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Reregistration Eligibility Decision for Pentachlorophenol

9458796

REREGISTRATION ELIGIBILITY
DECISION
for
Pentachlorophenol
List B
CASE 2505

Approved By:

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September 25, 2008

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	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
CMBS	Carbamate Market Basket Survey
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	Organophosphorus
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	Protection 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 pentachlorophenol and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of pentachlorophenol that pose risks of concern. As a result of this review, EPA has determined that pentachlorophenol containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document. The Agency is aware that research is ongoing regarding pentachlorophenol. The Agency may revisit this decision in the future.

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.

Pentachlorophenol (PCP) is a general biocide which has been used extensively as a fungicide, bactericide, herbicide, molluscicide, algaecide and insecticide by agriculture and other industries including textiles, paints, oil drilling and forestry. Pentachlorophenol also contains chlorinated dibenzodioxins and chlorinated dibenzofurans (CDDs and CDFs) and hexachlorobenzene (HCB) as contaminants formed during the manufacture process. These compounds are inherently toxic, as well as environmentally persistent, and their presence may increase the ecological risk associated with the use of pentachlorophenol. Pentachlorophenol is only one of many sources of CDDs, CDFs, and HCB in the environment making it difficult to quantify the portion of the aggregate environmental risk from CDDs, CDFs, and HCB that is attributable to pentachlorophenol wood treatment uses. The main use of pentachlorophenol, as a heavy duty wood preservative, is to treat utility poles. Although its only remaining use in the U.S. is as a heavy duty wood preservative, pentachlorophenol has been used in rice and sugar production, in water treatment, as a pre-harvest defoliant in cotton, and as a general pre-emergence herbicide. It has also been utilized in numerous products including adhesives, construction materials, leather and paper. Pentachlorophenol is currently classified as a Restricted Use Product (RUP) when used as a heavy duty wood preservative and is predominately used to treat utility poles and cross arms.

This document presents the Agency's revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for pentachlorophenol. The pentachlorophenol case consists of one PC Code: 063001. Pentachlorophenol has been used as a wood preservative since 1936; however, the first pesticidal product containing pentachlorophenol was registered in 1950. For a list of the current products, please see Appendix A.

Currently, all of the pentachlorophenol produced in the U.S. is utilized in wood preservation. There are approximately 60 million utility-owned wood poles and 54 million crossarms in service across the United States which have been treated with wood preservatives (mainly pentachlorophenol and creosote; EPRI 1993). Approximately 36 million of the wood poles in service have been treated with pentachlorophenol (Malecki, 1992), and approximately

95.8% of the crossarms in service were treated with pentachlorophenol (EPRI 1993). An estimated 3% of the treated poles are replaced annually.

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of pentachlorophenol as an active ingredient. Therefore, an FQPA hazard analysis is not necessary at this time.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of pentachlorophenol. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for pentachlorophenol in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (Docket ID EPA-HQ-OPP-2004-0402).

This document consists of six sections. Section I is the Introduction. Section II provides a Chemical Overview, a profile of the use and usage of pentachlorophenol and its regulatory history. Section III, Summary of pentachlorophenol Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management and Reregistration, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. 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

Pentachlorophenol was first registered as an active ingredient by the United Sates Department of Agriculture (USDA) on December 1, 1950. In 1970, the Environmental Protection Agency (EPA) was established and was charged with protecting human health and the environment, and assumed all pesticide registrations from USDA. Currently, there are six products containing pentachlorophenol as an active ingredient. Pentachlorophenol is a fungicide, bactericide, herbicide, molluscicide, algaecide and insecticide and is only registered for use as a heavy duty wood preservative.

The production of pentachlorophenol for wood preserving began on an experimental basis in the 1930s. In 1947 nearly 3,200 metric tons of pentachlorophenol was reported to have been used in the U.S. by the commercial wood preserving industry. Pentachlorophenol was one of the most widely used biocides in the U.S. prior to regulatory actions to cancel and restrict certain non-wood preservative uses of pentachlorophenol in 1987. Prior to the 1987 Federal Register Notice (Vol. 52, No. 13) which canceled and restricted certain non-wood uses, pentachlorophenol was registered for use as an herbicide, defoliant, mossicide, and as a disinfectant.

Indoor applications of pentachlorophenol are prohibited. These restrictions were imposed on pentachlorophenol registrations as part of the Agency's Special Review process as indicated in the *U.S.EPA Position Document 4 for Wood Preservative Pesticides: Creosote, Pentachlorophenol and Inorganic Arsenicals (1984, amended 1986)*. PD 4 announcing the termination of the Special Review for the non-wood uses of pentachlorophenol was signed 12/29/92 and was published 2/93.

The use of pentachlorophenol to treat wood intended for use in interiors is also prohibited, except for a few low exposure uses (i.e., those support structures which are in contact with the soil in barns, stables, and similar sites and which are subject to decay or insect infestation). Pentachlorophenol is a restricted use pesticide for sale and use by certified applicators only.

In 2000, the Agency canceled 12 products containing pentachlorophenol due to the registrant's failure to pay registration maintenance fees. This resulted in cancellation of all uses of pentachlorophenol as a remedial treatment (a non-pressure treatment using a brush) of utility poles.

The Agency has received requests by the registrants of pesticide products containing pentachlorophenol to voluntarily amend to terminate certain uses of affected products. Two registrants, KMG Chemicals, Inc. and Vulcan Chemicals, requested this action to be effective immediately. KMG Chemicals, Inc. requested that all non-pressure treatment and non-thermal treatments for their product (Pentacon 40) be deleted. Vulcan Chemicals requested to voluntarily cancel spray uses for two of their products (Vulcan GLAZD Penta and Vulcan Premium Four Pound [PCP-2] Concentrate). The Agency has processed these requests. These voluntary use cancellations leave only pressure and thermal wood treatment uses of pentachlorophenol.

B. Chemical Identification

Technical Pentachlorophenol

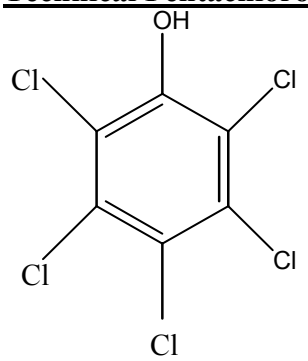

Figure #1. Molecular Structure of Pentachlorophenol

Common name: Pentachlorophenol

Chemical name: 2,3,4,5,6-pentachlorophenol

Chemical family: Aromatic Hydrocarbon Chlorophenol

Empirical formula: $C_6H\,Cl_5O$

CAS Registry No.: 87-86-5

Case number: 2505

OPP Chemical Code: 063001

Molecular weight: 266.34 g/mol

Other names: Pentachlorophenol is abbreviated as PCP. Product names include Dowicide EC-7, Penchlorol, Penta, Pentacon, Penwar, Priltox, Sinituho and Weedone.

Basic manufacturer: KMG-Bernuth, Inc.

Chemical properties: Pentachlorophenol is light brown to tan (Pure pentachlorophenol, however, is white needle-like crystals). It is a solid with a phenolic odor. Pentachlorophenol has a density of 1.978 g/ml; a dissociation constant (K_a) of 1.6×10^{-14}; has a pH of 4.99; and sublimes at 54 ± 2°C. Pentachlorophenol has a melting point of 190-191° C; and has a boiling point of 309° C (decomposes). The vapor pressure is 1.1×10^{-4} mm Hg at 25°C. Pentachlorophenol has a Log K_{OW} of 5.05 at pH 5.1; a Log K_{OC} of 2430 (Georgia, sandy loam), 3420 (Ohio, clay loam), 706 (California, sandy loam), 1410 (Nebraska, blue sandy loam); and its solubility at 20°C is 14 mg/L in water, 1.7 g/g in methanol, and 0.014 g/g in benzene.

C. Use Profile

The following information is a description of the currently registered uses of pentachlorophenol products, and an overview of use sites and application methods. A detailed table of the pentachlorophenol uses that are eligible for reregistration can be found in Appendix A.

Type of Pesticide: Pentachlorophenol is a restricted use pesticide used as a heavy duty wood preservative (fungicide, bactericide, herbicide, molluscicide, algaecide and insecticide).

Carpenter Ants
Mold
Lyctus Powderpost Beetles
Powderpost Beetles
Termites
Wood Rot/Decaying Fungus
Wood Rot/Decaying Organisms
Wood Stain Fungus

Use Classification: Restricted use.

Use Sites: The only registered use of pentachlorophenol is as a heavy duty wood preservative.

Lumber
Seasoned Lumber
Timbers
Wood
Wood Poles/Posts
Wood Products
Wood Pressure Treatment

Formulation Types: soluble concentrate and ready to use

D. Methods and Rates of Application:

A summary of the pentachlorophenol registered uses is given in Table 1 and a more detailed listing is included in Appendix A. Pentachlorophenol is registered for use as a heavy duty wood preservative. All other uses have been canceled.

Table 1: Pentachlorophenol Use Site and Application Rates

Company Name	Label #	Product Name	Formulation
KMG-Bernuth, Inc.	61483-1	Penta 5 Sure-Treat Wood Preserver	RTU
	61483-2	Dura-Treet 40 Wood Preserver	SC
	61483-3	KMG-B Penta Ol Technical Pentachlorophenol	Intermediate
	61483-58	Pentacon-7	RTU
	61483-59	Pentacon-10	RTU
	61483-62	Vulcan GLAZD Penta	Technical

Note: RTU is Ready to Use, and SC is Soluble Concentrate.

E. Disposal Information

In a broad sense, two types of waste are generated through the use of pentachlorophenol wood preservatives: wood treated with pentachlorophenol and industrial waste generated through the application of pentachlorophenol. The disposal requirements differ for each type of waste.

1. Treated Wood

Discarded pentachlorophenol treated lumber is usually land disposed in either construction and demolition landfills, municipal solid waste landfills, or industrial non-hazardous waste landfills. Many state and local governments may have specific regulations, guidelines, or recommendations for the management and disposal of discarded pentachlorophenol treated wood, either explicitly, or sometimes under the larger category of "treated wood." Therefore, EPA recommends that persons contact their state and local authorities regarding specific policies or regulations concerning the disposal of pentachlorophenol treated wood.

EPA estimates that there will remain a supply of pentachlorophenol treated wood that will ultimately require disposal, considering the amount of this building material currently in use, and its typical service life (which can be many years). EPA continues to evaluate the potential impacts of land disposal of discarded pentachlorophenol treated wood.

