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United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-08-005
June 2008

Reregistration Eligibility Decision for
the Tributyltin Compounds:
Bis(tributyltin) oxide,
Tributyltin benzoate, and
Tributyltin maleate
(Case 2620)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial tributyltin derivatives, (bis)tributyltin oxide, tributyltin benzoate, and tributyltin maleate (collectively known as "tributyltin" or "TBT"). Based on its review, EPA is now releasing its Reregistration Eligibility Decision (RED) and risk management decision for tributyltin. The enclosed Reregistration Eligibility Decision (RED) document was approved on June 30, 2008.

A Notice of Availability will be published in the *Federal Register* announcing the release of the RED. The RED and supporting risk assessments for tributyltin are available to the public on the U.S. Federal Government website www.regulations.gov. The docket is EPA-HQ-OPP-2008-0171.

The tributyltin RED was developed through EPA's public participation process, described in the Federal Register on September 10, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The Agency tailors the public participation process to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines. The public participation process for the TBT RED provided for the consideration of public comment on the preliminary risk assessments and ideas for risk mitigation. The Agency has now revised the assessments based on substantive comments submitted during the public comment period, or otherwise addressed such comments in a response to comments document. No comments were submitted on ideas for risk mitigation, but the Agency has provided additional opportunity for discussion with the registrants on risk mitigation measures proposed by the Agency.

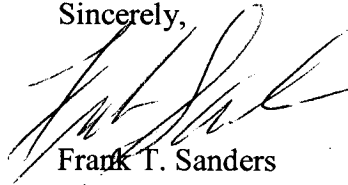
Please note that the tributyltin risk assessments and the enclosed RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational, residential and ecological risks posed by exposure to TBT alone. This document also identifies both generic and product-specific data that the Agency intends to

require via Data Call-In Notices (DCIs). The DCIs and instructions for responding will be sent to registrants at a later date.

The Agency has determined that most tributyltin uses will be eligible for reregistration provided that all the conditions identified in this document are satisfied. The Agency has determined that some uses of tributyltin are not eligible for reregistration, based on a consideration of the risks and benefits associated with those uses and the adequacy of the database supporting them. Sections IV and V of this RED document explain the eligibility decision for each use, and for those uses that are eligible, describe the necessary labeling amendments and data requirements. Instructions for registrants on submitting the revised labeling will accompany the product-specific DCI associated with this RED.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Jill Bloom, at (703) 308-8019. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,



Frank T. Sanders
Director, Antimicrobials Division

Enclosure

REREGISTRATION ELIGIBILITY DECISION

for the Tributyltin Compounds:

Bis(tributyltin) oxide, Tributyltin benzoate, and Tributyltin maleate

List D--CASE 2620

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
June 30, 2008

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Glossary of Terms and Abbreviations

a.i., ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC ₅₀	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD ₅₀	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number)--EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations under Section 24c of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for bis(tributyltin) oxide, tributyltin benzoate, and tributyltin maleate (collectively, “tributyltin” or “TBT”) and is issuing its risk management decision. The risk assessments, which are summarized below, are based on review of registrant-submitted data supporting the use patterns of currently registered products, citations from the open literature, and additional information received through the public docket. The risk assessments have been revised, as needed, according to information received since they were first made available to the public in April 2008. After considering the risk assessments, available information about alternatives to TBT for specific uses, public comments, and risk mitigation options, the Agency developed its risk management decision for uses of tributyltin. As a result of this review, EPA has determined that some uses of tributyltin are eligible for reregistration, provided that the prescribed risk mitigation measures are adopted and labels are amended accordingly, and required data are submitted. Other uses are not eligible for reregistration, based on a combination of critical data gaps and unacceptable risks. The decision and the associated risk mitigation measures are discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the Agency's revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for tributyltin. The tributyltin case consists of three active ingredients: bis(tributyltin) oxide (PC code 083001), tributyltin benzoate (083106), and tributyltin maleate (083118). There are currently 35 registered products and two pending registrations containing these three active ingredients. There are no pesticide inert uses for any of the three TBT compounds. The first pesticide product containing tributyltin was registered in 1961.

The tributyltin compounds act as fungicides, disinfectants, microbiocides, and microbiostats. They are used in water cooling towers, wood preservatives, hard surface disinfectants for farm premises; as materials preservatives in textiles, carpet backing, sponges, rope, fiberfill, foam, paper, and building materials (e.g., drywall, joint compound, grout); metal working fluids; and petrochemical injection fluids.

Some of the labeled uses for the tributyltin-containing chemicals have the potential to result in direct or indirect food exposures or other residential exposures that may impact children. Based on published literature studies on the immunotoxicity of tributyltin oxide and uncertainties surrounding the endpoint, the Agency believes that application of a database uncertainty factor is warranted. A database uncertainty factor of 10X has been applied to the endpoint dose ($BMD_{10} = 0.03 \text{ mg/kg/day}$) selected for the residential exposure scenarios.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of tributyltin. It includes summary information derived from the more detailed risk assessments that serve as support documents for the RED. The risk assessments are not provided as attachments to this document, but are available in the Public Docket at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0171). To access these documents on the electronic docket, go to www.regulations.gov. Select advanced docket search (right side of page). For Docket ID, enter OPP-2008-0171 and then submit (bottom of page). Double-click on the blue underlined Docket number for a listing of all the documents in that docket. Support documents can also be obtained by request from the Office of Pesticide Programs Regulatory Public Docket. The Docket Facility telephone number is (703) 305-5805.

This document consists of six sections. Section I is the Introduction. Section II provides a chemical overview, a profile of the use of the tributyltin compounds, and their regulatory history. Section III gives a summary of the human health and environmental risk assessments for tributyltin. Section IV presents the reregistration eligibility decision and describes the risk management approach for TBT. Section V details the changes needed to product labels to implement the risk mitigation measures outlined in Section IV, and the data required to support the eligible uses of TBT. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

The tributyltin case consists of three compounds: bis(tributyltin) oxide (PC code 083001), tributyltin benzoate (083106), and tributyltin maleate (083118). There are no inert uses of TBT in pesticides. Table I show the number of registrations associated with each active ingredient.

Table 1. Number of Active and Pending Registrations for TBT AIs

Active ingredient	Manufacturing-use Products	End-use Products	Pending
bis(tributyltin) oxide	4	28	1
tributyltin benzoate	0	2	0
tributyltin maleate	0	1	1

The first pesticides containing tributyltin were registered in the 1960s, for use in antifouling paints. Adverse ecological effects associated with TBT antifouling paints captured global attention in the 1980s. In 2005, the Agency implemented the cancellation of last TBT registration for ship hull antifouling. An international treaty prohibiting the use of TBT hull coatings becomes effective in September 2008.

The three existing tributyltin active ingredients serve as fungicides, disinfectants, microbiocides, and microbiostats in a number of commercial and residential applications. They are used in water cooling towers, wood preservatives, hard surface disinfectants for farm premises; as materials preservatives in textiles, carpet backing, sponges, rope, fiberfill, foam, paper, and building materials (e.g., drywall, joint compound, grout); metal working fluids; and petrochemical injection fluids.

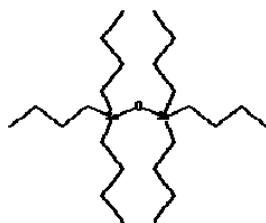
B. Chemical Identification

Common Names: bis(tributyltin) oxide (TBTO)
tributyltin benzoate (TBTB)
tributyltin maleate (TBTM)

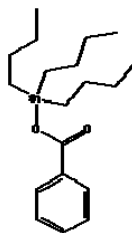
Chemical Names:	TBTO—hexabutyldistannoxane TBTB--stannane, (benzoyloxy)tributyl- TBTM--stannane, tributyl(3-carboxyacryloyl)oxy
CAS Registry Number:	TBTO—56-35-9 TBTB—4342-36-3 TBTM--4027-18-3 (“mono” form; incorrectly cited by some sources as 4275-57-1, which is the “bis” form)
Molecular Formula:	TBTO-- $C_{24}H_{54}OSn_2$ TBTB-- $C_{19}H_{32}O_2Sn$ TBTM-- $C_{16}H_{30}O_4Sn$
Highest % ai in EUP:	TBTO—29% TBTB—45.5% TBTM—25%

C. Chemical Structures

TBTO



TBTB



TBTM

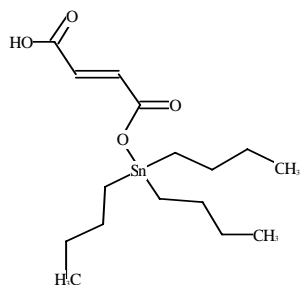


Table 2. Chemical Properties of TBT Compounds

Property	TBTO	TBTB	TBTM
Molecular Weight	596.12	411.18	405.13
Boiling Point	417 C	390 C	415 C
Melting Point	132 C	128 C	153 C
Vapor Pressure @ 25 C, mm Hg	7.8×10^{-06}	1.34×10^{-06}	1.74×10^{-07}
Log K _{ow}	3.84	4.69	3.79
Log K _{oc}	7.57	5.10	2.99
Solubility in water, mg/L	0.0896	0.257	4.086
Half-life in water	2.49 hrs	2.172 hrs	343.5 days
Half-life in air	0.125 days	0.241 days	25 hr

D. Use Profile

Detailed information on TBT use sites and applications can be found in Appendix A.

1. Type of Pesticide

Fungicide, disinfectant, algicide, microbiocide, microbiostat.

2. Use Sites**Cooling towers**

TBTO may be added to cooling tower water to prevent the build-up of biomass that can interfere with the cooling function. TBTO may be used in industrial and commercial recirculating cooling water towers, open recirculating cooling systems, air conditioning unit cooling towers atop commercial buildings, and evaporative condensers. The biocide may be added to cooling water with a metering pump or by drip-feed or open-pouring. Concentrations of salts in the cooling water (which increase with time) dictate when water is discharged and when new biocide is added. Cooling water additives containing TBT are labeled to show their pesticide content.

Wood preservatives

TBTO is used to formulate paint, stains, and waterproofing to be applied to decks, shingles, shakes, wood siding, fences, railings, floors, outdoor furniture, structural lumber, beams, timber, sills, millwork, roofs, trim, clapboards, plywood, porches, and greenhouses. These coatings serve as wood preservatives to discourage the growth of microorganisms that cause degradation of the wood. Some product labels indicate that the TBTO biocides must not be used in interior paints or coatings, based on earlier reports of adverse effects associated with residential exposure to TBTO in interior paint and the absence of data to allow the Agency to develop a quantitative risk assessment.

Wood preservatives may be applied via brushes, rollers, mops, spray equipment, or airless sprayers. Coatings containing TBTO are typically applied to exterior wood once every several years. These coatings are labeled to show that they contain TBT.

Hard surface disinfectant for farm premises

One product containing TBTO is used in a number of farm settings. TBTO is used for disinfecting housing for livestock, kennels, veterinary clinics, and animal laboratories and breeding facilities. The product is also used in poultry houses, hatcheries, incubators, egg rooms, egg trucks, and other farm vehicles, and on ventilation equipment, utensils, and ropes. It can also be used to decontaminate tools and tack via immersion, and in boot baths. This product may be applied to hard surfaces with a brush, wipe, or mop, or with a sprayer, hand-held fogger, thermal fogger, or automated fogger. TBTO may be applied as frequently as once a day in incubators with eggs present. Directions for use indicate that animals must be removed from the premises prior to treatment and for up to two days after treatment, although use directions also indicate that inter-depopulation treatments may be made to pens, hutches, etc. The disinfectant is not rinsed or removed from treated surfaces, except for feeding and watering equipment that is present during treatment. The disinfectant is labeled to show its TBTO content.

Materials preservatives in building materials

TBTO, TBTB, and TBTM are added to building materials to protect the materials themselves from microbial degradation. These building materials include drywall, joint compound, and medium density fiber board, and particulate board. TBT may also be used to preserve building material adhesives and adhesives for other manufacturing uses, including cardboard box production.

