030315, 00030316, 00080381, 00086552, 00086553, 00086554, 00124220

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
860.1340	171-4C	Residue Analytical Method - Plants	A,B	(DATA GAP) 00029834, 00029835, 00030259, 00030272, 00036021, 00036027, 00036029, 00080387, 00086472, 00086473, 00086534, 00086545, 00086561, 00086569, 00086571, 00086601, 00086603, 00124220, 00128877, 00142876, 00153228, 00156382, 00160465, 00160466, 00160467, 00160468, 00160469, 00165010, 00165025, 40149301, 40149302, 40149303, 40149304, 40149305, 40149401, 40149402, 41556601, 41556602, 41785201, 41785202, 41785203, 41785204, 42806101, 43617901, 43635501, 43838801, 43838802, 43855301, 43855302, 43855303, 43874701, 43874702, 44066301, 44066302
860.1340	171-4D	Residue Analytical Method - Animal	A,B	(DATA GAP) 00128877, 00142876, 42806101, 43635501, 43808101, 43808102, 44334401, 44334402
860.1380	171-4E	Storage Stability	A,B	(DATA GAP) 41556601, 41556602, 41785201, 41785202, 41785203, 42564801, 42806101, 42965101
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/ Egg	A,B	00053415, 00080381, 44334401, 44334402
860.1500	171-4K	Crop Field Trials (Sugar Beets)	A,B	DATA GAP 00086560, 00160468, 40149302, 40149401, 41556601, 43836601, 43838801, 43855303
860.1500	171-4K	Crop Field Trials (Carrot)	A,B	00160465, 40149305, 40149401
860.1500	171-4K	Crop Field Trials (Peanuts)	A,B	00157867, 40149301

Data Supporting Guideline Requirements for the Reregistration of Triphenyltin hydroxide

REQUIREMENT			USE PATTERN	CITATION(S)
860.1500	171-4K	Crop Field Trials (Pecan)	A,B	00086600, 00165025, 40149303, 40149401, 41267101
860.1500	171-4K	Crop Field Trials (Potato)	A,B	00086492, 00086494, 00157867, 00160466, 40149304, 40149401, 41556602, 43838802, 43855303, 44667001
860.1520	171-4L	Processed Food (Sugar Beets)	A,B	41785201, 41785203, 43836601, 43855301
860.1520	171-4L	Processed Food (Potato)	A,B	41556601, 41785202, 41785204, 43838802, 43855302
860.1360	171-4M	Multiresidue Method	A,B	(DATA GAP)
OTHER				
830.7050		UV/Visible Absorption	A,B	(DATA GAP-Elf Atochem 96% T, AgrEvo 96% T, Agtrol 96% T)
850.4400	122-2	Aquatic Plant Growth	A,B	(DATA GAP)
850.3020	141-1	Honey Bee Acute Contact	A,B	00018842

Appendix C. CITATIONS CONSIDERED TO BE PART OF THE DATA BASE SUPPORTING THE REREGISTRATION DECISION (BIBLIOGRAPHY)

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.

BIBLIOGRAPHY

MRID	CITATION
TOUOT	See MRIDs 125275 and 125276
TOUOT04	See MRID 125267
TOUOT05	See MRID 125270
TOUOT06	See MRID 125273
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00009378	E.I. du Pont de Nemours and Company (1976). Data Supporting Use of Lannate(R) D Methomyl Insecticide and Lannate(R) 5-D Methomyl Insecticide on Cotton. Summary of studies 226190-B through 226190-W. (Unpublished study received Sep 28, 1976 under 352- 380; CDL:226190-A)
00137668	M & T Chemicals, Inc. (1984). General Chemistry Data for Triphenyltin Hydroxide. (Unpublished study received Feb 29, 1984 under 5204-69; CDL:252557-A)
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00029834	Cannizzaro, R.D. (1979). Determination of Triphenyltin hydroxide Residues in Rough Rice by Gas Chromatography/Mass Spectrometry Promim. Method no. 28 dated Feb 26, 1979. (Unpublished study received Mar 28, 1980 under 0F2340; submitted by Thompson-Hayward Chemical Co., Kansas City, Kans.; CDL:099345-B)

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00030250 Ackerman, M.E.; Granata, S.V.; Tapprich, B. (1976). The Determination of Carbon-14 Labeled Residues Due to TPTH following Oral Administration of Rice Foliage Containing Residues from the labeled Fungicide to Lactating Goats: ADC Project # 270. (Unpublished study received Mar 28, 1980 under 0F2340; prepared by Analytical Development Corp., submitted by Thompson-Hayward Chemical Co., Kansas City, Kans.; CDL:099343-A)

00030251 Moring, S.; Nye, D. (1978). Identification of 14C-TPTH Residues in Weathered Rice Folage and Their Bioavailability to Rats via Single Oral Dose: Project 780316. Final rept. (Unpublished study received Mar 28, 1980 under 0F2340; prepared by Stoner Laboratories, Inc., submitted by Thompson-Hayward Chemical Co., Kansas City, Kans., CDL:099343-B)

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00030253 Wargo, J.P., Jr.; Wilkes, L.C.; Mulkey, N.S. (1977). Fate of 14C- Triphenyltin hydroxide (Du-ter) following Application to Rice ADC Project # 221. Includes methods dated Jun 27, 1977. (Unpublished study received Mar 28, 1980 under 0F2340; prepared by Analytical Development Corp., submitted by Thompson-Hayward Chemical Co., Kansas City, Kans.; CDL:099343-D)

00030254 Danhaus, R.G. (1976). Field Metabolism and Environmental (Rice Treated with 14C-TPTH): ADC Project # 278. (Unpublished study received Mar 28, 1980 under 0F2340; prepared by Analytical Development Corp., submitted by Thompson-Hayward Chemical Co., Kansas City, Kans.; CDL:099343-E)

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00030259 Thompson-Hayward Chemical Company (1970). Fentin acetate; Fentin chloride; Fentin hydroxide. (Unpublished study received Mar 28, 1980 under 0F2340; prepared in cooperation with Farbwerke Hoechst, A.G., N.V. Philips-Duphar and National Institute Public Health, Plant Protection Service; CDL:099342-A)

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Appendix D. COMBINED GENERIC AND PRODUCT SPECIFIC DATA CALL-IN

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 6; 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 Registrant's Response Form, (see section III-B); or

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. 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 six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms (Insert A) with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms (Insert B) with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms (Insert B) (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 (Insert B) within the time frames provided.