2. Waste Generated at Wood Treatment Facilities

There are also hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) that apply specifically to wastes generated at facilities where wood preservatives are used to treat wood. On December 6, 1990 EPA promulgated several hazardous waste listings applicable to wastes generated by wood treaters using certain wood preservative chemicals. (55 *FR* 50450; December 6, 1990 *Federal Register*). One of these hazardous waste listings (Hazardous Waste Number F032) can be found in the hazardous waste regulations at 40 CFR 261.31, and reads as follows:

- ***F032:*** Wastewaters (except those that have not come into contact with process contaminants), process residuals, preservative drippage, and spent formulations from wood preserving processes generated at plants that currently use or have previously used chlorophenolic formulations (except potentially cross-contaminated wastes that have had the F032 waste code deleted in accordance with Sec. 261.35 of this chapter or potentially cross-contaminated wastes that are otherwise currently regulated as hazardous wastes (i.e., F034 or F035), and where the generator does not resume or initiate use of chlorophenolic formulations). This listing does not include K001 bottom sediment sludge from the treatment of wastewater from wood preserving processes that use creosote and/or pentachlorophenol.

Because pentachlorophenol preservative is a "chlorophenolic formulation," wastes generated from its use falls within the scope of this hazardous waste listing. Thus, wood treaters using pentachlorophenol preservatives would be hazardous waste generators (with respect to any in-scope wastewaters, process residuals, preservative drippage, etc. that are generated) and would be subject to the applicable requirements under RCRA Subtitle C, for example, notification of hazardous waste activity, obtaining an EPA Identification number, use of a hazardous waste manifest for off-site shipments of waste, and most significantly, the use and maintenance of a drip pad as described in 40 CFR 262.34(a)(1)(iii) and part 265, subpart W.

III. Summary of Risk Assessments

A. Background on Wood Preservative Risk Assessment

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for pentachlorophenol. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2004-0402, and may also be accessed from www.regulations.gov. Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA 22202, and 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 pentachlorophenol risk assessment 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.

For almost all pesticides subject to reregistration, EPA employed an active ingredient-focused approach rather than an application method-focused approach. That is, EPA typically evaluated and made reregistration eligibility decisions for each active ingredient and its associated use sites rather than each use site and its associated active ingredients ("RED for active ingredient X" rather than "RED for applications made by application method X"). However, due to the unique nature in which the chemicals are applied, EPA made the decision

early in the reregistration process (circa 1988) to evaluate heavy duty wood preservative uses collectively using an application method-focused approach.

The term "heavy duty" wood preservative is used to differentiate wood preservatives applied using specialized high pressure treatment cylinders (also called "retorts") from those applied using non-specialized methods (e.g., brush, dip). Figure 1 presents a photograph of a treatment retort. There are three heavy duty wood preservative cases subject to reregistration: chromated arsenicals (Case 0132), pentachlorophenol (Case 2505), and creosote (Case 0139). Because these cases include only heavy duty wood preservatives, to improve readability the words "heavy duty" are often omitted in favor of the generic term "wood preservative" throughout the RED and supporting documents. The Agency notes that other heavy duty wood preservatives exist outside Case 0132, 2505, and 0139; however, uses of these preservatives were not subject to reregistration because the chemicals were not registered prior to November 1, 1984 and are therefore outside the scope of the three heavy duty wood preservative REDs. Heavy duty wood preservatives not included in Case 0132, 2505, and 0139 will be evaluated in the future under the registration review program.

Figure 1. Heavy Duty Wood Preservative High Pressure Treatment Cylinder (Retort)

Again, due to the unique nature in which heavy duty wood preservatives are applied, wood preservative risk assessment requires a different approach than those used for standard agricultural or antimicrobial pesticides. For example, unlike agricultural pesticide handlers who may be exposed to pesticides when mixing/loading, applying, or re-entering an area treated with

a pesticide, treatment facility workers may be exposed to pesticides when handling treated wood and/or performing activities related to operating the treatment cylinder.

This presents two challenges for risk assessment. First, because very few chemicals are applied using retorts, limited data are available to estimate worker exposure. Second, because many of the Agency's exposure models were designed to assess risk from agricultural chemicals, exposure estimates are expected to be conservative and may not be representative of "real world" exposure. The Agency acknowledges these challenges and considered these and other factors when making its reregistration and risk management decisions.

B. Human Health Risk Assessment

Pentachlorophenol is a general biocide which has been used extensively as a fungicide, bactericide, herbicide, molluscicide, algaecide and insecticide by agriculture and other industries including textiles, paints, oil drilling and forestry. However, the only remaining uses of pentachlorophenol are as a heavy duty wood preservative. Pentachlorophenol also contains chlorinated dibenzodioxins and chlorinated dibenzofurans (CDDs and CDFs) and hexachlorobenzene (HCB) as contaminants formed during the manufacture process. However, pentachlorophenol is only one of many sources of CDDs, CDFs, and HCB in the environment making it difficult to quantify the portion of the aggregate environmental risk from CDDs, CDFs, and HCB that is attributable to pentachlorophenol wood treatment uses.

CDDs and CDFs have been identified as micro-contaminants in technical grade pentachlorophenol. CDDs and CDFs have been found throughout the world at low concentrations in air, soil, water, sediment, fish and shellfish, and other food products such as meat and dairy products. CDDs and CDFs are members of a family of polychlorinated isomers of "dioxin-like" compounds. Physical and chemical properties and toxicity vary with the degree of chlorination. The most toxic congener of the family is 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD).

The dioxin/furan contaminants of pentachlorophenol present a unique case for purposes of risk characterization. Up to 17 CDD/CDF congeners are produced as contaminants in the manufacture of technical grade pentachlorophenol. All of these contaminants have chlorine substitution in at least the 2,3,7, and 8 positions, thus imparting these contaminants with "dioxin like" activity. Thus, all must be considered in the risk assessment for the contaminants of pentachlorophenol.

HCB has also been identified as a micro-contaminant in technical grade pentachlorophenol, and is not a naturally occurring compound. It is present in the environment through emissions into the atmosphere due to the manufacture of PCP and numerous emission processes, industrial discharge of HCB containing wastes into waterways as well as due to the manufacturing processes of some pesticides. Since HCB is a micro-contaminant in technical grade pentachlorophenol, it must also be considered in the risk assessment for the contaminants of pentachlorophenol.

1. Toxicity of Pentachlorophenol

A brief overview of the toxicity studies used for determining endpoints in the risk assessment is outlined below in Table 1. Further details on the toxicity of pentachlorophenol can be found in the "Pentachlorophenol-Toxicology Chapter for the Reregistration Eligibility Decision Document.," dated August 29, 2008; and the "***PENTACHLOROPHENOL:*** - Revised Toxicology Endpoint Report.," dated February 11, 2008. These documents are available on the Agency's website in the EPA Docket at: http://www.regulations.gov (Docket ID EPA-HQ-OPP-2004-0402).

The Agency has reviewed all toxicity studies submitted for pentachlorophenol and has determined that the toxicological database is sufficient for reregistration. The studies have been submitted to support guideline requirements. Major features of the toxicology profile are presented below. Table 1 gives a summary of the acute toxicity data and the toxicological endpoints selected for the exposure scenarios are summarized in Table 3. As stated previously, the Agency is aware that research is ongoing regarding pentachlorophenol. The Agency may revisit this decision in the future.

a. Acute Toxicity

The acute toxicity database for pentachlorophenol is considered complete. The acute toxicity of pentachlorophenol is low for dermal toxicity (Toxicity Category IV) and primary dermal irritation (Toxicity Category III) but shows higher toxicity for acute oral toxicity and primary eye irritation (Toxicity Category II). No dermal sensitization was observed with the technical test material. Acceptable acute inhalation toxicity data for pentachlorophenol were not available, but waivers were granted for these data.

The Pentachlorophenol Task Force previously submitted data to the Agency on efforts to develop methods to conduct inhalation studies. This effort was without success, based on an inability to generate consistent chamber concentrations of pentachlorophenol. The Agency has reviewed the documents in its possession regarding requests for waivers of inhalation toxicity data requirements, attempts at generating respirable atmospheres of pentachlorophenol, and conclusions reached in the Position Document 4 for Wood Preservatives (USEPA, 1984). Several difficulties were apparently encountered in the attempt to generate respirable particles of pentachlorophenol. It is concluded that, other issues notwithstanding, the real issue is the ability to maintain a consistent chamber concentration of pentachlorophenol. The previous decision to allow waivers for the acute and 90-day inhalation toxicity studies is upheld, but a Toxicity Category I for inhalation hazard will be assigned. The assignment of a Toxicity Category I is also consistent with regulatory decisions made previously for use of respirators from occupational exposure to pentachlorophenol (USEPA, 1984).

The following table summarizes the acute toxicity of pentachlorophenol. It is noted that the studies cited are older data, in which the test material may contain measureable concentrations of contaminants such as hexachlorodioxins and hexachlorobenzene.

Table 2. Summary of Acute Toxicity Data for Pentachlorophenol

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
Acute Toxicity				
870.1100 (§81-1)	Acute Oral	00101715	LD50 = 155 mg/kg (M); LD50 = 137 mg/kg (F)	II
870.1200 (§81-2)	Acute Dermal Toxicity	00101715	LD50 > 3980 mg/kg	IV
870.1300 (§81-3)	Acute Inhalation Toxicity	waiver granted		I
870.2400 (§81-4)	Primary Eye Irritation	00101715	Corneal involvement at day 7 post-instillation	II
870.2500 (§81-5)	Primary Dermal Irritation	00101715	Moderate irritation at 72 hours post-application	III
870.2600 (§81-6)	Dermal Sensitization	42594301	no sensitization observed using Buehler method	NA

b. Carcinogenicity

Pentachlorophenol was classified as a B2 carcinogen (probable human carcinogen) at a joint February 1990 meeting of the FIFRA Science Advisory Panel and Science Advisory Board. The SAP/SAB concluded that the liver tumors, pheochromocytomas, and hemangiosarcomas were treatment-related and supported the B2 classification. These tumors were observed in female mice from a study conducted by the National Toxicology Program in 1989 (NTP Technical Report 349, March 1989) using pure pentachlorophenol or a technical grade formulation, Dowicide EC-7. In November of 1990, the Health Effects Division's Carcinogenicity Assessment Review Committee met and concurred with the B2 classification and also recommended quantification of risk using the combined incidence of hemangiosarcomas, liver tumors, and pheochromocytomas in female mice from the two data sets generated with the two pentachlorophenol formulations used in the NTP study (Health Effects Division document # 013274, HED archive record series). Using a 3/4 scaling factor, an oral cancer risk estimate (q_1*) of 7.0 x 10^{-2} was calculated on this basis The slope factor was calculated as the geometric mean of the individual slope factors derived from two data sets: female mouse data for technical grade and Dowicide EC-7 pentachlorophenol.