TBT additives are combined with these materials during the manufacturing process. Materials treated with TBT preservatives are not labeled to show that they contain TBT.

Materials preservatives in textile, paper, and related uses

TBTO and TBTM are used by textile manufacturers in industrial settings to produce fabrics that are resistant to growth and staining by microorganisms, particularly mildew. While these products are “materials preservatives,” the materials they are used to treat (such as fiberfill, foam, rope, and paper) are being considered separately from materials preservatives used in building materials.

Laundry and clothing treatments with TBT reportedly are not supported by any formulator, but fabrics treated with TBT may be used for mattress pads and ticking, pillow ticking, cushions for outdoor furniture, canvas and other fabrics for outdoor uses (e.g., tents, tarps, awnings), and webbing (used with golf driving range protective netting, netting for baseball batting cages, and tennis nets). Nylon rope may also be treated.

In addition, TBT is used to protect sponges and sponge mop heads. Sponges typically are sold in a damp state so they will remain absorbent until used, and treatment with TBT prevents the growth of mold and mildew on the sponge in its original packaging.

TBT may also be used in rubber floor mats, carpet backing, fiberfill, polyurethane foam used in furniture, and air filters for heaters and air conditioners. It is not used to treat carpet face fibers.

Fabric may be treated with a coating (e.g., a polyvinyl coating) containing TBT. Ingredients for the coating are cold-mixed and then applied to fabric or carpet backing with a knife applicator: fabric is unwound from a feed roll onto a conveyor belt that passes the fabric beneath a coating dispenser and then past a blade that distributes the coating evenly and presses it into the weave. Fabrics may also be treated by an "exhaust" process in which fabric is soaked in a liquid bath containing diluted TBT product and then dried. TBT applied in this manner is dispersed throughout the fabric, rather than retained on the surface.

In the production of polyurethane foam, TBT is added to the other reactants in a "one shot" process. Similarly, TBT is added with other components during the manufacture of rubber and plastic. For fiberfill, TBT is co-applied with a silicone slip coating.

TBT products registered for use in paper bear labeling warning that such products may not be used in paper for direct or indirect food contact.

Textiles, paper, and related materials treated with TBT products are not labeled to show their TBT content.

Miscellaneous uses

TBT products also may be used in petrochemical injection applications, added to metal working fluids, incorporated into irrigation tubing for non-agricultural applications, incorporated into the rubber used to form sonar domes, and in antifoulant devices used in instruments deployed for monitoring oceanographic conditions. TBT additives for metal working fluids and petrochemical injection materials are labeled with their TBT content, as are the antifoulant devices used in oceanographic instruments. TBT for metal working fluids and petrochemical injection is added at the job site. Sonar domes are made from rubber impregnated with TBTO, while the antifoulant devices for oceanographic instruments are packaged separately from the conductivity sensors themselves and are installed without the opportunity for human contact. Metal working and petrochemical injection fluids to which the TBT materials preservatives have been added would not be labeled as containing TBT; neither would irrigation tubing or sonar domes. Packaging for the oceanographic antifoulant devices shows the TBT content of the devices.

III. Summary of Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of the risk assessments and to help the reader better understand the Agency's determination of reregistration eligibility. The human health and ecological risk assessment documents and supporting information are listed in Appendix C. As indicated earlier, to access these documents within the public docket, go to www.regulations.gov. Select advanced docket search (right side of page). For Docket ID, enter OPP-2008-0171 and then submit (bottom of page). Double-click on the blue underlined Docket number for a listing of all the documents in that docket.

These documents also may be found in the OPP Public Docket which is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The Agency's use of human studies in the TBT human health risk assessment is limited to those studies incorporated into the PHED and similar databases, and is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

1. Hazard profile

A detailed toxicology assessment for the tributyltin containing compounds is available from the docket. A summary of the key toxicological studies is presented in Appendix B.

a) Acute toxicity

Acute toxicity for the TBT containing-compounds is summarized in Table 3.

Table 3. Acute Toxicity Profile for Tributyltin Compounds

Guideline Number Study Type	MRID #(s)	Results	Toxicity Category
Tributyltin Oxide			
870.1100 Acute Oral – Rat	00085004, 92172013	LD ₅₀ =180 mg/kg (males) LD ₅₀ =150 mg/kg (females) LD ₅₀ =170 mg/kg (combined)	II
870.1100 Acute Oral – Rat	00085003, 92172004	LD ₅₀ =193 mg/kg (males) LD ₅₀ =123 mg/kg (females) LD ₅₀ =160 mg/kg (combined)	II
870.2600 Skin Sensitization– Guinea pigs	00104789, 92172014	Non-sensitizer	NA
Tributyltin Benzoate			
870.1100 Acute Oral – rat	42415801	LD ₅₀ =115 mg/kg (males) LD ₅₀ =115 mg/kg (females) LD ₅₀ =115 mg/kg (combined)	II
870.1200 Acute Dermal – rat	42415802	LD ₅₀ > 2000 mg/kg (combined)	III
870.2500 Primary Dermal Irritation – rabbit	42415803	Severe Irritation	I
Tributyltin Maleate			
870.1100 Acute Oral – Rat	43851201	LD ₅₀ = 224.7 mg/kg	II
870.2600 Skin Sensitization – Guinea pigs	44142303	No-sensitizer; minimal irritation in response to induction, no increase in response to challenge dose	NA

b) Endpoint selections; database uncertainty factor

The toxicological endpoints used for the human health risk assessment are identified in Table 4. The uncertainty factor for studies in animals is 100 (10X for inter-species extrapolation, 10X for intra-species variation). Where exposures contributing to aggregate risk are likely, an added database uncertainty factor of 10X is applied to the selected endpoint dose.

Table 4. Endpoint Selection for Tributyltin Compounds

Exposure scenario	Dose; data base uncertainty	Target Reference Dose or MOE	Study and toxicological effects
Dietary Risk Assessment			
Acute Dietary	No appropriate endpoints were identified in the oral toxicity studies that represent a single dose effect. An acute dietary risk assessment has not been conducted.		
Chronic Dietary (all populations)	BMD₁₀ = 0.03 mg/kg/day It is recommended that 10X data base uncertainty factor be applied.	Chronic RfD (cRfD) = 0.00003 mg/kg/day (A chronic dietary risk assessment has not been conducted because dietary exposure data are lacking. The endpoint is provided for future reference.)	Vos et al., (1990)¹ NOAEL = 0.025 mg/kg/day LOAEL = 0.25 mg/kg/day immunotoxic effects
Non-Dietary Risk Assessments			
Incidental Oral Short-Term (1-30 days) and Intermediate-Term (1- 6 months)	BMD₁₀ = 0.03 mg/kg/day. The 10X data base uncertainty factor is applied.	Target MOE = 1000	Vos et al., (1990) NOAEL = 0.025 mg/kg/day LOAEL = 0.25 mg/kg/day immunotoxic effects
Dermal (all durations)	BMD₁₀ = 0.03 mg/kg/day. The 10X data base uncertainty factor is applied.	Target MOEs occupational = 100 residential = 1000	Vos et al., (1990) NOAEL = 0.025 mg/kg/day LOAEL = 0.25 mg/kg/day immunotoxic effects
Inhalation (all durations)	BMD₁₀ = 0.03 mg/kg/day. The 10X data base uncertainty factor is applied.	Target MOEs occupational = 100 residential = 1000	Vos et al., (1990) NOAEL = 0.025 mg/kg/day LOAEL = 0.25 mg/kg/day immunotoxic effects
Dermal Absorption	In the absence of a guideline dermal toxicity study or an acceptable dermal absorption study, a 15% dermal absorption factor has been used (EPA/HED).		
Carcinogenicity	The carcinogenicity of tributyltin oxide has not been determined due to the high spontaneous incidence of tumors in the test species, incidence variability in the treated groups, and absence of a dose-effect relationship.		

¹ Vos et al., (1990) Immunotoxicity of bis (tri-n-butyltin) oxide in the rat: Effects on thymus-dependent immunity and on nonspecific resistance following long-term exposure in young vs. aged rats. Toxicol. Appl. Pharmacol. 105:144-155.

The additional database uncertainty factor is applied to the selected endpoint dose from a study reported in the open literature that suggests a potential for increased susceptibility in children to non-dietary TBT exposures. The Vos et al. (1990) study has been identified by several national and international entities as the basis of human health risk assessments for TBT. The immunosuppressive effects observed by the study authors are critical effects associated with a lower dose than the doses associated with other toxic effects, and suggest that weanling rats may be more sensitive than (year-old) adult rats to TBTO in the diet. The data base uncertainty factor is employed to address the unknowns in age-differentiated immune effects, and also to account for uncertainty in the magnitude of endocrine effects and dietary residues of TBT and degradates.

c) FQPA considerations

Under the Food Quality Protection Act (FQPA), P.L. 104-170, which was promulgated in 1996 as an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency was directed to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

The Agency has concluded that labeled uses for the tributyltin could result in direct or indirect food exposures and incidental exposures. As mentioned above, there is evidence in the open literature suggesting that children may be more sensitive to TBT exposures than adults. Other data from two developmental toxicity studies and one reproductive toxicity study with TBT compounds show no evidence of increased sensitivity for fetuses or offspring. The Agency has not at this time confirmed an increased sensitivity in young, so has not applied a special sensitivity factor for the pre- and post-natal exposures. In addition to uncertainties about differential sensitivity based on age, there is some uncertainty associated with the magnitude of endocrine effects from human exposures to TBT, and in dietary exposures to TBT. As a result, the Agency has applied a 10X data base uncertainty factor for exposures contributing to aggregate risk.

d) Endocrine disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the

program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCFA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, tributyltin oxide, tributyltin maleate and tributyltin benzoate may be subject to additional screening and/or testing to better characterize the known effects related to endocrine disruption, reproductive anomalies in marine invertebrates and thyroid effects in several other species.

In 1996, the White House's Office of Science and Technology Policy began coordinating efforts across the Federal government to investigate and manage endocrine disrupting chemicals. A report of that Office's National Science and Technology Council on those efforts, "The Health and Ecological Effects of Endocrine Disrupting Chemicals," states that "...many of the same hormones and their receptors are present across species, genera, classes and even phyla [suggesting] that effects reported in one species from exposure to endocrine disrupting chemicals could have widespread biological implications." (<http://www.epa.gov/endocrine/frametext.html>). It is on this basis that the Agency assumes that endocrine disruption effects observed in other species indicate the potential for endocrine disruption in humans.

The open literature includes many reports of endocrine effects associated with exposure to TBT, including well-documented effects in marine species. Upon exposure to TBT in antifouling paints, *Nucella lapillus*, a dogwhelk snail, has been shown to develop a pathological condition termed "imposex," in which male reproductive organs (the penis and the vas deferens) form in females of the species. The growth of the penis in a female dogwhelk blocks the oviduct, ultimately preventing the release of ovules and ultimately resulting in her death. It has been suggested that imposex can cause population reductions in affected species. TBT is the only known inducer of imposex in the marine snails. Reports of the endocrine disrupting effects of exposure to organotins also have been published for bivalves in the phylum *Mollusca* (abalone) and mysids of the phylum *Arthropoda*. The open literature also contains reports of *in vitro* endocrine effects on human enzymes involved in estrogen. As indicated previously, the magnitude of such effects in humans is a source of database uncertainty.

The Agency has proposed priorities for screening pesticide active ingredients for endocrine disruption, based primarily on the potential for human exposure rather than documentation of potential endocrine effects. Exposures in four pathways were considered: food, water, residential use, and occupational exposure. The organotin compounds are now produced in relatively low quantities in the US, and were not selected for the initial screening (*Draft List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening under the Federal Food, Drug, and Cosmetic Act*. 2007. 72FR 116, pp. 33486-33503, which can be found at http://www.epa.gov/scipoly/oscpendo/pubs/draft_list_frn_061807.pdf).