II-C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (Telephone number: 703-605-6000).

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 (Insert A), and the Requirements Status and Registrant's Response Form (Insert B).

The Data Call-In Response Forms (Insert A) must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms (Insert B) 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 (Insert A) and the Requirements Status and Registrant's Response Forms (Insert B) 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 (Insert A), 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 Registrant's Response Form (Insert B), 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 Registrant's Response Forms (Insert B). You must also complete a Data Call-In Response Form (Insert A) 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 (Insert A), Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form (Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert A). 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 (Insert B) and item 6b on the Data Call-In Response Form (Insert A). If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B) 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 (Insert B). 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 (Insert A), and the Requirements Status and Registrant's Response Form (Insert B), for product specific data. The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form (Insert B) also must be submitted for each product listed on the Data Call-In Response Form (Insert A) 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 (Insert A)

and Requirements Status and Registrant's Response Form (Insert B) (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 (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms (Insert B). 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. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form (Insert B) 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 (Insert A). 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 (Insert B). If you choose this option, you must submit the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B) 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 (Insert A) 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 (Insert B) 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 ungradable (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 guidelines 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 (Insert B) 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 (Insert B) 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 extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

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

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you did 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 Certification with Respect to Citations of Data (in PR Notice 98-5) (EPA Form 8570-34) . 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 (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) 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 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 submission of the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both documents 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 a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5 entitled "Standard Format for Data Submitted under FIFRA".

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 entitled "Standard Format for Data Submitted under FIFRA."

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 No. 8570-34, Certification with Respect to Citations of Data.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form (Insert A) 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 Registrant's Response Form (Insert B) 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 (Insert B). 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 (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), 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 (Insert B). 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 (Insert B). 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:

   a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B).

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

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

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

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

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

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

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

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

IV-C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding 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 (Insert A) and completed Requirements Status and Registrant's Response Forms (Insert B), 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 (Insert A) need be submitted.

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

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration 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 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

1. Chemical Status Sheets

TPTH DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 0021. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), and (5) a list of registrants receiving this DCI (Attachment 5). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for TPTH are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on TPTH 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 TPTH products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jane Mitchell at (703) 308-8061.

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

Jane Mitchell
Chemical Review Manager
Product Reregistration Branch
Special Review and Reregistration Branch 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **TPTH**

TPTH DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of TPTH. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), and (4) a list of registrants receiving this DCI (Attachment 5). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for TPTH are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on TPTH are needed. These data are needed to fully complete the reregistration of all eligible TPTH products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Loan Phan at (703) 308-8008.

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

Loan Phan, Chemical Review Manager
Special Review Branch
Special Review and Registration Division (H7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **TPTH**

2. Combined Generic and Product Specific DCI Response Forms (Insert A) 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" (Insert A) 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." (Insert A) 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 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

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 2137, 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 (INSERT A)

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.

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 (Insert B)

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.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS (INSERT B)

Generic and Product Specific Data Call-In

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 (Insert B) 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 initialed 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 canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

2 pages--Generic and Product Specific DCI Samples 2 pages

3. Generic and Product Specific Requirements Status and Registrants' Response Forms (Insert B) and Instructions

Instructions For Completing The "Requirements Status and Registrant's Response Forms" (Insert B) 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 2137, 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" (Insert B)

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 Registrant's Response Form(Insert B).

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" (Insert B) 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" (Insert B) 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 canceled this product. For these cases, please supply all relevant details so that the Agency can ensure that its records are correct.

9 pages--Insert Generic and Product Specific “Requirements Status and registrants’ response Forms” Here, including footnotes and definitions

4. EPA's Batching of TPTH Products for Meeting Acute Toxicity Data Requirements for Reregistration

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

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

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

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

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

Ten products were found which contain TPTH as the active ingredient. These products have been placed into three batches and a "no batch" category in accordance with the active and inert ingredients and type of formulation.

Due to the high acute toxicity and corrosive potential of TPTH, the acute inhalation and primary eye irritation guidelines for all products listed below, with the exception of 1812-351, may be waived and classified as category I.

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

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	1812-279	TPTH...96%	liquid
	45639-171	TPTH...96%	liquid
	5204-86	TPTH...96%	liquid
	55146-71	TPTH...96%	liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	1812-350	TPTH...80%	solid
	55146-72	TPTH...80%	solid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	1812-244	TPTH...40%	liquid
	45639-186	TPTH...40.4%	liquid

No Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	1812-351	TPTH...4.72% Maneb...32.63%	liquid
	45639-170	TPTH...47.5%	liquid

5. List of All Registrants Sent This Data Call-In Notice

Appendix E. LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

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

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.

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

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

1. The Office of Pesticide Programs' Web Site

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

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

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

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

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or

petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

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

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

Documents Associated with this RED

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

a. Health and Environmental Effects Science Chapters.
b. Detailed Label Usage Information System (LUIS) Report.