EPA is currently completing a new Integrated Risk Information System (IRIS) assessment that will include a cancer unit risk value for pentachlorophenol. Based on the ongoing re-evaluation of the science to estimate carcinogenic potential of pentachlorophenol, OPP will use the current risk estimate for pentachlorophenol until any new risk estimates are fully peer reviewed. However, the EPA process of regulating pesticides allows for reevaluation at any time if new information from the peer review process of the carcinogenic potential of pentachlorophenol warrants.

c. Toxicological Endpoints

On November 25, 1997, the Health Effects Division's Hazard Identification Review committee evaluated the toxicology data base of pentachlorophenol, selected doses and endpoints for acute dietary, chronic dietary (RfD) as well as occupational and residential exposure risk assessments, assessed the carcinogenic potential and addressed the sensitivity of infants and children from exposure to Pentachlorophenol as required by the Food Quality Protection Act (FQPA). In February of 2008, the Agency evaluated updated information with respect to the carcinogenicity of pentachlorophenol. The toxicity endpoints used in the current risk assessment are summarized below in Table 3.

Table 3. Toxicological Endpoints for Pentachlorophenol

Exposure Scenario	Dose Used in Risk Assessment, UF	Target MOE, Uncertainty Factory (UF) for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (all populations)	An acute dietary assessment is not needed for the registered antimicrobial uses of pentachlorophenol, however, an acute endpoint of 30 mg/kg/day was selected from a developmental toxicity study in rats (MRID 43091702), with an uncertainty factor of 100 to calculate the acute RfD.		
Chronic Dietary (all populations)	A chronic dietary assessment is not needed for the registered antimicrobial uses of pentachlorophenol; however, a chronic endpoint of 1.5 mg/kg/day, the LOAEL from a chronic toxicity study in dogs (MRID 43882701), was previously selected, with an uncertainty factor of 300 to calculate the chronic RfD.		
Non-Dietary Risk Assessments			
Incidental Oral	An incidental oral risk assessment is not required for the registered antimicrobial uses of pentachlorophenol.		
Dermal (short- and intermediate-term)	NOAEL = 30 mg/kg/day	MOE = 100	Developmental Toxicity study – rats MRID 43091702
Dermal (long-term)	LOAEL = 1.5 mg/kg/day UF: 3X for lack of a NOAEL	MOE = 300	Chronic Toxicity study – dogs MRID 43982701
Inhalation (all durations)	No inhalation data available for pentachlorophenol. Inhalation risks for occupational exposure were not performed because most inhalation values derived from the biomonitoring study in workers were below the level of quantitation, thus implying that the majority of worker exposure is through dermal contact with pentachlorophenol		

Exposure Scenario	Dose Used in Risk Assessment, UF	Target MOE, Uncertainty Factory (UF) for Risk Assessment	Study and Toxicological Effects
Carcinogenicity (oral)	Classified as a B2 (probable human carcinogen) carcinogen by the Health Effects Division Carcinogenicity Assessment Review Committee and EPA's Science Advisory Board. An oral cancer risk estimate (q_1*) of 7.0 x 10^{-2} was calculated based on the incidences of hepatocellular neoplasms, adrenal medullary neoplasms, and hemangiosarcomas that developed in female mice treated with technical grade PCP or Dowicide EC-7 (NTP, 1989). The slope factor was calculated as the geometric mean of the individual slope factors derived from two data sets: female mouse data for technical grade and Dowicide EC-7 pentachlorophenol.		

Notes: UF = uncertainty factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose.

2. Toxicity of Dioxin/Furan

The concept of toxic equivalency factors (TEFs) has been developed to facilitate risk assessment of exposure to chemical mixtures of CDDs and CDFs. In this procedure, individual TEFs are assigned to the various congeners of CDDs and CDFs. These values have been published by both the USEPA and the World Health Organization (Younes, 1998) and are based on assigning relative values in relation to 2,3,7,8-TCDD, which is assigned a TEF value of 1.0, it being the most potent congener. Multiplying the exposure concentration of individual congeners by their respective TEFs yields a toxic equivalency, which, when summed for all the components of the mixture, gives the toxic equivalency quotient (TEQ) for that mixture and is an indication of the additional exposure from the pentachlorophenol contaminants.

Recent developments in science policy in the Agency have resulted in a shift towards calculation of non-cancer risk from dioxins and furans using a body burden approach rather than a dose or intake approach. This is appropriate for dioxin/furan contaminants of pentachlorophenol due to the long half-life of these chemicals. The Agency's Office of Research and Development (ORD) has led the effort in characterizing hazards and risks from exposure to dioxins and dioxin-like compounds, and the OPP, in its assessment of non-cancer risks posed by the dioxin/furan contaminants in pentachlorophenol, is working with ORD to express these risks using the methodologies developed in ORD for calculation of body burdens from exposure to the contaminants in pentachlorophenol treated wood.

a. Acute and Chronic Toxicity

Acute and chronic non-cancer toxicity have not been determined and are pending assessment using models developed by the Agency's Office of Research and Development (ORD) to determine actual body burdens. Only long-term dioxin absorbed doses are presented for calculation of the lifetime average daily doses (LADDs).

b. Carcinogenicity

A carcinogenic endpoint related to absorbed doses of CDD and CDF micro-contaminants has been identified. A cancer risk greater than one in a million is of concern.

In 1985, EPA classified 2,3,7,8-TCDD and related compounds as "probable" human carcinogens based on the available data. Since that time, the database relating to the carcinogenicity of dioxin and related compounds has grown and strengthened considerably. Under EPA's current approach, 2,3,7,8-TCDD is best characterized as a "human carcinogen." This means that, based on the weight of all of the evidence (human, animal, mode of action), 2,3,7,8- TCDD meets the stringent criteria that allows EPA and the scientific community to accept a causal relationship between 2,3,7,8-TCDD exposure and cancer hazard. Other dioxin-like compounds are characterized as "likely" human carcinogens primarily because of the lack of epidemiological evidence associated with their carcinogenicity, although there is a strong inference based on toxic equivalency that they would behave in humans as 2,3,7,8-TCDD does.

At this time, the knowledge of the mechanism of action of dioxin, receptor theory, and the available dose-response data do not firmly establish a scientific basis for replacing a linear procedure for estimating cancer potency. Therefore, for purposes of cancer risk assessment, the Agency is using the currently published slope factor of 1.0×10^{5} $(mg/kg/day)^{-1}$ for the 2,3,7,8 congener.

For additional information, please see the *Pentachlorophenol- Risk Assessment for the Reregistration Eligibility Decision (RED) Document*, dated August 29, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

3. Toxicity of Hexachlorobenzene

The Agency has identified HCB as a persistent, bio-accumulative, and toxic (PBT) environmental pollutant contaminating water and food-chain sources. Human health effects associated with exposure to HCB include skin lesions, nerve and liver damage as short-term effects. Long-term effects from lifetime exposures include damage to liver and kidneys, reproductive effects, benign tumors of endocrine glands, and cancer.

The manufacturing process of pentachlorophenol produces several known contaminants of toxicological concern including HCB. The exposure and risk assessment for HCB in pentachlorophenol will focus on the use of pentachlorophenol as a wood preservative and the potential occupational exposure to HCB through this use.

a. Acute and Chronic Toxicity

The toxicology of hexachlorobenzene is discussed in detail within the 1991 "Drinking Water Criteria Document for Hexachlorobenzene", prepared by the U.S. EPA's Office of Health and Environmental Assessment (U.S. EPA, 1991) and the "ATSDR Toxicological Profile for Hexachlorobenzene" (ATSDR, 2002). Both assessments characterize the acute toxicity of HCB as low, with oral LD50 values in the range from 3500-10,000 mg/kg in rats, and other data citing 1700 mg/kg in rats, 2600 mg/kg in rabbits, and 4000 mg/kg in mice.

b. Carcinogenicity

The Agency has classified HCB as a B2 (probable human) carcinogen, based on data sets that showed induction of tumors of the thyroid, liver, and kidney in three rodent species (U.S.EPA, IRIS, 1996). In the IRIS database, the oral cancer slope factor was 1.7 $(mg/kg/day)^{-1}$ based on hepatocellular carcinomas in female Sprague-Dawley rats using a 2/3's animal to human scaling factor. However, based on current Agency policy a 3/4's scaling factor is applied to adjust the slope factor. The cancer slope factor for HCB was modified by 0.6X to account for the newer factor. For this evaluation, carcinogenic risk was assessed for non-dietary exposure to HCB using the modified cancer slope factor of 1.02 $(mg/kg/day)^{-1}$.

c. Toxicological Endpoints

The Agency has selected toxicity endpoints for HCB for use in exposure and risk assessments. These endpoints were selected using the available scientific literature on HCB (U.S. EPA, 2003). A summary of these endpoints is shown below in Table 4.

Table 4. Toxicological Endpoints for Hexachlorobenzene

Exposure Scenario	Dose	Endpoint	Study	Target MOE
Non-Dietary Risk Assessments				
Incidental Oral: Short-Term	NOAEL= 40 mg/kg/day	body weight loss, hyperesthesia, tremors, convulsions in maternal rats at 60 mg/kg/day.	Developmental Toxicity- Rat (Khera, 1974)	100
Incidental Oral: Intermediate-Term	NOAEL= 0.5 mg/kg/day	increased incidence of liver porphyrin levels in female rats at 2 mg/kg/day	15 Week Oral Toxicity- Rat (Kuiper- Goodman et al, 1977)	100
Dermal: Short-Term	Oral NOAEL = 40 mg/kg/day	body weight loss, hyperesthesia, tremors, convulsions in maternal rats at 60 mg/kg/day.	Developmental Toxicity- Rat (Khera, 1974)	100
Dermal: Intermediate-Term	Oral NOAEL = 0.5 mg/kg/day	increased incidence of liver porphyrin levels in female rats at 2 mg/kg/day	15 Week Oral Toxicity- Rat (Kuiper- Goodman et al, 1977)	100
Dermal: Long-Term	Oral NOAEL =0.08 mg/kg/day	hepatic centrilobular basophilic chromogenesis at 0.29 mg/kg/day	Chronic Toxicity - Rat (Arnold et al., 1985)	100
Inhalation: Short-, Intermediate-, and Long-Term	No route-specific endpoints are available for HCB. Therefore, in accordance with Agency policy, oral endpoints and route extrapolation are employed to estimate inhalation risks as needed.			1000
Oral Cancer Slope Factor (CSF)	Q*=1.02 $(mg/kg/day)^{-1}$ (Extrapolated using a Q*of 1.7 $(mg/kg/day)^{-1}$ derived from a linearized multistage model to which a 3/4 scaling factor was applied: 1.7 x 0.6 =1.02)	B2 (probable human carcinogen) based on data showing significant increases in liver and renal tumor incidences in hamsters and rats	Sourced to EPA REDs for DCPA, November 1998, and Chlorothalonil, April 1999 and EPA's IRIS Database.	The Agency typically will not allow Occupational non-dietary risks to exceed 10^{-6}.

Recommended MOEs of 100 are based on applied uncertainty factors used to account for inter-species extrapolation (10x) and intra-species variability (10x).