2. Incident reports

The following databases were consulted: Incident Data System of (EPA's) Office of Pesticide Programs, Poison Control Centers, California Department of Pesticide Regulation, and the National Pesticide Information Center. In addition, some incident reports associated with TBT health hazards are published in the scientific literature. The incidents reported in these databases are summarized here.

Primary systemic effects associated with the incidents recorded in these databases are nausea, dizziness, headache, and sore throat. The primary dermal effects that have been reported are rash, burning sensation, and itching.

Several incidents were reported for exposures to walls and joists treated with TBTO wood preservatives. They occurred when TBTO was used in combination with other chemicals. Exposures were associated with effects in residents and workers, including muscle weakness, tremors, and numbness in the extremities, eye irritation, respiratory distress, poor coordination and unsteadiness. Dermal exposure led to effects including rash, hives/welts, itching, blisters, color alteration, eye irritation, headache, nausea, and dizziness. Inhalation of the chemical vapors in one case resulted in chest pain and another resulted in seizures.

One incident was reported in which a woman was exposed to pillows treated with a product containing tributyltin maleate. The exposure routes were dermal and ocular. The woman developed swelling in her mouth, cheeks, neck, lips, and throat. She had difficulty speaking. She also suffered irritation of the eyes and mouth, quivering of the jaws, and a lack of concentration.

3. Dietary and drinking water risk summary

A more complete discussion of the dietary exposures considered for this RED is available on the Docket in the dietary risk assessment, dated March 20, 2008. This document is available in the Docket at www.regulations.gov (docket # EPA-HQ-2008-0171).

a) Residues in Food

TBT compounds are labeled for use in the following sites where a potential for food contact may occur: water cooling systems for pasteurization/canneries, paper, and adhesives. All of the TBT product labels for these use sites include specific prohibitions against the use of treated materials for food contact uses or use otherwise include directions intended to minimize indirect dietary exposures. The Agency believes that a dietary assessment is not warranted for these uses.

TBTO is also used as a disinfectant in livestock operations. For some applications, animals are removed prior to the treatment of the facilities, and the feeding equipment is rinsed with water prior to reuse. The Agency typically assumes that such conditions result in negligible residues. Product labels do not direct users to rinse or remove TBT solution or fogging residue

from surfaces after treatment, except for feeding and watering equipment. For some applications, animals are present when premises are treated. Eggs usually are present during treatment of egg hatching and storage areas. The Agency typically assumes that incubating eggs do not absorb pesticide residues on their shells. The registrant has indicated that the removal of eggs to avoid deposition of residues during application is not feasible, and that premises may be treated as frequently as once a day. No dietary residue data are available to assess potential exposures resulting from any of these uses.

The Agency does not ordinarily require residue data for antimicrobial pesticides that are used in animal premises, but because TBT residues are not physically removed from surfaces, animals, or eggs in treated areas, and because TBT is very persistent in the environment and is bioaccumulative, the Agency believes that it is possible for residues to remain in and on animals, eggs, and animal premises long after a treatment has occurred, and to concentrate in animals via incidental or dermal exposure. Consequently, there is a potential for human dietary exposure associated with the livestock premises uses. These potential exposures cannot be quantified without residue data.

b) Residues in drinking water

Discharges of treated cooling water, disposal of excess TBT solution from farm premises treatments, and leaching of TBT from treated exterior building materials and irrigation tubing may have potential to impact drinking water sources. A quantitative drinking water assessment has not been conducted as an appropriate method for assessing exposure data is lacking.

4. Occupational and residential risk assessment

Details of the residential exposure assessment can be found in the occupational and residential exposure assessment available on the Docket. This document is available at www.regulations.gov (docket # EPA-HQ-2008-0171). The Agency selected representative scenarios for residential exposures. These scenarios reflect high-end exposure estimates.

a) Residential handler exposures

Short-term inhalation and dermal exposures were assessed for applications of wood preservatives on houses—exterior siding, decks, etc. Tributyltin vapor pressure is low; inhalation exposures were assessed for aerosols only.

b) Residential post-application exposures

Post-application scenarios have been selected to represent high-end exposures and include dermal exposure and/or incidental ingestion exposures from treated fabric. Bystander inhalation of aerosols generated during painting is assumed to be less than exposures to the applicator and was not assessed separately. Post-application exposures to vapors that result from the wood preservative use are assumed to be negligible.

The Agency has used available data to estimate exposures to treated clothing and mattress covers. Two leaching studies for fabric treated with TBT were submitted to the Agency during the public comment period on the risk assessments for the RED. A detailed discussion of these studies is provided in the revised occupational and residential exposure assessment available at www.regulations.gov (docket # EPA-HQ-2008-0171). The registrant believes that the transfer of TBT from fabric to skin is much less than the default value of 100%. EPA has reviewed both of the studies and has concluded that the submitted studies by themselves are not adequate to support the use of the lower transfer rate. In particular, the second study does not supply sufficient information for calculating the amount of TBTO transferred from fabric to skin; the weight of the material is unknown and the 10 ppb concentration cannot be converted to ug/cm² of material. Risks were assessed for 100% and 5% transfer rates, to represent high- and low-rates of transfer.

c) Residential risk characterization

Data sources and methodologies utilized for both the handler and post-application residential risk assessment include: the HED Residential Standard Operating Procedures (SOPs) (USEPA, 1997a), the USEPA Exposure Factors Handbook (USEPA 1997b), Recommended Revisions to the Residential SOPs (USEPA, 2001), and the Human and Environmental Risk Assessment (HERA) Guidance Document (2003). The specific input parameters and assumptions are discussed in the revised occupational and residential risk assessment available from the Docket. Residential handler exposure and risk estimates are summarized below. The target MOE for residential exposures is 1000, resulting from a 10X factor to account for species-to-species variability, a 10X factor for within-species variability, and the 10X database uncertainty factor described above.

Table 5. Residential handler MOEs for applying paints and stains containing TBT

Exposure Scenario Application Method	Application Method	MOE (Target MOE = 1000)	
		Inhalation	Dermal
Staining/Painting	Paint brush	60	<1
	Airless sprayer	3	<1

Modeled exposures are much lower than the target MOE and are of concern.

For post-application exposures to treated fabric, the Agency calculated MOEs for a high and low dermal transfer rate. The Agency also used transfer values from the first study submitted by the registrant to estimate exposures.

Table 6. Post-application MOEs for Toddlers and Adults Contacting Treated Textiles

Exposure Scenario	Percent residue transferred from clothing to skin	Dermal MOE (Target MOE = 1000)
Clothing, blankets		
Toddler	100	<1
	5	2
Adult	100	<1
	5	3
Study #1 Application Rate (2.58% product by weight, product containing 1% TBTO)		
Toddler	NA	35
Mattress covers		
Children	100	<1
	5	7
Adults	100	<1
	5	11
Study #1 Application Rate (2.58% product by weight, product containing 1% TBTO)		
Children	< 10 ppb	8

All the scenarios assessed yielded MOEs well below the target. Dermal transfer rates are not relevant to potential incidental exposures to toddlers mouthing treated textiles. The Agency estimates that the MOE for incidental oral exposure is 2, well below the target MOE of 1000.

5. Aggregate risk

In order for a pesticide registration to continue, it must be shown that the use does not result in “unreasonable adverse effects on the environment.” Section 2 (bb) of FIFRA defines this term to include “a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with standard under section 408...” of FFDCA. As mandated by the FQPA amendments to FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency must consider total potential aggregate exposure from food, drinking water and residential sources of TBT. Aggregate exposure is the total exposure to a single chemical that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from plausible exposure routes (oral, dermal, and inhalation). Typically, aggregate risk assessments are conducted for acute (1 day), short-term (1-30 days), intermediate-term (1-6 months) and chronic (6 months to lifetime) exposures.

The Office of Pesticide Programs has published guidance outlining the necessary steps to performing aggregate exposure and risk assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>). Steps for deciding whether to perform aggregate exposure and risk assessments are listed, which include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which

possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk.

Risks are of concern for individual uses that contribute to TBT aggregate exposure, therefore, the aggregate risks would be of a concern as well.

6. Cumulative Exposure and Risk

Section 408 of the FFDCA requires that the Agency must consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when making a determination about unreasonable adverse effects for a pesticide.

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, no common mechanism of toxicity finding relative to TBT and any other substances has been made, and for the purposes of this RED, EPA has not assumed that the TBT compounds have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

7. Occupational Exposure and Risk

a) Occupational handler exposure scenarios

The Agency has assessed the exposures and risks for occupational workers who handle TBT-containing products and who are exposed to TBT after application. A detailed discussion of occupational risks can be found in the revised occupational and residential exposures assessment posted to the TBT Docket (www.regulations.gov, docket # EPA-HQ-2008-0171). Post-application exposures were assessed for machinists handling TBT-preserved metalworking fluids and workers re-entering a hatchery after fogging with the TBT disinfectant.

Occupational handler exposures to TBT can occur during applications of materials preservatives, applications to farm premises, cooling water towers, oilfield and petrochemical injection systems, metalworking fluids, and when applying wood preservatives. Application of materials preservatives refers to the scenario of a worker adding the TBT preservative to the material being treated (joint compound, adhesives, paper, etc.) through either open pouring or a metering pump. Open pouring is the transferring of antimicrobial product from a small container to an open vat. Use of a metering pump involves transferring the antimicrobial product by connecting a chemical metering pump from a tote or by gravity flow to be diluted for use. These same processes are used for cooling towers, oilfield and petrochemical injection systems, and metal working fluids. Workers may apply wood preservatives through several methods,

including paint brushes and airless sprayers. Handlers of TBT products for farm premises applications may apply the material by brush, mop, wipe, spray, or fogger (thermal, automated, or otherwise).

For materials preservatives, cooling towers, and oilfield and petrochemical injection fluids, EPA expects that occupational exposures will be negligible or minimal for handling tributyltin-containing products via closed loading, assuming that label-specified PPE (i.e., long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves) are consistently utilized.

b) Occupational post-application exposure scenarios

Occupational post-application exposures are believed to be minimal except for machinists working with metal working fluids and workers reentering farm premises after TBT treatments. Post-application exposures to machinists using metal working fluids with TBT additives are considered to be long-term

c) Occupational risk characterization

Data sources and assumptions are fully discussed in the revised occupational and residential risk assessment available from the Docket. Most occupational exposures are considered to be short- and intermediate-term.

Table 7. Risks for Occupational Handlers

Exposure Scenario	Method of Application	MOE (Target MOE = 100)	
		Inhalation	Dermal
Agricultural Premises and Equipment			
Agricultural/farm/poultry structures/buildings and equipment	Brush-on	4500	47 (350 w/gloves)
	Wipe	360	57
	Mop	1300	300
	Spray (hand held)	930	22
	Spray (mechanical)	1300	420
	Fogger (hand-held)	2	<1
Material preservatives			
Caulk (representing joint compound, adhesives, etc.)	Open pour	210	36
	Metering pump	360	2
Metal working fluids	Open pour	68	21
Industrial Processes and Water Systems			
Paper	Open pour or metering pump	Closed loading systems are expected to result in minimal	
Cooling water			

Exposure Scenario	Method of Application	MOE (Target MOE = 100)	
		Inhalation	Dermal
		exposure.	
Oil fields and petrochemical water injection systems	Open pour	3	3
	Metering pump	Closed loading systems are expected to result in minimal exposure.	
Wood preservatives			
Painting/staining (commercial)	Paint brush	24	<1
	Airless sprayer	<1	<1

Occupational post-application exposures are assumed to be negligible except for the machinist exposed to TBT-treated metalworking fluids and workers re-entering farm premises after treatment. Dermal and inhalation MOEs for machinists are 3 and 36, respectively. It is not considered feasible for a machinist to wear protective PPE due to the nature of the work. Workers re-entering treated farm premises are considered to be adequately protected (i.e., MOE at or above 100) after a restricted entry interval of 2 hours.

B. Environmental Risk Assessment

Detailed information on environmental fate is presented in the environmental fate assessment available at (www.regulations.gov, docket # EPA-HQ-2008-0171). A brief summary is provided below. For purposes of this risk assessment, TBTO is the primary focus of the environmental fate discussion.

TBTO is essentially stable to hydrolysis and photolysis in freshwater and saltwater. Based on its low vapor pressure, it is not expected to volatilize from water. Biodegradation is considered to be the major breakdown pathway of this chemical when it is present in either water or sediments. Half-lives are in the range of several days to weeks in water and from several days to more than a year in sediments (the open literature supports the longevity of TBT and degradates, especially in the sediment.). The octanol/water partition coefficient is very high. TBTO has a high tendency to bioconcentrate (e.g., concentrate in the tissues of species that may ingest the chemical) and bioaccumulate (e.g., concentrate in the food chain).

1. Ecological toxicity for wildlife species

A detailed ecological hazard and environmental risk assessment for TBTO is available at www.regulations.gov (docket # EPA-HQ-2008-0171). A summary of findings is presented below. A quantitative ecological risk assessment has been conducted for TBTO wood preservative applications. Data are not available for environmental exposures resulting from other uses, but the Agency has highlighted those it believes have the potential to contaminate drinking water and natural waters.

a) Acute and dietary toxicity to birds and mammals

Acute oral and dietary studies indicate that technical-grade TBTO is moderately toxic to birds if ingested. Based on these study results, an avian precautionary statement is not warranted for the TBT product labels. The guidelines for avian acute-oral toxicity (OPPTS 850.2100) and avian dietary toxicity (OPPTS 850.2200) are satisfied. Mammalian acute toxicity data from several studies indicate that TBT compounds are moderately toxic to small mammals on an acute-oral basis.

b) Non-target insects – honeybees

No guideline data are available for TBTO. In the absence of data on residues in honey and beeswax and acute toxicity of treated wood residues to bees, risks to honeybees cannot be assessed. The Agency believes that precautionary labeling on the use of TBT wood preservatives on wood used for beehive construction can be used to address these uncertainties.

c) Acute toxicity -- freshwater fish

Two acute toxicity studies with the TGAI are required to establish the toxicity of TBTO compounds to freshwater fish. The acute toxicity data characterize technical-grade TBTO as being very highly toxic to freshwater fish. A precautionary statement is triggered for product labels. The guideline for freshwater-fish acute toxicity (OPPTS 850.1075) is satisfied.

d) Acute toxicity -- freshwater invertebrates

A study with the TGAI is required to establish the acute toxicity of TBT to freshwater invertebrates. The preferred test species is the water flea, *Daphnia magna*. Results from two guideline studies categorize technical-grade TBTO as being very highly acutely toxic to the water flea. A precautionary statement is triggered for product labels. A study testing dibutyltin dichloride categorizes this degradate as moderately toxic. The guideline requirement (OPPTS 850.1010) is satisfied.

e) Estuarine and marine fish and invertebrates, acute toxicity

Two guideline fish toxicity studies are available. The results of these studies indicate that TBTO compounds are very highly toxic to estuarine/marine fish. The guideline for estuarine/marine-fish acute toxicity (OPPTS 850.1075) is satisfied. Acute toxicity data are available for a number of estuarine/marine invertebrate species, including the Eastern oyster (*Crassostrea virginica*), Pacific oyster (*Crassostrea gigas*), bay mussel (*Mytilus edulis*), fiddler crab (*Uca pugilator*), pink shrimp (*Penaeus duorarum*), and grass shrimp (*Palaemonetes pugio*). The acute toxicity data indicate that TBT is very highly toxic to estuarine/marine invertebrates.

f) Chronic toxicity for aquatic organisms

No guideline studies are available to assess chronic risks of TBT-containing compounds to freshwater fish and invertebrates. However, EPA's (2003) *Ambient Aquatic Life Water Quality Criteria for Tributyltin (TBT) – Final* presents chronic toxicity values for a 32-day early life-stage study with the fathead minnow (*Pimephales promelas*) and for two 21-day life-cycle studies with *Daphnia magna*. NOEC values for adverse reproductive affects ranged from 0.1 to 0.19 $\mu\text{g ai/L}$ across the three studies. Two guideline studies with the sheepshead minnow are available to assess the chronic toxicity of TBTO to estuarine/marine fish. These studies fulfill the guideline (850.1400) for a fish early life-stage (freshwater) study. No valid guideline studies are available for aquatic invertebrates.

The open literature contains abundant information on the toxicity of TBT to aquatic invertebrates including reports of shell deformation in oysters and reproductive aberrations in certain marine snails (imposex). Research suggests that sensitive species may exhibit severe toxic effects in water at TBT concentrations in the parts-per-trillion range. In addition, TBT has been shown to bioaccumulate in the aquatic environment, and there are reports of toxicity in marine mammals exposed in the natural environment, including suggestions of immunotoxic effects. As mentioned previously, TBT is a known endocrine disruptor with documented effects in wildlife. The bibliography for this RED includes several citations on the effects of TBT on marine mammals.

2. Acute and chronic sediment toxicity

No guideline studies are available. Acute and chronic sediment toxicity data are needed to support TBT uses with the potential for contaminating sediment, because pertinent environmental fate data predict that residues will move into the aquatic environment and be deposited and persist in sediments. The $K_d > 10$ for acute and > 50 for chronic, the $\log K_{ow} > 3$, the $K_{oc} > 1,000$, and soil aerobic half-life has been reported as 127 days in laboratory testing.

3. Aquatic plants

No guideline studies have been submitted for TBT. Aquatic plant growth testing (850.5400) with the TGAI or TEP is required for all pesticides that entail wood preservative uses. The EPA (2003) *Ambient Aquatic Life Water Quality Criteria for Tributyltin (TBT) – Final* provides some information indicating that phytotoxicity of TBTO to aquatic plants may be of concern.

C. Environmental risk assessment criteria

Risk assessment and characterization integrate exposure and toxicity information to evaluate the potential for adverse ecological effects to occur at concentrations of the pesticide that may be found in natural waters. Risk quotients (RQs) are determined for each taxon or ecological group by comparing exposure estimates (Estimated Environmental Concentrations, EECs) to the available acute and chronic ecotoxicity values, where:

$$\text{RQ} = \text{Exposure estimate (EEC)} / \text{Toxicity value}$$

RQs are compared to OPP's levels of concern (LOCs). Exceedance of an LOC indicates a potential for acute or chronic adverse effects and identifies a need for regulatory action to mitigate risk.

Table 8. Levels of Concern for Wildlife Subgroups

Presumption	Aquatic Animals	Terrestrial Animals	Plants
Acute risk	0.5	0.5	1
Acute risk, listed species	0.05	0.1	1
Chronic risk	1	1	n/a

When available, toxicity measures or other appropriate information from non-guideline studies or from the open literature also may be used to characterize risk.

OPP generally uses computer simulation models to estimate exposure of aquatic organisms to an active ingredient. These models estimate EECs in surface waters using product-label information (e.g., treatment site, application rate, application method,) and available environmental-fate data to determine how fast the pesticide breaks down and its expected movement in the environment. For some scenarios which the Agency believes may result in environmental contamination with TBT, data and models are lacking to estimate environmental concentrations, including farm premises uses, cooling tower discharges, disposal of metal working fluids and petrochemical injection liquids after use, leaching from treated irrigation tubing. The Agency is able to estimate environmental concentrations associated with TBTO-containing wood preservatives. The model and results are summarized below and described in more detail in the ecological risk chapter posted to the TBT Docket at www.regulations.gov (docket # EPA-HQ-2008-0171).

D. Aquatic and Terrestrial Risk Characterization

EECs for the leaching of TBTO from treated wood into soil and surface waters were calculated for six uses: transmission poles, fence posts, fences, deck posts, decks, and houses. The methodology for this analysis is based on an environmental risk assessment previously prepared by the Rohm and Haas (2006) for 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone (DCOIT). Soil concentrations and other input data are then used with EPA's Express model EXAMS-PRZM Exposure Simulation Shell (version 1.03.02) to estimate concentrations in surface water. Data compensation will need to be made for the use of Rohm and Haas' study.

TBT is expected to accrue in aquatic sediments, with half-lives from several days to months or more (EPA 2003); thus, sediments may be a long-term source of exposure of aquatic organisms. The risks associated with the presence of TBT in the sediment cannot be adequately assessed without acute and chronic sediment-toxicity data. There is evidence in the open literature that certain sediment concentrations can trigger severe effects in various aquatic organisms, and the particulars of the various effects are discussed in more detail in the supporting ecological hazard chapter.

Potential risks to aquatic plants cannot be quantitatively assessed without the relevant toxicity data.

Based on the values calculated for the ecological risks, acute risks to listed (i.e., endangered or threatened) fish and invertebrates are presumed to result from aquatic exposure to TBTO resulting from wood preservative use. This presumption of risk necessitates a more comprehensive risk assessment for listed species, but is not included in the current assessment (see Endangered Species Considerations section). Although the Agency's calculated chronic LOC is not exceeded for either fish or aquatic invertebrates, evidence exists that chronic exposure may be a concern for some organisms. EPA considers TBT-containing compounds to be a concern in the aquatic environment due in part to TBT's persistence and its link to imposex and immunosuppression in aquatic organisms. Through its authority under the Clean Water Act, the Agency developed ambient water quality criteria for TBT-containing compounds (EPA 2003), based on a broad selection of published data. These criteria, in combination with characteristics of local water bodies, are used by the States to establish permit limits under the National Pollutant Discharge Elimination System.

TBT is moderately toxic to birds and mammals, and acute effects are possible if TBT-contaminated food is eaten. Because TBT bioaccumulates in tissues of organisms, food sources such as earthworms and fish could expose species of birds and mammals. At this time, the Agency is unable to assess risks to birds and mammals that eat contaminated food.

The Agency conducted a quantitative assessment of the risks associated with the use of TBT as a wood preservative. For other uses which may result in TBT releases in the aquatic environment, risks are addressed in a qualitative manner. The following table shows only those wood preservative uses with RQs which exceed LOCs.

Table 9. Acute Ecological Risks for the Wood Preservative Use of TBTO

Use	RQ	Acute LOCs exceeded
Freshwater Invertebrates		
House	0.05	listed species
Estuarine/Marine Invertebrates		
House	0.45	listed species
Fence	0.32	listed species
Deck Post	0.20	listed species
Fence Post	0.12	listed species
Deck	0.09	listed species

A more refined assessment should include analyses for direct and indirect exposures of non-target organisms, and habitat effects.

E. Endangered species considerations

Section 7 of the Endangered Species Act (ESA), 16 U.S.C. Section 1536(a)(2), requires that federal agencies consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or with the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species is to "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species," (50 C.F.R. §402.02).

To comply with subsection (a)(2) of the ESA, EPA's Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly appreciably reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). If any of the Listed Species LOC Criteria are exceeded for either direct or indirect effects in the Agency's screening-level risk assessment, the Agency identifies any listed or candidate species that may occur spatially and temporally in the footprint of the proposed use. Further biological assessment is undertaken to refine the risk. The extent to which any species may be at risk determines the need to develop a more comprehensive consultation package as required by the ESA. The comprehensive assessment has not been conducted at this time for the TBT compounds.

IV. Reregistration Eligibility and Risk Management Decisions

The Agency typically assesses tolerances for pesticides as part of the reregistration decision. At this time, there are no existing tolerances for TBT or metabolites and no data to indicate if residues are present in food commodities as a result of the use of TBT. No tolerance assessment has been conducted at this time.

TBT is highly bioaccumulative and very persistent in the environment. The Agency does not ordinarily require residue data for antimicrobial pesticides that are used in farm premises. The Agency believes that the persistence and bioaccumulative potential of TBT could result in residues of TBT in animals and eggs inhabiting, incubating, or held in areas that have been treated. Residues deposited in the treated area may remain long after a treatment has occurred, and may concentrate in animals via incidental or dermal exposure. Based on the use of the farm premises disinfectant and the environmental fate characteristics of TBT, the Agency has

determined that TBT residue data are required to support the use of TBTO on farm premises; these data, once reviewed, could indicate a need for the establishment of tolerances.