For additional information, please see the *Pentachlorophenol- Risk Assessment for the Reregistration Eligibility Decision (RED) Document*, dated August 29, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

4. Dietary Exposure and Risk from Food and Drinking Water

There are no existing food uses for the wood preservative uses of pentachlorophenol. Dietary monitoring data assembled by the Food and Drug Administration indicated the presence of pentachlorophenol in certain food items (i.e. milk, pears, pork, but these data are old (i.e. 1991), and FDA discontinued monitoring for pentachlorophenol residues after 1992 based on lack of detectable residue. Since wood treated with pentachlorophenol is not available for sale to the general public, and play activities in children around treated utility poles is not likely to occur, residential risk assessment is not necessary for pentachlorophenol and a FQPA analysis is not needed. However, population-based biological monitoring data from the National Health and Nutrition Surveys (NHANES) were available to assess the exposure of the general population to pentachlorophenol. The NHANES data provides an encompassing review of all pentachlorophenol exposures; the specific pentachlorophenol treated wood contribution to total pentachlorophenol exposure cannot be differentiated. Because NHANES does not include exposures to children under the age of 6 years old, the Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) study (Wilson, et al. 2007) was used to include estimates of exposures to children under 6 years old. For additional information on the potential risks resulting from residential exposure, please see section 6 Residential Exposure and Risk.

It should be noted that the majority of developmental toxicity studies on pentachlorophenol show no teratogenic effects, but some older studies, especially those of Schwetz et al. (1974) and Welsh et al. (1987), showed toxic effects of pentachlorophenol in offspring that occurred at dose levels below those producing maternal toxicity. In addition, it is recognized that the contaminants hexachlorodioxin and 2,3,7,8 tetrachlorodioxin are considered teratogenic chemicals. Due to this reason combined with the knowledge that hexachlorodioxin is a contaminant of pentachlorophenol, the warning labels on pentachlorophenol formulations with respect to potential teratogenic effects have remained.

For additional information, please see the *Previous Pentachlorophenol Dietary Exposure and Risk Chapter Used In 2004 for the Reregistration Eligibility Decision (RED) Document*, dated March 7, 2008; *Previous Polychlorinated dibenzo-p-dioxins (CDDs) and Polychlorinated dibenzofurans (CDFs) Dietary Exposure Chapter Developed in 2005 for the Pentachlorophenol Reregistration Eligibility Decision (RED) Document*, dated March 7, 2008; *Previous Hexachlorobenzene (HCB) Dietary Exposure Chapter Developed in 2005 for the Pentachlorophenol Reregistration Eligibility Decision (RED) Document*, dated March 7, 2008; and *Revised PCP Human Exposure RED Chapter*, dated September 8, 2008 located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

a. Dietary and Drinking Water

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic. This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

b. Pentachlorophenol

Typically a dietary risk assessment would not be necessary for pentachlorophenol based upon the current restrictions on use of this pesticide that have been in place since 1984. However, monitoring data from FDA from 1991 showed levels of pentachlorophenol in only a few food items, and at levels that approached the limit of detection. Therefore, the Agency conducted a dietary assessment based on available monitoring data. Using conservative assumptions and the dietary monitoring data collected when pentachlorophenol was still present in certain foods (1991), exposure to pentachlorophenol through food (based on FDA monitoring data) represents 2.4% of the chronic RfD for the most exposed subpopulation in the U.S. (Children ages 1-6). Exposure to all other groups represents less than 0.5% of the chronic RfD.

Surface water runoff from pentachlorophenol treated utility poles may be a possible source for pentachlorophenol or its transformation products in drinking water or in foods. Estimated Environmental Concentrations (EECs) for surface water have been calculated by the Agency. Drinking water levels of concern (DWLOCs) for acute and chronic dietary risk from drinking water were calculated. DWLOCs calculated for surface water for pentachlorophenol were 10,465 ppb for adult males and females and 2,990 ppb for children ages 1-6. Using the PRZM-EXAMS model, available environmental fate data, and conservative assumptions, the estimated environmental concentrations calculated by the Agency for surface water were less than 1 ppb. EECs for groundwater were not available for comparison against DWLOC values; however, based on pentachlorophenol's physical/chemical characteristics and available monitoring data, it is not expected to add significantly to this risk assessment.

For additional information, please see the *Previous Pentachlorophenol Dietary Exposure and Risk Chapter Used in 2004 for the Reregistration Eligibility Decision (RED) Document*, dated March 7, 2008; and, *Estimated Environmental Concentrations (EECs) for Pentachlorophenol Using PRZM-EXAMS Models*, dated March 3, 2008 located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

c. Dioxins and Furans

A dietary risk assessment was not necessary for pentachlorophenol; however, the Agency has examined residue data that demonstrates there are potential sources of dietary exposure to low concentrations of dioxins/furans found throughout the world.

Dietary intake is generally recognized as the primary source of human exposure to CDDs and CDFs. Residue data are available for meat, fish, dairy products, eggs and fruits and vegetables. Residue data are reported in terms of both parts per trillion (ppt) and in terms of toxicity equivalents for both CDDs and CDFs.

Very little residue data are available for crops for residues of CDD and CDF; however, there is a limited amount of residue data available for foods of Canadian and U.S. origin for fruits, vegetables and wheat. The only residues reported for these commodities were for the octachlorodibenzodioxin congener and ranged from 0.6 - 8 ppt.

Samples of vegetable oil from the U.S. were analyzed for CDD and CDF cogence. No residues of tetrachlorodibenzodioxin (TCDD) were detected in the samples. Residues of the other cogence of CDDs and CDFs analyzed for ranged from 0.22 ppt - 33.1 ppt. The 33.1 ppt value is for the octachlorodibenzodioxin congener.

Toxicity equivalent residue data are reported for both environmental media and food. Food residue data are for levels found in both Canadian and U.S. vegetable fats, fish, shellfish, milk and dairy products, eggs, meat and poultry. Mean residues are all reported at levels of less than 2 ppt CDD and CDF toxicity equivalents. The maximum mean CDD/CDF toxicity equivalent residues were reported in freshwater fish at 1.2±1.2 ppt.

For additional information, please see the *Previous Polychlorinated dibenzo-p-dioxins (CDDs) and Polychlorinated dibenzofurans (CDFs) Dietary Exposure Chapter Developed in 2005 for the Pentachlorophenol Reregistration Eligibility Decision (RED) Document*, dated March 7, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

d. Hexachlorobenzene

A dietary risk assessment was not necessary for pentachlorophenol; however, there are other potential sources of dietary exposure to HCB. Therefore, the Agency has also examined residue monitoring data for HCB in food commodities.

There are currently no HCB pesticide tolerances established for food commodities and there are no registered uses for HCB on food commodities. However, dietary exposure to residues of HCB will likely occur as an incidental residue on terrestrial crops as a result of direct application of a pesticide containing HCB as an impurity to agricultural crops in the field. Dietary exposure to HCB residues on terrestrial crops and aquatic organisms can also occur as a result of HCB emission into the atmosphere from various sources followed by deposition of HCB onto agricultural crops, and from industrial discharge or agricultural pesticide run-off into waterways. The source of HCB residues occurring in food commodities cannot be distinguished in an analysis for residues. Therefore, it is not certain that these residues result from use of PCP-treated wood.

Residue monitoring data for HCB are available from the USDA Pesticide Data Program; the USDA Field Safety and Inspection Service; the FDA Pesticide Residue Monitoring Program on meat, milk, fish and various other agricultural commodities; and the FDA Total Diet Study. The monitoring data reflect the analyses of thousands of food samples and cover a period of several years.

The data show few residues of HCB were detected in monitoring samples from FDA or USDA. The majority of detected residues were reported in fish. Detectable residues were more likely to be found in domestic monitoring samples than in imported samples. The majority of reported HCB residues are trace amounts (0.01 ppm range).

For additional information, please see the *Previous Hexachlorobenzene (HCB) Dietary Exposure Chapter Developed in 2005 for the Pentachlorophenol Reregistration Eligibility Decision (RED) Document*, dated March 7, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

5. Residential Post-application Exposure and Risk

The opportunity for residential consumer contact is limited since pentachlorophenol treated wood is not sold to the general public; however, population-based biological monitoring data from the National Health and Nutrition Surveys (NHANES) were available to assess the exposure of the general population to pentachlorophenol. The NHANES data provides an encompassing review of all pentachlorophenol exposures; the specific pentachlorophenol treated wood contribution to total pentachlorophenol exposure cannot be differentiated. Because NHANES does not include exposures to children under the age of 6 years old, the Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) study (Wilson, et al. 2007) was used to include estimates of exposures to children under 6 years old. For additional information, please see the "Revised PCP Human Exposure RED Chapter," September 8, 2008.

Sources of pentachlorophenol other than the currently registered pressure treatment of wood include hexachlorobenzene and lindane, as an emission from incineration of chlorine-containing waste, and also during pyrolysis of polyvinyl chlorides (ATSDR 2001). In the past, PCP was also registered as a termiticide, fungicide, herbicide, molluscicide, algaecide, disinfectant, and for antifoulant paint. It was also used as a preservative for timber used in the construction of log homes. The use of PCP was restricted to wood treatment in 1984.

a. Residential Post-application Non-cancer Exposure and Risk Using NHANES

The following information has been excerpted from Cohen (2008). Since the 1960s, the National Center for Health Statistics, a division of the Centers for Disease Control and Prevention has conducted the National Health and Nutrition Surveys (NHANES), a series of US national surveys of the health and nutrition status of the non-institutionalized civilian population. NHANES 2001 to 2002 included laboratory measurements on 9,929 subjects. This analysis uses urinary concentrations of pentachlorophenol measured in urine spot samples of at least 20 mL collected from a random one-third sample of 3,028 subjects of ages 6 and older. The dose conversion calculations also used the NHANES measurements of creatinine concentrations, body weight, body height, as well as the age, gender, and race of each subject. The NHANES 2001-2002 data were obtained from the NHANES website: www.cdc.gov/nchs/nhanes.htm. Although pentachlorophenol data have been collected for the 2003-2004, these data have not yet been publicly released. The data are expected to be released by the end of 2008.

EPA evaluates health effects in terms of toxicity endpoints that represent an exposure level in mg or µg per kilogram body weight that is not expected to be associated with adverse health effects. The conversion of measured spot urine concentrations to daily doses can be difficult because of variable dilution caused by wide fluctuations in fluid intake and excretion. Dose calculation is also difficult because there is no way to determine from the NHANES data

from what route of exposure (i.e., oral, dermal, inhalation) and when (i.e., duration and time interval prior to measurement) the exposure to PCP occurred, and because of uncertainty and variability in the absorption, distribution, metabolism, and excretion (ADME) parameters.

The long-term target MOE of 300 was used to assess the pentachlorophenol non-cancer risks. The non-cancer risk drivers are for pentachlorophenol, not HCB (i.e., pentachlorophenol non-cancer risks are greater than those of HCB). Therefore, only the non cancer risks for pentachlorophenol were provided. The Agency is following the outcome of the current EPA's Office of Research and Development (ORD) body burden approach/research for the non-cancer risks to dioxin. The Agency is aware that research is ongoing regarding pentachlorophenol. The Agency may revisit this decision in the future.

Total potential exposures and risks from NHANES are presented for the following age groups and subpopulations: all age groups (MOE of 70730); ages 6-11 (MOE of 69544); ages 12-19 (MOE of 58512); ages 20-59 (MOE of 74329); ages ≥ 60 (MOE of 69980); male (MOE of 75512); females (MOE of 66666); Mexican-American (MOE of 134690); white (MOE of 71396), non-Hispanic (MOE of 71396); and black, non-Hispanic (MOE of 47774). The total exposure and risk calculated using the NHANES data demonstrates that for pentachlorophenol (e.g., assuming all pentachlorophenol exposure results from pentachlorophenol treated poles, presentation of various dose conversion methods including the assumption that all individuals excrete a daily urine volume of the 95th percentile of the population), the total risks result in no unreasonable adverse effects from the currently registered wood preservative use.

b. Residential Post-application Non-cancer Exposure and Risk Using CTEPP

The long-term target MOE of 300 was used to assess the non-cancer risks to children 1.5 to 5 years old. The CTEPP data indicate 89 and 99 percent of the samples had detectable levels of pentachlorophenol in NC and OH, respectively. However, the total potential exposure and risk calculated using the CTEPP data demonstrates that for children 1.5 to 5 years old, risks resulting from pentachlorophenol exposure below the Agency's level of concern. MOEs range from 2,400 to 95,000.

c. Residential Post-application Cancer Exposure and Risk Using NHANES and CTEPP

The lifetime average daily dose (LADD) is estimated by combining the results of both the CTEPP and NHANES data sets. The LADD is estimated by averaging the estimated daily dose for each year in a lifetime of 75 years. This assumes the frequency and lifetime duration of exposure is constant (i.e., exposed 365 days per year and 75 years of exposure). CTEPP data are used to estimate the ages 0 to 5 years and NHANES is used to estimate ages 6 to 75 years. In addition to the LADD, the 95th percent lower and upper confidence intervals are also provided for the means. A detailed description of the LADD estimate combining both CTEPP and NHANES data sets are provided in Cohen (2008).

There are currently other sources of pentachlorophenol exposure that are not attributable to pentachlorophenol pressure treated wood; however, the general population biological monitoring data do not allow for the proportioning of exposure to source of contamination. Therefore, the exposures and risks reported are based on the total exposure to pentachlorophenol. Direct measurements of dioxins/furans and HCB exposures for the general population attributed to pentachlorophenol pressure treated wood are not available for this assessment. Therefore, to be inclusive of determining potential exposures to pentachlorophenol contaminants, the amounts of dioxins/furans and HCB in pentachlorophenol are used to extrapolate pentachlorophenol measured exposures to estimate dioxin/furan and HCB exposures.

The potential cancer risks for pentachlorophenol, HCB, and dioxin are 9.8E-7, 1.1E-9, and 5.8E-7, respectively. The risks at the 95th percent upper confidence interval for pentachlorophenol, HCB, and dioxin are 1.5E-6, 1.6E-9, and 8.7E-7, respectively. Future refinements to this assessment should focus on determining contributions of sources to total pentachlorophenol exposure.

6. Aggregate Risk Assessment

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Typically in a case such as pentachlorophenol, the Agency would not conduct acute and chronic aggregate assessments based on the lack of dietary exposure, the lack of pentachlorophenol to enter or persist in groundwater, and the lack of residential applications.

However, as discussed above, the Agency used the NHANES and CTEPP data to estimate the exposure of the general public to pentachlorophenol from a national survey of random individuals. Based on the wide survey and number of samples, these data provide a broad view of pentachlorophenol exposure from all sources. Although a typical aggregate assessment was not conducted, the NHANES and CTEPP data have provided actual aggregate exposure information for pentachlorophenol. Additional information can be found in the *Revised PCP Human Exposure RED Chapter*, dated September 8, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

7. Occupational Exposure and Risk

Workers can be exposed to pentachlorophenol through mixing, loading, applying a pesticide or re-entering treated sites. There are potential exposures from use in commercial and industrial settings *via* the dermal and inhalation routes.

Significant exposure is not expected due to mixing/loading per se because treatment plants utilize automated methods for chemical preservative delivery (metered feed/pump) and closed application techniques (treatment cylinder). However, there is the potential for workers near the treatment cylinder door to inhale treatment solution mist when the door is opened following treatment and/or to contact treatment solution residue on equipment such as charge cables and the treated wood itself. Although in many cases treated wood is moved mechanically (e.g., forklifts), this is not required on current product labeling and is currently accomplished manually in some cases.

For treatment facility exposure scenarios, where possible the Agency estimated risk for each job function that could be performed at a typical treatment facility. Although an effort was made to differentiate risk estimates by job function, the Agency acknowledges that the studies used to estimate exposure reflect actual treatment facility practices in that one person often performed more than one job function. Therefore, estimated risks presented by job function are not considered representative of one individual performing one job function and may reflect additional exposure and risk incurred by performing tasks outside the definitions presented below.

- ***Treatment Operator (TO):*** Primary duties for a pressure treatment operator include opening closing valves transferring treatment liquids, opening and closing treatment vessel doors, cleaning pentachlorophenol residues on doors and latches, performing tram maintenance and positioning, and handling leads, chains and cleanup.

- ***Treatment Assistant (TA):*** TAs perform many of the same functions as the TO including opening and closing valves and doors, cleaning pentachlorophenol residues on doors and latches, performing tram maintenance and positioning, and handle leads and chains and cleanup. However, TAs may perform more manual duties such as drip pad and filter cleaning.

- ***Loader Operator (LO):*** LOs operate open-cab forklifts used to load untreated wood onto charge trams, move charges into and out of treatment cylinders, remove charge leads and bands from treated wood, distributed treated wood to load-out area, and load treated wood for shipment. Most work is done in and around drip pad area. LOs may perform certain out-of-cab tasks such as collecting tank samples and performing test boring and lab analysis of treatment solutions in wood.

- ***Tram Setter (TS):*** TSs manually position trams for loading, place wood spacers on trams where needed to elevate wood to be treated and place drawbridges for treatments. TSs also performs lead and chain handling and operates cylinder door controls. They perform various labor and cleanup duties in treatment and drip pad area including sweeping pressure-washed drip pad and tracks; removing and shredding all bands from treated stacks of lumber, picking up and disposing of treated CCA wood waste, cleaning cylinders, and handling hazardous waste.

- ***Stacker Operator (SO):*** SOs work at a fixed position at a facility that mechanically remove wood spacers from stacks of treated (including freshly treated) lumber. They operate lumber stacking devices which arrange treated boards in stacks for banding and shipment to customers, and remove wood spacer sticks from bundles of treated boards. The major task is to manually position ends of all treated loose boards moving through device so they are evenly positioned. They also perform minor maintenance on the equipment and site.

- ***Supervisor (S):*** The Supervisors mainly perform the duties of a second LO when the LO at this site is busy performing other tasks. They take test borings and pressure-wash the drip pad. In addition, Ss perform tasks away from the treatment areas including bringing untreated wood to the treatment loading dock from other parts of the plant.

- ***Test Borer (TB):*** The TB bores lumber after treatment. TB cuts borings from treated poles or ties for on-site analysis to test for preservative penetration. They also perform other QC laboratory duties. Most time is spent away from the treatment area.

- ***Tally Man (TM):*** The main duties of the TM include counting and inspecting incoming and outgoing truckloads of wood products (untreated and treated wood), and supervision of loading and unloading of lumber trucks at drip pad and elsewhere. They also perform some treatment-related duties, such as end-marking of treated items or chaining of charges for treatment and removal of lead cables after treatment.

a. Pentachlorophenol Occupational Handler Exposure and Risk

The Agency has determined that there are potential worker risks of concern for mixers, loaders, applicators, and handlers associated with the currently registered uses of pentachlorophenol. For occupational handlers, potential short and intermediate-term non-cancer risks are not of concern (i.e., MOE greater than 100); however, potential non-cancer long-term dermal risks (i.e., MOE less than 300) for the pressure treatment operators using liquid formulation (MOE of 230) are of concern. For pressure treatment assistants using both crystalline grade product (MOE of 130) and liquid formulation (MOE of 79) potential long-term non-cancer risks are also of concern.

Total potential cancer risks for all four handler scenarios assessed are of concern (i.e., risks greater than 1.0×10^{-6}). (insert 10-4 to 10-6 is ok when benefits are seen) The results for the cancer risk estimates indicate that cancer risks are of concern for the treatment operator handling both crystalline grade product (7.9×10^{-5}) and liquid formulation (1.7×10^{-4}), and for the treatment assistant handling both crystalline grade product (3.1×10^{-4}) and liquid formulation (4.9×10^{-4}).

b. Dioxin Occupational Handler Exposure and Risk

Handler exposure to pentachlorophenol wood preservatives, as product concentrates and treatment solutions result in potential exposure to CDDs and CDFs during handler operations (mixers, loaders, and applicators of pentachlorophenol) in pressure treatment plants.

Non-cancer handler risks have not been calculated and are pending assessment using models developed by the Agency's Office of Research and Development (ORD) to determine actual body burdens. Only long-term dioxin/furan absorbed doses are presented for calculation of the lifetime average daily doses (LADDs) used for the handler cancer risk assessment.

Occupational handler cancer risk estimates have been calculated for dioxin/furan exposures resulting from the registered uses of pentachlorophenol. A cancer risk estimate greater than one in a million ($1.0x10^{-6}$) is of concern. Most of the assessed occupational handler scenarios exceed the Agency's level of concern for potential worker cancer risks. Potential cancer risks are greater than $1.0x10^{-4}$ for the pressure treatment operator handling liquid formulation ($2.0x10^{-4}$), the pressure treatment assistant handling crystalline product ($3.6x10^{-4}$), and the liquid formulation ($5.6x10^{-4}$). Potential cancer risks are greater than $1.0x10^{-5}$for the treatment operator handling the crystalline product ($9.0x10^{-5}$).

c. Hexachlorobenzene Handler Exposure and Risk

Handler exposure to pentachlorophenol wood preservatives, as product concentrates and treatment solutions result in potential exposure to HCB during handler operations (mixers, loaders, and applicators of pentachlorophenol) in pressure treatment plants.

For absorbed short-, intermediate- and long-term exposures to HCB, the Agency's level of concern are MOEs that are less than 100. None of the occupational handler scenarios assessed exceeded the Agency's level of concern for potential non-cancer risks.