A. Determination of reregistration eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing a pesticide active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data to support reregistration of products containing TBT compounds. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of some uses of TBT. Other uses are lacking data the Agency has determined are necessary for the support of TBT reregistration. These studies are identified in Section V of this document.

Based on available data, the Agency has completed its assessment of the residential, occupational, and ecological risks associated with the use of pesticide products containing TBT active ingredients. The Agency has determined that some TBT uses are eligible for reregistration with the following caveats: 1) all risk mitigation measures described in this document must be implemented, 2) current data gaps and confirmatory data must be addressed, and 3) label amendments must be made as described in Section V.

Some uses of TBT are not eligible for reregistration. For some products with uses not eligible for reregistration, registrants have requested termination of the subject uses or cancellation of the subject registrations. At a minimum, if the Agency were to consider the registration of these uses of TBT in the future, uses identified as ineligible would be subject to additional data requirements not included in the data gaps identified in Section V.

The following table shows which uses are eligible for reregistration and which are not. The reregistration eligibility decisions are explained under “Regulatory Rationale” below.

Table 10. Eligibility of Uses of TBT for Reregistration

Eligible for Reregistration	Not Eligible/ Request for Voluntary Cancellation
Farm premises ²	
livestock premises	inter-depopulation treatments
kennels	tack
veterinary clinics	equipment with direct animal contact
animal laboratories	tools
breeding facilities	immersion treatments
hatcheries	boot bath
egg rooms	
incubators, setters	

² Eligibility dependent on labeling that prohibits application when animals or eggs are present, application via hand-held fogger (thermal or otherwise)

Eligible for Reregistration	Not Eligible/ Request for Voluntary Cancellation
egg trucks	
Wood preservatives	
	all uses
Materials preservatives in building materials	
drywall, joint compound	
fiber board, particulate board	
adhesives	
Materials preservatives in textiles and related materials	
fiberfill, foam ³	clothing, including hosiery
carpet backing	mattress covers, pillow covers, ticking
air filters	sponges, mop heads
rubber mats	laundry treatments
canvas/other fabrics for tarps, tents, awnings	canvas/other fabrics for cushions, hammocks
webbing for nets in sport applications	rope ⁴
paper ⁵	textiles with potential for direct dermal contact
Cooling water	
	all uses
Metal working fluids	
	all uses
Petrochemical injection	
	all uses
Irrigation tubing for non-agricultural applications	
	all uses
Antifouling	
sonar domes	previously cancelled: ships, boats, crab/lobster/bass pots
antifoulant devices in oceanographic conductivity sensors	

The Agency has determined that some TBT products, labeled and used according to label directions, may present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measures, make the label changes identified in this document, and submit confirmatory data, the Agency may take regulatory action to address the risk concerns from the uses of these TBT registrations. If the registrants comply in entirety with all requirements outlined in this document for products otherwise eligible for reregistration, then, for the purposes of this determination, no risks of concern will exist for the registered uses of TBT. When the endangered species assessment for TBT is completed, further changes to TBT registrations may be necessary.

B. Public comments and responses

³ Except if used in mattress covers

⁴ Request for use termination pending

⁵ Eligibility dependent on labeling that prohibits use in paper for direct or indirect food contact

Through the Agency's public participation process, EPA has solicited input from stakeholders (including the general public) for consideration in formulating the regulatory decision for TBT. EPA released its preliminary risk assessment of the TBT compounds for public comment on April 2, 2008. The Agency received just one comment (from a registrant) during the 60-day public comment period, which closed on June 2, 2008. This comment included observations on the Agency's human health risk endpoint selection, leaching of TBT from treated sponges, and transfer of TBT from treated textiles to human skin. The comments have been addressed through revisions to the risk assessments or in a separate "response to comments" document that is posted to the TBT docket along with other supporting information at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0171).

C. Regulatory Rationale

The Agency has determined that some uses of TBT are eligible for reregistration, with several caveats and conditions. For those uses that are eligible, risk mitigation measures and label changes must be implemented as outlined in this document, and required data must be submitted. Requirements for revised label language are set forth in Table 12 in Section V of this document.

Eligibility decisions for the different uses of TBT are all influenced by an overarching concern associated with the environmental fate characteristics of TBT. In particular, TBT compounds are very persistent in the environment and have a high potential for bioaccumulation. These characteristics increase opportunities for exposure to TBT in the environment and the food chain.

The environmental persistence of TBT increases opportunities for human and wildlife exposures because organisms are exposed to TBT residues for a long time after the pesticide is introduced into the environment. Aquatic organisms remain in contact with contaminated water or sediment, or may ingest food items contaminated with TBT residues, long after the initial contamination occurs. Because TBT is bioaccumulative and lipophilic, TBT may concentrate in the food chain, so that species at the top of the food chain, like predator species and man, may be exposed to concentrations above what is present in individual food sources, water, or sediment.

Another overarching concern affects decision-making for TBT. Research findings indicating that TBT is an endocrine disruptor in a number of species represent a toxicological impact that EPA's current risk assessment methodologies cannot account for quantitatively. The Agency is working to understand the scope of endocrine effects associated with pesticides and the relationship between endocrine effects in wildlife and effects in humans. For the time being, the Agency is assuming that exposures that result in adverse endocrine effects in animals have the potential to cause adverse endocrine effects in humans.

1. Human Health Risk Management

a) Dietary (food) and drinking water risk mitigation

The Agency was unable to conduct a quantitative food or water dietary exposure assessment for TBT because empirical exposure data are lacking. However, TBT is highly toxic, so that even very small exposures may be associated with unacceptable risks. Instead of a quantitative exposure assessment, the Agency considered the fate and toxicological characteristics of the TBT compounds, the nature of potential dietary exposures, and the type of data that would facilitate a quantitative dietary assessment. The Agency has concluded that there is a potential for dietary exposures of concern associated with the use of TBT disinfectants on farm premises.

In order to address the potential for harmful dietary exposures associated with the farm premises uses, the Agency is prescribing the following risk mitigation measures:

- Animals must be removed from premises (e.g., livestock housing and breeding facilities) prior to treatment of premises and surfaces within these premises with TBT. Animals must not be returned to premises for at least 48 hours following the conclusion of treatment. As required by current labeling, feeding and watering bowls and equipment must be removed prior to treatment, or washed with soap and water after treatment and before reuse.
- The use of TBT in egg handling facilities and vehicles (hatcheries, egg rooms, incubators, egg trucks, etc.) when eggs are present is prohibited. The registrant has not provided data showing that repeated and frequent applications of TBT do not result in transfer of residues in eggs through the shell or in hatched chicks. Labels allow that eggs may be treated daily before hatching, and because TBT is both persistent and bioaccumulative, the Agency is concerned that TBT could concentrate in the eggs and enter the food supply in chickens raised from treated eggs, posing a risk of dietary exposure. Several products containing other active ingredients are registered for similar uses, including some registered to the registrant holding the TBT farm premises product. The Agency has concluded that only a small percentage of egg producers use the TBT product, suggesting that effective alternatives are available and preferred by many producers.
- Treatment of tack (halters, etc.) with TBT is prohibited. Animals may have constant, direct contact with tack; there is potential for TBT transfer from treated tack to livestock that may be used to produce meat and milk, or companion animals. By the same reasoning, treatment of other equipment or tools that come into direct contact with livestock is prohibited.

Other risk mitigation measures for the farm premises use are explained in the sections on occupational handler and post-application exposures below. If the risk mitigation measures and revised labeling are implemented, and if related data needs are satisfied, the use of TBT on farm premises is eligible for reregistration. The Agency is requiring data on residues of TBT and metabolites in meat, milk, and eggs in support of the use of TBT on farm premises, as noted in Section V of this RED.

Although the Agency believes there are a number of TBT use sites with potential for contaminating water sources and underlying sediments, data and appropriate models are lacking to conduct a drinking water risk assessment for TBT. (The same use sites have the potential to pose risks of concern to wildlife. These other uses and the rationale for the associated reregistration eligibility decisions are discussed below under Environmental Risk Management below. Per the Agency's concern about TBT residues in both drinking water and wildlife habitat, these uses are not eligible for reregistration.)

b) Related issues; risks to domestic animals

The same TBT product registered for use on farm premises is also registered for use in animal housing facilities in non-farm situations (e.g., kennels, veterinary clinics, and breeding facilities). Although the treatment of such facilities is not expected to result in dietary exposures, the Agency believes it is prudent to apply similar risk mitigation measures to these use sites, based on concerns about dermal exposures to companion animal veterinarians, veterinary technicians, laboratory workers, and owners and handlers of domestic animals. The risks associated with these exposures cannot be quantified, but potential risks can be mitigated via the same measures applied to the farm premises uses. Therefore, the risk mitigation measures of farm premises will apply to non-farm animal premises. Other risk mitigation measures for this use are explained in the sections on occupational handler and post-application exposures below.

The use of TBT in animal housing facilities in non-farm situations will be eligible for reregistration if all appropriate risk mitigation measures and labeling revisions are implemented.

c) Residential risk mitigation

Wood preservative handlers

Short-term residential handler risks were estimated for people who apply wood preservatives to outdoor construction and building components. The target MOE for these applications is 1000. Risks were estimated for application by brush and airless sprayer. Both dermal and inhalation MOEs were much lower than the target—ranging from <1 to 60. These MOEs represent application of 2 gallons (by brush) and 15 gallons (by airless sprayer). It is not feasible to reduce residential handler risks by requiring personal protective equipment or engineering controls.

Other measures, such as reductions in the percentage of active ingredient in TBT products, would have to effect a reduction of exposure by a factor on the order of 1000 (to increase the MOE of <1 to the target MOE) in order to provide adequate protection. An application rate of this magnitude would likely result in an inefficacious product. It is unlikely that even a combination of measures would reduce the risks to residential handlers adequately. There currently are no data available to refine the assessment, and the Agency believes that any such data would be unlikely to yield MOEs of 1000 or more. Because of the very low MOEs, the lack of feasible mitigation options, and the absence of data which do or could be expected to yield adequately protective refined MOEs, the Agency has determined that TBT products used

for wood preservation on homes, buildings, building components, and outdoor furniture are not eligible for reregistration. Additional discussion of the risks and mitigation for this use are explained in the sections on occupational risk mitigation and environmental risk management below.

Post-application residential risk mitigation; textiles and related uses

Residential post-application risks were estimated for dermal exposures to clothing and mattress covers treated with TBT; incidental oral exposure for toddlers mouthing treated fabric was also estimated. In all cases, MOEs were well below the target MOE of 1000. It is not likely that application rate reductions or refined estimates for fabric to skin transfer or dermal absorption would be adequate to increase these MOEs by a factor of 100 or more to the target MOE.

Although there are no data for use in quantifying residential post-application exposures from the use of treated sponges and mop heads, the Agency is concerned about exposure to dishes, counters, floors, and other residential surfaces washed with treated sponges or mops.

Data are also lacking for exposures associated with fiberfill or foam in upholstered furniture, carpet backing (not face fibers), treated air filters, rubber mats, canvas and other fabrics for outdoor applications (such as tarps, awnings, and tents), and webbing (used with golf driving range protective netting, netting for baseball batting cages, and tennis nets), but the Agency believes that these uses would result in negligible or no post-application residential exposure.

Based on the risk assessment and the assumptions cited above, and in the absence of relevant data, the Agency has determined that the uses of TBT on textiles and related materials that have the potential for prolonged dermal exposure or incidental oral exposure (e.g., clothing, mattress and pillow covers and ticking, sponges, mop heads, canvas or other fabrics for furniture cushions and hammocks) are not eligible for reregistration. The uses of TBT in textiles and related materials that are not associated with prolonged human exposure (e.g., paper, fiberfill or foam in upholstered furniture (but not for mattress pads); carpet backing; air filters; rubber mats; canvas and other fabrics for tarps, awnings, and tents; and webbing used for golf course/driving range protective netting, netting for baseball batting cages, and tennis nets) are eligible for reregistration. Labeling is required to prohibit the use of paper containing TBT for direct and indirect food contact.