Occupational handler cancer risks have been calculated for HCB exposures resulting from the registered uses of pentachlorophenol. A cancer risk greater than one in a million ($1.0x10^{-6}$) is of concern. None of the occupational handler scenarios assessed exceeded the Agency's level of concern (i.e., $1.0x10^{-6}$).

d. Pentachlorophenol Occupational Post-application Exposure and Risk

The Agency has determined that there are no potential non-cancer risks of concern relating to occupational post-application exposure to individuals following pentachlorophenol applications in wood pressure treatment facilities. However, potential post-application cancer risks for pressure treatment loader operator ($6.9x10^{-5}$), pressure treatment test borer ($6.1x10^{-5}$), general helpers ($3.6x10^{-5}$), and electrical utility linemen ($2.5x10^{-5}$) are of concern. A potential cancer risk that is greater than one in a million (i.e., $1.0x10^{-6}$) is of concern.

For additional information, please see the *Revised PCP Human Exposure RED Chapter*, dated September 8, 2008, located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

e. Dioxin/Furan Occupational Post-application Exposure and Risk

Occupational post-application exposure scenarios for dioxins and furans resulting from the registered uses of pentachlorophenol were identified primarily for pressure treatment workers. In addition, a scenario was included for utility linemen. Post-application or reentry exposures in treatment plants may occur after the wood has been pressure treated. Individuals may be exposed to dioxins and furans through contact with pentachlorophenol treated wood products or equipment used to pressure treat wood. Exposure activities include sampling pentachlorophenol retort mixtures, moving trams and treated poles, boring wood cores, and performing cleanup activities on drip pads. The industrial workers involved in post-application activities for this assessment include the test borer, loader operator, and general helper (as representative of pressure treatment plant workers), and the utility linemen involved with post-application handling of pentachlorophenol treated utility poles. The average doses for the pressure treatment operator and treatment assistant were used to estimate long-term exposure to dioxins and furans resulting from the uses of pentachlorophenol. Where applicable, the pentachlorophenol exposures were converted into CDD and CDF equivalents using the TEQ approach in order to estimate exposure and assess risk. These long-term dioxin absorbed doses were calculated for the representative scenarios by adjusting the pentachlorophenol absorbed doses by the EPA-TEQ factor of 0.813 ng/mg as derived from EPA industry monitoring data for pentachlorophenol production years 1998-1999.

Potential non-cancer post-application risks have not been quantified and are pending assessment using models developed by the Agency's Office of Research and Development (ORD) to determine actual body burdens. Only long-term dioxin absorbed doses are presented for calculation of the lifetime average daily doses (LADDs) used for the post-application cancer risk assessment.

Potential occupational post-application cancer risks have been calculated for dioxin/furan exposures resulting from the registered uses of pentachlorophenol. A cancer risk estimate greater than one in a million ($1.0x10^{-6}$) is of concern. Most of the assessed occupational handler scenarios exceed the Agency's level of concern for potential worker cancer risks. Potential cancer risks are greater than $1.0x10^{-5}$ for the pressure treatment loader operator ($8.0x10^{-5}$), pressure treatment test borer ($6.5x10^{-5}$), general helpers ($4.7x10^{-5}$), and electrical utility linemen ($3.0x10^{-5}$).

For additional information, please see the *Occupational Exposure and Risk Assessment of Dioxins and Furans (CDDs/CDFs) in Pentachlorophenol*, dated September 8, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

f. Hexachlorobenzene Post-application Exposure and Risk

Occupational post-application exposure scenarios for HCB resulting from the registered uses of pentachlorophenol were identified primarily for pressure treatment workers. In addition, a scenario was included for utility linemen. Post-application or reentry exposures in treatment plants may occur after the wood has been pressure treated. Individuals may be exposed to HCB

through contact with pentachlorophenol treated wood products or equipment used to pressure-treat wood.

The Agency has determined that Margins of Exposure (MOEs) of 100 or greater are appropriate for acceptable risks from absorbed short-, intermediate- and long-term exposures to HCB. None of the occupational post-application scenarios assessed exceeded the Agency's level of concern for non-cancer aggregate risks.

Potential occupational post-application cancer risks have been calculated for HCB exposures resulting from the registered uses of pentachlorophenol. A cancer risk estimate greater than one in a million ($1.0x10^{-6}$) is of concern. None of the occupational post-application scenarios assessed exceeded the Agency's level of concern (i.e., $1.0x10^{-6}$) for potential cancer risks.

For additional information, please see the *Occupational Exposure and Risk Assessment of Hexachlorobenzene (HCB) in Pentachlorophenol*, dated March 6, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

8. Pentachlorophenol Human Incident Data

An extensive body of literature exists on the health effects (acute and chronic) of pentachlorophenol in humans. Many of the pentachlorophenol incident reports are well structured and appear in the literature to be well executed. Populations are well defined, controls are generally selected appropriately, and analyses are appropriate and adequate. However, major weaknesses in exposure assessment methods often limit the validity of reported findings, either positively or negatively. Of the 24 original articles reviewed for this document, a large majority used questionnaire or interview data, provided either by the study participants or by surrogates, as exposure variables. Often, this information was for mixed exposures including known or unknown contaminants rather than for pentachlorophenol alone. Industrial hygiene monitoring data was rarely available for the assessment of individual exposures. Therefore, in some instances, industrial hygiene expertise was used to judge exposures.

Even considering the above limitations, a reasonably strong argument can be made that exposure to pentachlorophenol is associated with increased risks of a number of diseases, namely chloracne, soft tissue sarcoma (STS), and non-Hodgkin's lymphoma (NHL). Increased risks of developing STS were reported in six studies, although statistical significance was reached in only three. Of five studies reporting increased risk for NHL, only one was statistically significant. Increased risks were also reported for lymphatic cancer, hematopoietic cancer, and Parkinson's Disease, but the associations were generally not significant. While it is known that nerve conduction velocity is slowed by exposure to chlorophenols, as well as many other chemicals, studies with this dysfunction as an endpoint showed ambivalent results. Two studies showed associations between exposure of parents to chlorophenols and negative effects in subsequently born offspring, but results in these studies were not statistically significant.

Considering the number of studies, the consistency among a number of outcomes, as well as the general absence of statistical significance, there appears to be reasonable evidence that exposure to chlorophenols may often be associated with chloracne, STS, NHL, and possibly abnormal births. Whether these health effects result from exposure to pentachlorophenol specifically, or to one or more other chemicals typically found as contaminants, is not clear. Based on the evidence collected to date, careful control of exposures to chlorophenols, including pentachlorophenol, is certainly warranted.

For additional information, please see the *Epidemiology and Incident Reports Associated with Pentachlorophenol*, dated March 9, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

D. Environmental Risk Assessment

Pentachlorophenol is used mainly as a wood preservative and is usually applied to wood as a liquid formulation (5% solution) composed of pentachlorophenol plus hydrocarbon diluents such as P-9 oil, No. 2 fuel oil, kerosene or mineral spirits. Formulated products may include from 5% to greater than 80% active ingredient and typically include water repellents such as paraffin. Introduction of pentachlorophenol into the environment may occur from spills and runoff, and through releases from treated wood by leaching and/or volatilization; these may occur at wood treatment, storage and disposal sites as well as at the locations of wood usage. Pentachlorophenol may also enter the environment by wastewater discharge or holding pond overflow, both of which may occur at wood treating facilities.

Pentachlorophenol contains chlorinated dibenzodioxins and chlorinated dibenzofurans (CDD and CDFs) as contaminants formed during the manufacture process. The main use of pentachlorophenol, a wood preservative, is to treat utility poles. There are an estimated 36 million pentachlorophenol treated utility poles in service in the United States. Annually, nearly 1 million additional utility poles are replaced (3 percent replacement rate) on land and in water. The Agency has estimated that the utility poles in service contain approximately 374 kg of dioxin toxicity equivalents (I-TEQs). The CDD and CDFs in these poles may be released into the environment via volatilization and leaching. In addition, CDD and CDFs may enter the environment during the pressure-treatment of the utility poles when the utility poles are removed from service and are disposed in landfills. These compounds are inherently toxic, as well as environmentally persistent, and their presence may increase the ecological risk associated with the use of pentachlorophenol. There are many congeners of CDDs and CDFs, ranging from monochlorinated to octachlorinated. The most toxic for each compound seems to be the 2, 3, 7, 8-tetrachlorinated congener, referred to as TCDD or TCDF for dioxin or furan, respectively.

Pentachlorophenol is only one of many sources of CDDs and CDFs in the environment making it difficult to quantify the portion of the aggregate environmental risk from CDDs and CDFs that is attributable to pentachlorophenol wood treatment uses.

Hexachlorobenzene (HCB) is also a contaminant formed during the manufacturing process of pentachlorophenol and is a very stable chlorinated aromatic compound that was commonly used as a pesticide until 1965. Currently, there are no commercial uses of the

substance in the United States. HCB may be formed as a byproduct during the manufacture of chemicals used as solvents, pesticides and other chlorine-containing compounds. Small amounts of this compound can also be produced during combustion processes such as burning of city wastes.

HCB is widely distributed throughout the global ecosystem because if its mobility and resistance to degradation. It has been detected in all environmental media and in numerous types of living organisms including insects, aquatic biota, birds and mammals. HCB has also been shown to bioaccumulate in both aquatic and terrestrial organisms.

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated ecological hazards and environmental risks for the currently registered antimicrobial uses of pentachlorophenol and its micro-contaminants.

1. Environmental Fate and Transport

In general, the environmental fate and transport of pentachlorophenol in soil and water will depend on the pH of the systems. The chemical behavior and the physical properties of pentachlorophenol will depend on whether it exists primarily as the phenol (under more acidic conditions) or the phenolate anion (under basic conditions).

a. Pentachlorophenol

- ***Water:*** Pentachlorophenol is hydrolytically stable in water at pH 4 to pH 9, precluding hydrolysis as a major degradation process in the environment. Chemical degradation of pentachlorophenol in water will occur mainly through photo-degradation. In surface water, pentachlorophenol will rapidly photo-degrade when exposed to direct sunlight, with more rapid degradation occurring with increased pH (when the compound is dissociated).