Other risk mitigation measures for these uses are explained in the section on occupational handler mitigation below.

d) Aggregate risk

Aggregate risks were not estimated because risks associated with some individual contributors to post-application residential risk exceed levels of concern.

e) Occupational risk mitigation--handlers

Occupational handler exposures may be associated with commercial application of TBT wood preservatives, adding TBT products to cooling water, applying TBT disinfectant in farm and animal premises, manufacturing treated materials such as textiles and building materials, using TBT in oil field and petrochemical water injection systems and metalworking fluids.

Cooling towers

TBT is currently registered for use in commercial and industrial recirculating cooling towers. For handlers adding TBT products to cooling tower water, data are not available to estimate exposures for open-pour or metering-pump applications. The Agency's practice for handler risk mitigation for this use pattern is to take into account both the volatility of the pesticide and its toxicity. In the case of TBT, volatility is not a big concern, but the toxicity of TBT suggests occupational exposures will pose risks. The Agency does not always require the closed loading systems for antimicrobial pesticides, but in the case of TBT, given its toxicity, the Agency believes that a closed loading system with a dry coupling (i.e., a system in which the TBT additive can be withdrawn from the product container via a dry coupling and fed into the cooling system without opportunity for human contact with the additive) is needed. The Agency is also believes that long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves are needed to protect handlers. The combination of these measures is expected to reduce handler exposures adequately.

Risk management for this use also is discussed in the section on Environmental Risk Management below. Per that discussion, this use is not eligible for reregistration.

Wood preservatives

Inhalation and dermal short- and intermediate-term risks for commercial applicators of paints and stains containing TBT were well below the target MOE, for applications both by paint brush and airless sprayer. These risk estimates are consistent with what has been estimated for residential applicators; the MOEs are the same or lower. Because of the very low MOEs and the lack of feasible mitigation options, the Agency has determined that TBT products used for wood preservation on homes, buildings, building components, and outdoor furniture are not eligible for reregistration. Additional discussion of the risk management for this use is provided in the section on environmental risk management below.

Disinfectant for Farm Premises

Exposures for workers who apply TBT hard surface disinfectants in farm and related animal husbandry situations were assessed for several methods of application: brush-on, wipe, mop, hand held and mechanical sprayers, and hand-held foggers. The product also is applied via thermal foggers and automated foggers. The following methods are associated with dermal risk estimates below the target MOE of 100: wipe, hand-held spray, and hand-held fogger. Information was available on the effect of gloves on exposures for brush-on applications only; the use of gloves increased the MOE for this application method to a level above the target

MOE. Based on a comparison of with and without glove dermal risk estimates for the brush-on method, it seems likely that risk estimates for both the wipe and hand-held spray methods would be increased above the target MOE if handlers wore gloves. For inhalation exposures, all methods are associated with MOE estimates above the target except for hand-held foggers. Information is not available for estimating the impact of PPE on inhalation exposure.

The registrant has provided information on the size of various poultry facilities that indicates the size of incubators, setters, and egg rooms is much less than the volumes the Agency assessed for handler exposures in poultry facilities. It is not clear that the size of individual incubators, etc. alone is representative of handler exposures because numerous incubators, etc. may be treated by one individual during a work day. It is anticipated that the use of an automated fogger, with appropriate precautions, would not pose inhalation risks of concern for handlers.

The Agency has not quantified occupational handler exposure for immersion treatments of tack, tools, and equipment with TBT, or boot baths. No data are available to assess these exposures or to assess the impact of PPE on those exposures, but the Agency believes that they represent areas of concern.

The Agency has concluded that the handler risks associated with the disinfectant use are likely to be above the target MOE for the following application methods, if PPE includes chemical-resistant gloves: brush-on, wipe, mop, hand-held sprayers, and mechanical sprayers. Data will be required on the impact of gloves on handler risks for the wipe and hand-held sprayer application methods. The application of TBT on farm premises via a hand-held fogger (thermal or otherwise) is prohibited. Additional discussion of the risks and potential mitigation measures associated with this use is provided in the sections on dietary risk mitigation (above), and post-application occupational risk mitigation and environmental risk management (below).

Materials preservatives in building materials

For the manufacture of treated building materials, the Agency assessed exposures to workers who add the TBT product to building materials during the production process. The exposures were modeled on the use of TBT in the caulk manufacturing process, in which a formulation of TBT is added with the other ingredients of caulk to be mixed together prior to finishing and packaging. The scenario was assessed for handlers adding TBT by pouring from an open container and by automated dispensing via a metering pump system. Data were available for evaluating the impact of gloves on handler risk. The target MOE is 100. Inhalation MOEs were well above the margin of exposure, but dermal MOEs were estimated at 36 for open-pouring and 2 for the metered pump. Systems using metered pumps typically handle greater volumes of biocide than systems in which handlers open-pour the biocide by hand.

Although data are lacking to calculate the impact of engineering controls on handler exposure to TBT products added during the manufacture of building materials, the Agency believes that the margin of exposure can be adequately increased through use of a closed loading

system that uses a dry coupling, along with wearing long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves.

The use of TBT in caulk and related materials is permitted by product labels, but it is now our understanding that TBT is no longer used in caulk production. The use of TBT in building materials appears to be limited to joint compound, drywall, adhesives, medium density fiber board, and particulate board. We have been informed that TBT is also used in the manufacture of grout, although grout is not specifically listed on products labels as an acceptable use site. If registrant support for this use can be confirmed, the registrant may request that grout be added to the use sites via a request for an amendment to the registration, as long as all pertinent risk mitigation measures are implemented. The Agency is requiring that TBT products for use in producing these materials, and any as-yet-unidentified but legal uses in building materials production, must be added to such materials via a closed loading system with dry coupling and the PPE discussed above.

TBT also is used as a preservative for industrial adhesives that may be used in assembly of cardboard boxes. The Agency is not able to assess quantitatively the risks to manufacturing handlers who add TBT products to adhesives for use in cardboard boxes because there are no available exposure data specific to the corresponding scenario. Also, as in the case of the building materials discussed directly above, data are lacking to calculate the impact of engineering controls on the potential exposures of handlers adding TBT products during the adhesives production process. Drawing a parallel between these exposures and the exposures of workers adding TBT to building materials, the Agency is requiring that handlers of TBT additives for incorporation into all adhesives use closed loading systems with dry coupling, and wear long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves.

Materials preservatives in textiles, paper, and related uses

The Agency did not assess exposures specifically for handlers involved in the treatment of textiles and related materials with TBT, but has used estimated exposures for handlers involved in the production of treated building materials to understand the potential risks (see above). For this use of TBT, the Agency found that the inhalation MOEs for both open-pour and metered pump applications were well above the target margin of exposure of 100 while dermal MOEs fell well below the target.

The Agency believes that handler risks for textile treatment, paper production, and related use sites can be adequately addressed through use of a closed loading system with a dry coupling device, and long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves.

Post-application residential risk mitigation for these uses is discussed above.

Oil field and petrochemical water injection systems

The Agency assessed exposures to workers who add the TBT product to water injection systems, either via an open-pouring process or a metering pump, while wearing gloves. Risks were quantified for the open-pour option only. The target MOE is 100. The inhalation and

dermal MOEs (both 3) fell well below the target; workers adding TBT via a metering pump system were estimated to be exposed to higher volumes of TBT solution and so the MOEs would be expected to be even lower. The Agency believes that handler risks for adding TBT into these water injection systems could be addressed through use of a closed loading system with a dry coupling device, along with wearing long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves.

Additional discussion of the risks and potential mitigation measures associated with this use is provided in the section on environmental risk management (below). Per that discussion, this use is not eligible for reregistration.

Metal working fluids

The Agency assessed exposure for workers adding TBT to metal working fluids via open-pouring. The target MOE is 100, and the Agency estimates that dermal risks are associated with an MOE of 21, while the inhalation MOE is estimated at 68. Risks were not quantified for other means of application such as the use of metering pumps, although it is anticipated that larger volumes of TBT products would be added in circumstances where automated equipment is used, so that exposures are potentially greater for this equipment than when the product is added by pouring. The Agency believes that handler risks for adding TBT to metal working fluids could be addressed through use of a closed loading system with a dry coupling device, along with wearing long pants, long-sleeved shirts, protective eyewear, and chemical resistant gloves.

Additional discussion of the risks and mitigation potential for this use is provided in the section on post-application occupational risk mitigation (below). Per that discussion, this use is not eligible for reregistration.

f) Occupational risk mitigation—post-application

Occupational post-application exposures are assumed to be negligible except for workers reentering farm premises where TBT disinfectants have been applied by fogging and machinists using TBT-treated metalworking fluids.

Disinfectant for Farm Premises

The Agency has estimated exposures for workers reentering poultry buildings after fogging treatments for various periods after the completion of treatment. The TBT farm premises product label states that after a fogging treatment, the treated area should be well-ventilated and not entered until 1 to 4 hours after fogging. If the building must be entered, the label states individuals entering the building must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants. Exposures have been estimated for a person entering the building 1, 2, and 4 hours after fogging. Reentry at 1 hour after fogging is associated with an inhalation MOE of 17, well below the target MOE of 100. After two hours, the MOE is estimated to have increased to 900. The Agency is requiring that the label indicate a mandatory reentry interval of (no less than) two hours.

Tools and equipment present during premises treatments and tack and tools treated via immersion with TBT may transfer TBT to human skin. Because of the potential for worker exposure, the immersion application is prohibited. Labels will require that tools and instruments be removed from premises prior to treatment or washed with soap and water after treatment and before re-use.

Additional discussion of the risks and mitigation potential for this use is provided in the sections above on dietary risk mitigation, risks to domestic animals, and occupational handler risk mitigation (above), and on environmental risk management (below).

Metal working fluids

Dermal and inhalation exposure to TBT occur after the chemical has been incorporated into the metalworking fluid and a machinist is using a TBT treated end-product. MOEs calculated for dermal and inhalation risks are 3 and 36, respectively, well below the target MOE of 100. Because feasible means of reducing exposure to metal workers are limited, e.g., machinists cannot work effectively while wearing gloves and are not reasonably expected to do so, the Agency has concluded that the use of TBT in metal working fluids is not eligible for reregistration.

Discussion of other risks associated with this use is provided in the section on occupational handler risk mitigation (above).

2. Environmental risk management

The Agency has assessed the ecological risks associated with the use of TBT wood preservatives on houses, parts of houses, and architectural structures. For other uses, risks have not been quantitatively assessed, primarily because data are not available to characterize environmental exposures, but these uncertainties and insights gained from the published literature have led to Agency concerns about uses that might potentially contribute to environmental concentrations of TBT and its degradates.

Historically, TBT derivatives such as TBTO have been used in the formulation of antifouling paints. TBT antifouling paints are very efficacious, because TBT is extremely toxic to fouling organisms that attach to ship hulls (e.g., slime-producing bacteria, algae, tubeworms, barnacles) and it can be formulated into paint systems that slough off spent layers as the ship moves through the water, exposing fresh toxin and providing a long service life.

Unfortunately, the same toxicity that makes TBT such an efficacious antifoulant represents toxicity to nontarget aquatic organisms. Marine organisms including oysters important to the seafood industry and marine snails have demonstrated serious developmental and reproductive effects at concentrations of TBT in the parts-per-trillion range. In addition, TBT is very persistent in the aquatic environment, particularly in the sediment, or benthos, where many types of aquatic animals live and feed. TBT bioaccumulates in exposed organisms, and has been shown to concentrate in the bodies of predator species including marine mammals. It

has also been detected in seafood for human consumption. TBT is a known endocrine disruptor that has been shown to affect the endocrine systems of a range of species. Data are lacking for sediment toxicity, and for calculation of risk quotients for honeybees and aquatic plants. Limited non-guideline data indicate that TBT is highly phytotoxic to some algae and diatoms.