- ***Soil:*** Wood treated with pentachlorophenol may release the compound through volatilization or leaching. Additionally, pentachlorophenol may be photo-degraded on the wood surface, making degradates available for leaching. All three processes are affected by the solvent systems/carriers used in the application of the compound. The leaching of pentachlorophenol out of utility poles may also partially depend on the method of application (pressure or thermal treatment). Pentachlorophenol may be leached from the poles as the compound moves with either aqueous solution (as from rain) or with the solvent down the pole, either at the surface or within the pole. Based on experimental data, it was determined that the main mechanism for the leaching of pentachlorophenol and its micro-contaminants is the downward migration of the oil carrier along the vertical axis of the pole, designated as "Gravitational Induced Downward Migration of Oil" (GIDMO). Leaching of pentachlorophenol in aqueous solution from rainwater is not considered to be as important as GIDMO, as the replenishment rate at pole surfaces is a limiting factor with respect to the availability of the compound for leaching. Thus, contamination of subsurface soil found in the vicinity of utility poles may result from the downward movement of pentachlorophenol within the

pole, with subsequent leaching from the bottom part of the pole to the soil surface or to the subsoil near the underground portion of the pole, as well as from the downward movement of pentachlorophenol from the surface soils to the subsoil. When leaching of pentachlorophenol from treated poles occurs, the simultaneous leaching of the carrier solvents may affect the mobility of the compound in the soil. Literature and laboratory studies indicate that pentachlorophenol applied in oil is rapidly transported from the upper portion of the poles to the underground portion for the first few years of use, and became relatively constant with time.

Because of the demonstrated tendency for pentachlorophenol to adsorb to soils and the moderately rapid degradation of the compound in the environment, it is not likely that groundwater contamination will result from usage of utility poles, except in situations where the bottom of the pole is directly in contact with the water table (or with a fluctuating water table) or where the leaching occurs from multiple poles in a wood storage or treatment area.

- ***Air:*** Pentachlorophenol is a relatively volatile compound, while its sodium salt in nonvolatile. In the atmosphere, volatilized pentachlorophenol may undergo photolytic degradation or may react with photo-chemically produced hydroxyl radicals. Atmospheric pentachlorophenol which is associated with particulate matter or moisture will be lost from the atmosphere through wet deposition. Based on pentachlorophenol's low Henry's law constant, volatilization from aqueous systems will not be a significant mode of transport in the environment.

For detailed discussions of the environmental fate and transport of pentachlorophenol, see the *Environmental Fate and Transport Assessment of Pentachlorophenol (PCP) for Reregistration Eligibility Decision (RED) Process*, dated February 16, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

b. Dioxins/Furans

Presence of CDDs and CDFs in the environmental compartments resulting from the wood preservative use is due to volatilization into air; leaching from PCP treated poles into water and soil; dry and wet deposition onto air, water, and soils; and sorption into soils. The available data indicate that CDDs and CDFs, particularly the tetras- and higher chlorinated congeners, are extremely stable under most environmental conditions. However, some of these congeners, under certain conditions, are photolytically unstable and in some cases undergo photo-oxidation. Most of the congeners are also resistant to biodegradation under aerobic or anaerobic soil conditions and most are persistent in soils**.**

The process of bioaccumulation has been observed in the benthic organisms, however, bio-transformation processes up the food chain have not been observed. Fish and invertebrates can likely bioaccumulate 2,3,7,8-substituted CDD and CDFs from water columns and sediments. However, because most CDD and CDFs in a water column and sediment are associated with particulate matter and dissolved organic matter, bioaccumulation most likely starts with uptake

of CDD and CDFs by benthic organisms directly from sediment pore waters and by ingestion of contaminated particles. Organisms preying on benthic organisms would possibly transfer the CDD and CDFs up the food chain but no sound scientific data have been obtained.

For detailed discussions of the environmental fate and transport of dioxins/furans, see the *Environmental Fate Modeling of Dioxin in Technical Grade Pentachlorophenol*, dated March 4, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

c. Hexachlorobenzene

HCB is a stable and highly persistent molecule and does not hydrolyze in aqueous medium and is likely to become immobile in soils. It has large sorption partition coefficients. Aerobic and anaerobic biodegradation half lives are long and therefore the main route of dissipation would possibly be through sorption to soils in the terrestrial settings and to sediment organic and inorganic particulate matter in aqueous medium. Because the K_{OC} is high it has a tendency to bind strongly with soil particles and therefore less mobile, the possibility of contamination by HCB of ground water does not seem likely. Because of high binding constants with soils, HCB may possibly accumulate in benthic sediment and bioaccumulate in benthic organisms. Based on monitoring data, it is unlikely that HCB concentration in surface water would exceed 10 ppt (0.01 µg/L).

For detailed discussions of the environmental fate and transport of hexachlorobenzene, see the *Environmental Fate Modeling of Hexachlorobenzene in Technical Grade Pentachlorophenol*, dated March 4, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

2. Terrestrial and Aquatic Organism Exposure and Risk

An ecological risk assessment was conducted to assess impacts of pentachlorophenol residues from treated wood uses. Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects.

a. Pentachlorophenol

The environmental risk assessment indicates that typical concentrations of pentachlorophenol in terrestrial and aquatic environments from wood treatment uses are not expected to be of sufficient quantity or duration to adversely impact terrestrial or aquatic organisms.

b. Dioxins/Furans

Currently there are no FIFRA guideline studies required for the micro-contaminants dioxin/furan, since they are not currently registered, and data on the ecological effects of CDDs and CDFs are relatively limited. Most research efforts have been focused primarily on 2,3,7,8-chlorinated CDD and CDFs, especially 2,3,7,8-TCDD. CDDs and CDFs are very highly toxic to

birds, mammals and aquatic organisms. CDDs (and possibly furans) are capable of producing lasting toxic effects; even a relatively short exposure to TCDD (as little as 6 hours) can result in mortality of fish eggs occurring as much as 80 days later. TCDD is a known endocrine disruptor, and it is likely that other dioxin congeners and furans produce similar effects. Available literature indicates that there are potential acute and chronic risks to birds and chronic risks to mammals from CDDs and CDFs from pentachlorophenol treated wood, especially considering the tendency of CDDs and CDFs to persist and bioaccumulate.

Acute and chronic risks to aquatic organisms are unlikely to occur from runoff of CDDs and CDFs from pentachlorophenol treated wood. However, due to uptake of these compounds by sediment, coupled with the persistence and bioaccumulation of CDDs and CDFs, they may eventually reach toxic levels and pose risks to aquatic organisms through the food web.

Pentachlorophenol is only one of many sources of CDDs and CDFs in the environment making it difficult to quantify the portion of the aggregate environmental risk from CDDs and CDFs that is attributable to pentachlorophenol wood treatment uses.

All environmental exposure and risk assessments are associated with uncertainties which may range from low to high, thus affecting the reliability or certainty of the risk estimations. In the case of the environmental assessment for CDDs and CDFs the uncertainties associated with this assessment are considered high. However, there are no well-established environmental exposure models or methods for determining wildlife (and, particularly, terrestrial wildlife) exposures to 2, 3, 7, 8-TCDD, CDDs, or CDFs released from pentachlorophenol-treated utility poles into the environment.

For the terrestrial environmental assessment, where estimated Risk Quotients (RQs) exceed acute and chronic Levels of Concern (LOCs) for avian and small mammal species, the Agency recognizes that these risk calculations are highly conservative and contain a high degree of uncertainty. Because of this conservatism and uncertainty, EPA believes that these risk calculations may overestimate the potential terrestrial risks which may occur. It is possible, for example, that the present calculated RQs may be orders of magnitude lower than determined.

In an attempt to better characterize this terrestrial assessment the Agency wants to point out the two highly conservative and unrealistic assumptions used in this assessment:

- ***Feeding Activity**:* It is assumed that small mammals and birds will selectively feed (all day and every day until mortality or reproductive effects occur) within a 5 cm (or 2 inches) area surrounding a pentachlorophenol-treated telephone pole; and

- ***Diet**:* It is assumed that 100 % of a small mammal's or bird's diet will be contaminated with 2, 3, 7, 8-TCDD, CDDs, and/or CDFs (while feeding within the 2 inches area).

Although the Agency used these assumptions, we acknowledge that both are highly conservative, unrealistic, and unlikely to occur because:

- ***Home ranges**:* The home ranges (where animals roost/rest, nest, breed, feed) for the surrogate species (bobwhite quail and meadow vole), as well as for other species, are considerably larger (in acres) than a 2 inches area around a pentachlorophenol-treated utility pole. This aspect negates the assumption that organisms will selectively feed within 2 inches of a pentachlorophenol-treated utility pole.

- ***Animal food items**:* Considering the home ranges and feeding habits of small mammals and birds, it is highly unlikely that 100 % (or possibly any portion) of these organisms' diets will be contaminated with dioxins. The assessment addresses a 2 inches area around a pentachlorophenol-treated pole and ingestion of only soil and plant matter. However, birds and small mammals will move freely throughout their home ranges and consume dietary items that typically include animal matter as well as plant matter. Further, soil ingestion often occurs incidentally unless (as with birds) the organism is actively seeking grit in its diet.

Additionally, the Agency notes that:

- ***Environmental fate**:* CDD and CDFs are highly lipophilic (fat soluble), neutral organic compounds that are tightly sorbed onto soils and therefore have limited tendencies to move from the point of deposition. They are primarily sorbed to clay and organic matter because of high surface area and chemical reactivity of these soil components. As a result, the characteristics of these compounds and the soil components are expected to negate the assumption that 2, 3, 7, 8-TCDD, CDDs, or CDFs might move significant distances from pentachlorophenol-treated utility poles into large portions of an animal's home range (thus, providing for increased exposure).

- ***Environmental modeling**:* The environmental modeling used to estimate soil EECs for bobwhite quail and meadow voles is based primarily on dioxin levels released via wood erosion as opposed to leaching. Thus, the estimated concentrations in soils immediately adjacent to pentachlorophenol-treated utility poles are based on the accumulation of wood particles which break away from the pole due to wood erosion. This creates additional uncertainty for the terrestrial risk assessment since soil ingestion by small mammals and birds may, or may not include ingestion of such wood particles. Further, these soil EECs were used to estimate the EECs in plant dietary matter. This creates more uncertainty in the assessment as well.

Considering the above, the Agency does not want to discount the highly toxic nature of 2, 3, 7, 8-TCDD, CDDs, or CDFs, which may be released from pentachlorophenol-treated utility poles into the environment. However, the Agency acknowledges the difficulties in estimating terrestrial wildlife exposures since there are no well-established environmental exposure models or methods for determining terrestrial wildlife exposures to 2, 3, 7, 8-TCDD, CDDs, or CDFs released from such utility poles into terrestrial environs. We recognize that the terrestrial risk assessment approach used is conservative and has a high degree of uncertainty. That being said,

we believe the weight of evidence indicates that the terrestrial risks for birds and mammals foraging near pentachlorophenol-treated utility poles is minimal.