Because of its ecological effects and widespread manifestations of ecological risk, the global community has developed an international treaty prohibiting the use of TBT antifouling systems. The prohibition will become effective in September 2008.

In the US, the last TBT-based antifouling hull paint registration was cancelled in 2005. It remains legal to produce and sell TBT antifouling systems for two applications. TBT is incorporated into rubber for the formation of sonar domes used in US Navy vessels. This application is considered to be critical for naval operations and releases a much smaller amount of TBT into the aquatic environment than did the antifouling hull coatings. TBT is also used in antifoulant devices within oceanographic instruments deployed by government researchers to monitor global ocean conditions (i.e., conductivity sensors). The total amount of TBT present in the instruments is very small, and the use is considered to be critical by government research organizations such as the National Oceanographic and Atmospheric Administration.

Other uses of TBT also have the potential to contaminate natural waters. In the case of the wood preservatives, the Agency is able to estimate environmental concentrations for particular applications. In the case of the use in cooling towers, immersion treatments on farm premises, petrochemical injection systems, and irrigation tubing for non-agricultural applications, data or models do not exist to allow the quantification of environmental exposures, but other evidence points to the need for risk mitigation or the use pattern suggests that aquatic contamination is possible. The remaining antifouling uses of TBT are also discussed in this section.

a) Recirculating cooling towers

Cooling towers are designed to recirculate cooling water for a period of time before salts and debris in the cooling water necessitate the discharge of water and replacement with fresh water and biocidal additives. It is the Agency's understanding that most of the discharge is directed to municipal water treatment facilities. Evidence from California strongly suggests that the discharge of cooling water containing TBT biocide can result in levels of TBT in treated water that are higher than risk- and site-specific discharge permit levels.

The use of TBT in cooling tower water is prohibited in nine California counties around the San Francisco Bay (Alameda, Contra Costa, Marin, Napa, San Francisco, San Mateo, Santa Clara, Solano, and Sonoma), based on the exceedance of discharge standards for the Bay, as reported by the California Department of Pesticide Regulation (<http://www.cdpr.ca.gov/docs/legbills/calcode/040301.htm>). In 1994, the Palo Alto Regional Water Quality Control Plant calculated that the equivalent of one gallon of 2% TBT solution discharged into the sewer system and treated with other wastewater would contaminate over

2 billion gallons of effluent at concentrations exceeding the 5 ppt discharge limit (<http://www.city.palo-alto.ca.us/civica/filebank/blobdload.asp?BlobID=2469>). The City of Palo Alto concluded that even very small discharges from one or two cooling towers could place the city in violation of its discharge permit.

The problem in the San Francisco Bay suggests that even moderate use of TBT in cooling towers can pose permit problems and a threat to nearby water bodies. It also suggests that water treatment facilities are not effective in removing TBT from the water, and the Agency is not aware of any information to the contrary. The Agency has not attempted to draw conclusions about drinking water exposure and risks from this information, but since TBT causes adverse effects in non-target organisms at extremely low concentrations, the Agency believes there is a potential for ecological risks of concern associated with the cooling tower use.

Both the California Department of Pesticide Regulation and the City of Palo Alto have reported that effective alternatives to TBT cooling water additives are available at comparable prices (<http://www.city.palo-alto.ca.us/civica/filebank/blobdload.asp?BlobID=2469>) and (<http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/eh9507.pdf>), and the Agency has estimated that TBT represents less than 3% cooling water biocide usage annually in the US. In the absence of additional information, these findings strongly suggest that the benefits associated with TBT cooling water additives are limited.

For purposes of this reregistration eligibility decision, the Agency has concluded that the risks associated with the cooling tower use of TBT are unacceptable, and that this use of TBT is not eligible for reregistration. Discussion of other risks associated with this use is provided in the section on occupational handler risk mitigation (above).

b) Wood preservatives

The Agency calculated risk quotients for the leaching into the water column of TBT from various wood preservative-treated use sites (from highest estimated environmental concentration to lowest): whole house, fences, deck posts, fence posts, decks, and transmission poles. Based on registrant-submitted toxicity data for test species, the Agency concluded that the acute risk LOC is equaled or exceeded for listed (e.g., endangered and threatened) freshwater and estuarine/marine invertebrates exposed in the water column. In addition, the published literature indicates that marine species exhibit adverse chronic effects from TBT in concentrations at or below those estimated for the same wood preservative scenarios.

The Agency has determined that the wood preservative uses of TBT are not eligible for reregistration. Discussion of other risks associated with this use is provided in the sections on residential and occupational handler risk mitigation (above).

c) Disinfectant for farm premises

The registrant reports that excess solution from immersion treatments with TBT is typically discharged on-site or to municipal wastewater facilities. Information was not available

specifically for disposal of used/excess boot bath solution, but the registrant has noted that this use is a very small portion of TBT use on farm premises. Based on our previously noted assumption about the inability of municipal wastewater facilities to remove or adequately reduce the concentration of TBT in wastewater, the Agency believes that excess solution may potentially contaminate farm premises, drinking water, and aquatic habitats. Based on these conclusions and the presumed low benefits of the boot bath application of TBT, the Agency believes that the environmental risks outweigh the benefits for the farm premises immersion and boot bath uses, as related to disposal of excess treatment solution. Discussion of other risk concerns associated with the immersion treatment and boot bath use is provided in the sections on occupational handler and occupational post-application risk mitigation (above).

d) Oil field and petrochemical injection

The Agency believes that fluids used for these purposes may reenter groundwater and surface waters after use. Environmental concentrations in water and drinking water exposures cannot be estimated, and means of precluding environmental contamination are not apparent. This use is not eligible for reregistration.

e) Irrigation tubing

The Agency believes that irrigation water from treated tubing may contain TBT residues that may enter groundwater and surface waters. Although such tubing is not used in agricultural settings, there is a potential for environmental exposures in water and drinking water exposures. This use is not eligible for reregistration.

f) Antifouling for sonar domes and oceanographic instruments

The Agency has recently completed a lengthy review of TBT used in antifouling systems, which culminated with the cancellation of all uses of TBT in antifouling systems used on boat and ship hulls and underwater drive units. During the course of that review, the Agency determined that the use of TBT in sonar domes is critical for U.S. military readiness. The Agency also determined that there were exceptional benefits associated with the use of TBT devices used to protect conductivity sensors in oceanographic research instruments. In addition, the quantity of TBT used in these instruments is very small. Because of the favorable benefits situation for these two uses and the very small volumes used in research instruments, the Agency has determined that these uses are eligible for reregistration. It is not anticipated that occupational risk mitigation for sonar dome production that parallels measures required for other materials preservatives will preclude the use of TBT in this critical application.

3. Labeling requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all manufacturing use products containing TBT. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed species considerations

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each Federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species," (50 C.F.R. § 402.02).

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

5. General risk mitigation

TBT end-use products (EPs) may also contain other registered pesticide active ingredients. The Agency has determined that the use of TBT in wood preservatives is not eligible for reregistration, in part because of potential risks to federally listed species. The same determination has not been made for other uses of TBT. According to published schedules for reregistration (http://www.epa.gov/oppsrrd1/reregistration/decision_schedule.htm) and registration review (http://www.epa.gov/oppsrrd1/registration_review/schedule_summary.pdf; schedule dated 11/07, will be updated periodically), the Agency will be evaluating other pesticides, some with end-use products that also contain a TBT active ingredient. The Agency requires that registrants adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) will be adopted.

V. What Registrants Need to Do

The Agency has determined that TBT is eligible for reregistration provided that: 1) additional data that the Agency intends to require confirm this decision is submitted; 2) required

label amendments are made; and 3) all other risk mitigation measures identified in this document are adopted. Required labeling amendments and the required risk mitigation measures to be implemented via revised labeling are set forth in the Label Changes Summary Table below (Table 13). TBT data requirements the Agency intends to impose will include the elements listed below in Table 12.

Registrants of TBT products will be required respond to these data requirements within 90 days of receipt of the generic data call-in (DCI) to be issued subsequent to the release of the RED by submitting:

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
2. any time extension and/or waiver requests with a full written justification.

Furthermore, within the time limit specified in the generic DCI, the registrants must cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Jill Bloom at (703) 308-8019 or bloom.jill@epa.gov with questions regarding generic reregistration. Mail delivery addresses:

By US mail:
 Document Processing Desk
 Jill Bloom
 Office of Pesticide Programs (7508P)
 U.S. Environmental Protection Agency
 1200 Pennsylvania Ave., NW
 Washington, DC 20460-0001

By express or courier service:
 Document Processing Desk
 Jill Bloom
 Office of Pesticide Programs (7508P)
 U.S. Environmental Protection Agency
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202

For end-use products containing the active ingredients TBT, registrants must submit the following items for each product:

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an “application for reregistration”;
3. five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;
4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
6. the product-specific data responding to the PDCI.

Please contact Marshall Swindell at (703) 308-6341 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI must be addressed as follows:

By US mail:
 Document Processing Desk
 Marshall Swindell
 Office of Pesticide Programs (7510P)
 U.S. Environmental Protection Agency
 1200 Pennsylvania Ave., NW
 Washington, DC 20460-0001

By express or courier service:
 Document Processing Desk
 Marshall Swindell
 Office of Pesticide Programs (7510P)
 U.S. Environmental Protection Agency
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202

A. Manufacturing use products

1. Generic Data Requirements

The generic database supporting the reregistration of TBT has been reviewed and reregistration eligibility decisions have been made for the various uses of TBT. The following data requirements have been identified by the Agency as needed to facilitate a refined assessment of TBT and to determine if any adjustments need to be made to the TBT registrations. In some cases, data gaps are cited for the support of uses deemed not eligible for reregistration. These data would be the kind of data EPA would require if a reconsideration of the eligibility decisions for specific uses appeared to be warranted. Such data submissions are likely to be evaluated as a part of the registration review project, although the Agency has not yet scheduled the assessment of TBT active ingredients that will take place under registration review. Pesticides in registration review generally undergo reassessment on a 15-year cycle.

A generic data call-in (DCI) will be issued at a later date for the TBT active ingredients. Table 11 provides a summary of data gaps, but distinctions are not made for the three different

TBT compounds. The generic DCI will detail and confirm the data required to be submitted for each active ingredient.

Table 11. Data Requirements for Reregistration of Tributyltin Oxide, Tributyltin Benzoate, and Tributyltin Maleate

Guideline Number	Study Title
171-4 & 850.3020	Honey/beeswax residues and acute toxicity of treated materials to bees
850.1735	Whole sediment: acute freshwater invertebrates
850.1740	Whole sediment: acute marine invertebrates
No Guideline	Whole sediment: chronic invertebrates
850.5400	Freshwater diatom; TGAI or EP
	Marine diatom; TGAI or EP
	Blue-green cyanobacteria; TGAI or EP
	Freshwater green alga; TGAI or EP
850.4400	Freshwater floating macrophyte duckweed; TGAI or EP
850.4225	Freshwater rooted macrophyte rice seedling emergence; EP
850.4250	Freshwater rooted macrophyte rice vegetative vigor; EP
860.1300, .1340, .1380, and .1480	Residues in meat, milk, and eggs
870.1200	Acute Dermal – Rabbit
870.1300	Acute Inhalation – Rat
870.2400	Primary Eye Irritation – Rabbit
870.2500	Primary Dermal Irritation – Rabbit
870.2600	Dermal Sensitization
870.3250	90-day Dermal Toxicity – Rodent
870.3700	Developmental Toxicity – rodent
870.5100 to .5915	Mutagenicity
875.1200, .1600	Dermal Indoor Exposure (inc. impact of chemical resistant gloves)
875.1400	Indoor Inhalation Monitoring
875.1700, .2700	Product Use Information (handler, post-application)
875.2800	Description of Human Activity (post-application)

Appendix B to this RED shows the data requirements that will be imposed for each active ingredient based on specific use sites.

2. Labeling for technical and manufacturing use products

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. According to the timeline for label changes, technical and MUP labeling must bear the language shown in Table 12, Label Changes Table.

B. End-use products

1. Product-specific data requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data for a pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining the required data for each product or set of products, will be sent to registrants at a later date.

2. Labeling for end-use products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 13, Label Changes Table.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to “Existing Stocks of Pesticide Products; Statement of Policy,” *Federal Register*, Volume 56, No.123, June 26, 1991.

3. Label changes summary table

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

Table 12. Labeling Changes Summary Table for Products Containing TBT

for Manufacturing Use Products containing TBT		
Description	Amended Labeling Language	Placement on Label
For all manufacturing-use products	<p>“This product may be formulated into products for the following uses only: farm and animal premises when animals and eggs have been removed (livestock housing, kennels, veterinary clinics, animal laboratories, breeding facilities, hatcheries, egg rooms, egg trucks, incubators, and setters, but not tack, tools, equipment, or boot baths), fiberfill, polyurethane foam (except in mattress covers), carpet backing, air filters, rubber mats, canvas and other textiles with outdoor applications (tarps, tents, and awnings, but not furniture components or hammocks), webbing for nets in sports applications (golf courses/driving ranges, batting cages, tennis nets), paper (except in paper with direct or indirect food contact), adhesives, particulate board, medium density fiberboard, drywall, grout, joint compound, sonar domes, and in antifoulant devices within oceanographic instruments (conductivity sensors).”</p> <p>“Not for formulating wood preservatives, paints, or stains; cooling tower/cooling water treatments; antifouling paints for ships, boats, fish nets, or crab, bass, or lobster pots; oilfield and petrochemical injection fluids; or metal working fluids. Not for use in manufacturing irrigation tubing.”</p>	Directions for Use
Environmental Hazards Statement	<p>"This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters. 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 authorities are 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."</p>	Precautionary Statements

for End-Use Products containing TBT		
Description	Amended Labeling Language	Placement on Label
<p>For all end-use products containing TBTO, TBTB, or TBTM</p>	<p>Allowable use sites for an end-use product are one or more of the following: farm and animal premises when animals and eggs have been removed (livestock housing, kennels, veterinary clinics, animal laboratories, breeding facilities, hatcheries, egg rooms, egg trucks, incubators, and setters but not tack, tools, equipment, or boot baths), fiberfill, polyurethane foam (except in mattress covers), carpet backing, air filters, rubber mats, canvas and other textiles with outdoor applications (tarps, tents, and awnings, but not furniture components or hammocks), webbing for nets in sports applications (golf courses/driving ranges, batting cages, tennis nets), paper (except in paper with direct or indirect food contact), adhesives, particulate board, medium density fiberboard, drywall, grout, joint compound, sonar domes, and in antifoulant devices within oceanographic instruments (conductivity sensors).”</p> <p>The registrant must list the allowable use site(s) on the product label. The registrant must not label a product containing TBT with any of the following uses: wood preservatives, paints, or stains; cooling tower/cooling water treatments; oilfield and petrochemical injection fluids; metal working fluids; antifouling paints for use on ships, boats, fish nets, or crab, bass, or lobster pots; or irrigation tubing.”</p>	<p>Directions for Use</p>
<p>Environmental Hazards Statement</p>	<p>"This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters. 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 authorities are 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."</p>	<p>Precautionary Statements</p>

for End-Use Products containing TBT		
Description	Amended Labeling Language	Placement on Label
Personal Protective Equipment (for all use sites except antifouling devices in conductivity sensors for oceanographic instruments)	“Handlers must wear long sleeve shirts, long pants, socks, shoes, protective eyewear, and chemical resistant gloves. Materials that are chemically resistant to this product include [registrant must provide examples of chemical resistant materials here].”	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	<p>“Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment. If no such instructions for washables exist, use detergent and hot water. Keep and wash Personal Protective Equipment separately from other laundry.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the Personal Protective Equipment requirements
Engineering controls (for all use sites except farm and animal premises treatments and antifouling devices in conductivity sensors for oceanographic instruments)	“Handlers must use closed loading systems with dry coupling for introducing this material into treatment and manufacturing systems.”	Immediately following User Safety Requirements

for End-Use Products containing TBT		
Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	<p>“User Safety Recommendations”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/ Personal Protective Equipment immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove Personal Protective Equipment immediately after handling this product.”</p> <p>“Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Directions for Use
Entry restrictions for products with directions for use on farm and animal premises	“Do not re-enter treated area for at least 2 hours after treatment is complete.”	Directions for Use
Site-Specific Directions for Use	<p>End-use product labels must be amended to contain directions for use only on the allowed use sites. All other use sites and the corresponding directions for use must be removed from end-use product labels.</p> <p>“Do not use materials containing TBT for underwater uses on wood, textiles, or rope.”</p>	Directions for Use associated with the specific use site

for End-Use Products containing TBT		
Description	Amended Labeling Language	Placement on Label
<p>Site-Specific Directions for Use: Farm/animal premises uses</p>	<p>“Animals and eggs must be removed from premises prior to treatment of premises and surfaces within premises. Animals must not be returned to premises for at least 48 hours following the conclusion of treatment. Remove all feeding and watering bowls and containers prior to treatment, or wash with soap and water after treatment and before re-use.”</p> <p>“Do not use as immersion treatment. Do not treat tack or tools or other equipment that come into direct contact with animals; remove from premises prior to treatment or wash with soap and water after treatment and prior to re-use.”</p> <p>“Do not use in boot baths or otherwise on footwear.”</p> <p>“Application is prohibited via hand-held foggers, thermal or otherwise. Applications may only be applied via brush, wipe, mop, hand-held and mechanical sprayers, or automated foggers when handlers are wearing required personal protective equipment.”</p>	<p>Directions for Use associated with the specific use-site</p>
<p>Site-Specific Directions for Use: Treatment of textiles and related materials</p>	<p>“Do not use on clothing, mattress and pillow covers and ticking, sponges, mop heads, upholstery fabric, covers of furniture cushions or parts of furniture which contact human skin during normal use, hammocks, or materials that will be used to make these items, or as a laundry treatment. Do not use on textiles for applications with potential for direct contact with human skin. Do not use on rope.”</p>	<p>Directions for Use associated with the specific use-site</p>

VI. APPENDICES

Appendix A. Table of Representative Use Patterns for TBTO, TBTB, TBTM

Table of Representative Use Patterns for TBT Compounds				
Use Site	Formulation	Method of Application	Application Rate/ No. of applications ^a	Use Limitations
Materials Preservative				

Appendix B. Generic Data and Studies Used for the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #4122 (organic esters of phosphoric acid) covered by this RED. It contains generic data requirements that apply to organic esters of phosphoric acid in all products, including data requirements for which a “typical formulation” is the test substance.

The data table is organized in the following formats:

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

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

- (1) Agricultural premises and equipment
- (2) Food handling/ storage establishment premises and equipment
- (3) Commercial, institutional and industrial premises and equipment
- (4) Residential and public access premises
- (5) Medical premises and equipment
- (6) Human water systems
- (7) Materials preservatives
- (8) Industrial processes and water systems
- (9) Antifouling coatings
- (10) Wood preservatives
- (11) Swimming pools
- (12) Aquatic areas

Bibliographic Citation (Column 5). If the Agency has acceptable data in its files, this column list the identify 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.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
<u>PRODUCT CHEMISTRY</u>				
830.1550	61-1	Product Identity and Composition		
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		
830.1670	61-2b	Formation of Impurities		
830.1700	62-1	Preliminary Analysis		
830.1750	62-2	Certification of Limits		
830.1800	62-3	Analytical Method		
830.6302	63-2	Color		
830.6303	63-3	Physical State		
830.6304	63-4	Odor		
830.7200	63-5	Melting Point		
830.7220	63-6	Boiling Point		
830.7300	63-7	Density		
830.7840 830.7860	63-8	Solubility		
830.7950	63-9	Vapor Pressure		
830.7370	63-10	Dissociation Constant in Water		

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		
830.7000	63-12	pH		
830.6313	63-13	Stability		
830.6314	63-14	Oxidizing/Reducing Action		
830.6315	63-15	Flammability		
830.6316	63-16	Explodability		
830.6317	63-17	Storage Stability		
830.7100	63-18	Viscosity		
830.6319	63-19	Miscibility		
830.6320	63-20	Corrosion Characteristics		
830.6321	63-21	Dielectric breakdown voltage		
<u>ECOLOGICAL EFFECTS</u>				
850.2100	71-1	Avian Acute Oral Toxicity Test		
850.1075	72-1	Acute Freshwater Fish (bluegill)		
850.1075	72-1	Acute Freshwater Fish (rainbow trout)		
850.1010	72-2	Acute Freshwater Invertebrate (daphnia magna)		
<u>TOXICOLOGY</u>				
870.1100	81-1	Acute Oral – Rat		

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.1200	81-2	Acute Dermal – Rabbit		
870.1300	81-3	Acute Inhalation – Rat		
870.2400	81-4	Primary Eye Irritation – Rabbit		
870.2500	81-5	Primary Dermal Irritation – Rabbit		
870.2600	81-6	Dermal Sensitization		
870.3100	82-1a	90-Day Feeding-Rodent		
870.3200	82-2	21/28-Day Dermal Toxicity – Rat		
870.3250	82-3	90-day Dermal Toxicity – Rodent		
870.3465	82-4	90-Day Inhalation – Rat		
870.3700a	83-3a	Developmental Toxicity – rodent		
870.3700	83-3b	Teratogenicity – Rabbit		
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro		
870.4100	83-1a	Chronic Feeding Toxicity – Rodent		
	83-1b	Chronic Feeding Toxicity - Non-Rodent (dog)		
870.4200	83-2a	Oncogenicity – Rat		
	83-2b	Oncogenicity – Mouse		
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity		

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.5100	84-2	Bacterial reverse mutation test		
870.5300		In Vitro mammalian cell gene mutation test		
870.5265	84-2a	Gene Mutation – ames		
870.5385	84-2b	Structural Chromosome Aberration		
870.5395	84-2	<i>In Vivo</i> mammalian micronucleus test /Mammalian erythrocyte micronucleus test		
870.5450		Rodent dominant lethal assay		
870.5900	84-2	Mammalian cytogenetics (sister chromatid exchange)- hamster		
870.7485	85-1	General Metabolism		
870.7600	85-2	Dermal Absorption		
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2300	133-3	Indoor Surface Residue Dissipation (Dermal Residue Transfer Studies for Textiles/Clothing, Mattress/Mattress Ticking and Carpet Shampoo/Cleaner)		
875.1200	233	Dermal Indoor Exposure		
875.1400	234	Inhalation Indoor Exposure		

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
875.1600		Applicator Exposure Monitoring Data Reporting		
875.1700 875.2700		Product Use Information		
875.2800	133-1	Description of Human Activity		
875.2900	134	Data Reporting and Calculations		
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis		

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the April 19, 2006 preliminary risk assessment and the related supporting science documents. EPA then considered comments on the risk assessment and revised the risk assessment and supporting chapters as necessary. The revised risk assessment will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

<http://www.regulations.gov>

These documents include:

- Preliminary Risk Assessment; Notice of Availability, /08.

Preliminary Risk Assessment and Supporting Science Documents (RED Supporting Documents):

Revised Risk Assessment and Revised Supporting Science Documents (RED Supporting Documents):

-

Appendix D. Bibliography

Bibliography

MRID #

Citations

Other Supporting Documents

Web References

HERA. 2003. Human and Environmental Risk Assessment, Guidance Document Methodology, April 22, 2002 (<http://www.heraproject.com/files/Guidancedocument.pdf>).

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of TBT End-use Products

The Agency will complete the batching for acute toxicity data requirements for reregistration at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of 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:

Document Number	Document Name	URL
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

Document Number	Document Name	URL
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 that 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.