Environmental RQs for terrestrial, aquatic, and plant species have been calculated using non-guideline studies for CDDs and CDFs resulting from all potential sources. Avian acute and chronic RQs (63 and 68 respectively), and mammal chronic RQs (4) are of concern. The Agency typically considers RQs above 0.5 data to be of concern. The RQs for aquatic organisms and plants (both terrestrial and aquatic) were calculated and are not of concern. For additional information, please see Chlorinated Dibenzo Dioxins (CDDs) and Chlorinated Dibenzo Furans (CDFs) as Contaminants of Pentachlorophenol Ecological Hazard and Risk Assessment for the Pentachlorophenol Reregistration Eligibility Decision (RED) Document, dated September 18, 2008. This document is located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

c. Hexachlorobenzene

Currently there are no FIFRA guideline studies for the micro-contaminant HCB, since it is not currently registered, and data on the ecological effects of HCB are relatively limited. Scientific literature indicates that HCB has a limited potential to adversely affect aquatic organisms in the short-term, primarily due to its very low solubility in surface water. Release of HCB from pentachlorophenol treated wood into terrestrial or aquatic environments at a concentration of 6 ug/L is not expected to result in adverse acute or chronic effects to non-target or listed species of birds, mammals or aquatic animals. However, reviewed literature indicates that HCB may have potential to adversely affect both aquatic and terrestrial organisms due to its persistence in the environment and its ability to readily accumulate in the aquatic and terrestrial food webs. No honey bee toxicity data are available for HCB.

HCB concentrations in the tissues of aquatic organisms equilibrate very slowly with concentrations in the water. As a result, the chronic toxicity tests for fish species (e.g., rainbow trout and fathead minnows) may not have been of sufficient duration to allow for the full equilibration of HCB in fish tissue with surface water concentrations. Also, due to the tendency of HCB to bioaccumulate in the aquatic food web, there is the potential for adverse effects to higher-trophic level organisms from exposure to HCB in their diet.

Once in birds, HCB is excreted into the eggs, which results in uptake by the embryos. HCB concentrations measured in the eggs of sea birds and raptors from a number of locations around the world approach those associated with reduced embryo weights in herring gulls (1.5 mg/kg), suggesting that HCB has the potential to harm embryos of avian species. For mammals, a sensitive endpoint for chronic HCB exposure is the reduction of birth weight and increased mortality in mink offspring exposed to 1 ppm HCB (0.16 mg/kg BW-day) for 47 weeks. This observation is ecologically significant because field studies have observed HCB concentrations in fish tissue at a number of sites worldwide that are within an order of magnitude of the dietary toxicity level of 1 ppm. This suggests that HCB has the potential to cause adverse effects in mink and perhaps other fish-eating mammals, especially given HCBs tendency to bioaccumulate. The contribution of HCB from pentachlorophenol uses vs. non-pesticidal sources in aquatic and terrestrial environments is a large uncertainty.

3. Risks to Listed Species

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 andronomus 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 CFR §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.

An environmental risk assessment to CDDs and CDFs to listed species has not been conducted at this time; however, there are potential acute and chronic risks to birds and chronic risks to mammals from CDDs and CDFs resulting from pentachlorophenol treated wood. The results of the environmental risk assessment indicate that threatened and endangered species would not be expected to be adversely affected directly by exposure to the micro-contaminant HCB present in pentachlorophenol. However, as discussed above, the strong tendency of CDDs, CDFs, and HCB to persist and bioaccumulate could lead to secondary adverse effects to higher trophic level organisms, or direct effects to organisms exposed to CDDs, CDFs, and HCB from pentachlorophenol use over longer periods of time. Sensitive animals, such as endangered and threatened species may also be at risk; however, it is important to note that pentachlorophenol is not the only source of HCB, CDDs and CDFs in the environment. They are one of many making it difficult to quantify the portion of the environmental risk from HCB, CDDs and CDFs that is attributable to pentachlorophenol wood treatment uses.

Based on the use patterns for pentachlorophenol, there is potential for pentachlorophenol wood treatment uses to overlap with listed species and a more refined assessment may be warranted. This assessment would include direct, indirect and habitat effects, and the refined assessment should involve clear delineation of the action area associated with pentachlorophenol wood treatment uses and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment. An endangered species effect determination will not be made at this time.

For detailed discussions of all aspects of the environmental risk assessment, see the *Ecological Hazard and Environmental Risk Assessment RED Chapter for Pentachlorophenol*, dated February 26, 2008; *Ecological Hazard and Environmental Risk Assessment RED Chapter for Chlorinated Dibenzo Dioxins and Chlorinated Dibenzo Furans (CDDs and CDFs) – Supplement to the Pentachlorophenol RED*, dated February 26, 2008; and, *Ecological Hazard and Environmental Risk Assessment RED Chapter for Hexachlorobenzene (HCB) – Supplement to the Pentachlorophenol RED*, dated February 26, 2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2004-0204).

IV. Reregistration Eligibility and Risk Management Decisions

A. Reregistration Eligibility Decision

Section 4(g)(2)(A) of FIFRA calls for EPA to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. EPA has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of wood preservative products containing pentachlorophenol as an active ingredient. The Agency has reviewed these generic data, and has determined that the data are sufficient to support a reregistration eligibility decision for the wood preservative uses of pentachlorophenol (see Appendix B).

EPA considered the available information and, after a thorough evaluation of the risks and benefits associated with each use, has determined that the wood preservative uses of pentachlorophenol presented in Appendix A will not pose unreasonable risks to humans or the environment provided that (1) all risk mitigation measures are implemented, (2) label amendments are made as described in Section V, and (3) confirmatory data requirements are satisfied. Accordingly, should a registrant fail to implement any of the conditions and requirements for reregistration identified in this document, the Agency may take regulatory action to address the potential risk concerns from the use of pentachlorophenol.

1. Regulatory Rationale

The Agency has determined that wood preservative uses of pentachlorophenol are eligible for reregistration provided that the registrants implement the conditions and requirements in this RED including amended labeling and submission of additional data. With amended labeling, EPA believes that the uses presented in Appendix A will not present risks inconsistent with FIFRA and that the benefits of pentachlorophenol to society outweigh the remaining risks. A summary of EPA's rationale for reregistering and managing risks associated with continued use is presented below.

a. Summary of Risks

As discussed in Section III of this document, EPA acknowledges the complexity and uncertainties associated with assessing potential risk from exposure to pentachlorophenol and its micro-contaminants, dioxin/furans and hexachlorobenzene. Therefore, the risks presented in this document may overestimate actual risk. Notwithstanding, EPA identified the following risk estimates of concern associated with the continued use of wood preservatives containing pentachlorophenol:

- Potential occupational cancer and non-cancer risk from dermal exposure to pentachlorophenol.

- Potential environmental risk from exposure to dioxin/furan resulting from pentachlorophenol use.

- Without the adoption of additional protective measures to reduce exposure to pentachlorophenol and its micro-contaminants continued use would not meet the "no unreasonable adverse effects" criteria of FIFRA.

b. Summary of Benefits and Alternatives

A detailed discussion of pentachlorophenol benefits and alternatives is presented in the document entitled, "A Qualitative Economic Impact Assessment of Alternatives to Pentachlorophenol as a Wood Preservative" dated April 14, 2008.

Chemical alternatives to pentachlorophenol wood preservatives include chromated arsenicals, creosote, copper and zinc naphthenates, ammoniacal/alkaline copper quaternary (ACQ), copper azole (CBA), sodium borates (SBX), and copper HDO (CX-A). Non-chemical alternatives include virgin vinyl, plastic wood composites, high density polyethylene, rubber lumber, concrete, fiberglass, steel, naturally resistant wood poles, and glass.

Although many chemical and non-chemical alternatives exist for wood treated with pentachlorophenol, many are not truly interchangeable due to safety, environmental, efficacy, and/or economic considerations. In the case of utility poles, for example, the material selected can affect the maintenance personnel's safety. Although steel utility poles may result in less human or environmental exposure to pentachlorophenol, they also increase the likelihood of electrocution for workers. For poles treated with chemical alternatives, certain alternatives make poles more slippery and therefore harder to climb which may also affect worker safety. Although the risk of electrocution and slippage cannot be compared quantitatively to potential environmental exposure, the Agency considers direct and indirect safety consequences as a result of its decisions.

Alternatives also vary in their potential effects on the environment. The potential short- and long-term environmental impacts of many chemical and non-chemical alternatives are unknown. Pentachlorophenol, on the other hand, has been the subject of numerous toxicity, exposure, environmental fate, and ecological effects studies. Because there are varying amounts of information on each alternative, it is difficult to quantitatively or qualitatively estimate the potential environmental impacts of alternatives; however, the potential environmental impacts of pentachlorophenol and its micro-contaminants are relatively well understood compared to certain chemical and non-chemical alternatives.

Chemical and non-chemical alternatives also vary in efficacy. In many cases, efficacy is the determining factor for selecting the preservative and/or material used. For example, pentachlorophenol treated crossarms are less likely to warp, crack, twist (causing stress on the wires), or drip then some of the alternatives. In addition, utility and other public works companies require products proven to be capable of withstanding extreme conditions for long periods of time. In the short-term, a product treated with an alternative preservative may offer comparable efficacy compared to a product treated with a pentachlorophenol; however, comparable efficacy may or may not be observed over the entire expected lifespan of the product (e.g., a utility pole may require replacement much sooner than if it had been treated with

pentachlorophenol). Because certain alternatives do not offer the same level of efficacy and because the end products themselves (e.g., utility poles) may not last as long as pentachlorophenol, they also cannot be considered as direct replacements.

Finally, economic considerations almost always impact decisions regarding project materials. Included in economic considerations are initial costs (e.g., cost of wood treatment), lifespan and maintenance costs of the product, and disposal costs. Although many exceptions exist, pentachlorophenol generally offer lower initial costs than many alternatives, offer documented and predictable lifespan, and in many cases can be disposed of in municipal landfills. Because certain alternatives, although lower in initial costs, do not offer the same resistance and/or do not last as long as pentachlorophenol treated products, they also cannot be considered as direct replacements. Economic considerations are particularly relevant to utility and other public works uses because increased costs are frequently passed on to the public.

c. Risk/Benefit Finding

In its risk assessments, EPA identified potential risks of concern for workers exposed to pentachlorophenol at wood treatment plants. Notwithstanding, eliminating these uses could result in reliance on products with greater safety risks, increased adverse effects on the environment, reduced effectiveness, and higher costs that could be passed on to the general public (e.g., public works entities). Therefore, after a thorough evaluation of the risk estimates and benefits, EPA has determined that certain uses of wood preservative uses of pentachlorophenol will not pose unreasonable risks to humans or the environment provided that (1) all risk mitigation measures are implemented, (2) label amendments are made as described in Section V, and (3) current data gaps and confirmatory data requirements are satisfied.

2. Endocrine Disruptor Effects

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 its authorities under FIFRA and/or the FFDCA to require any necessary data on endocrine-related effects. As the science develops and resources allow, screening for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

3. Cumulative Risks

Risks summarized in this document are those that result only from the use of pentachlorophenol. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information"

concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pentachlorophenol. EPA has not assumed that the pentachlorophenol share a common mechanism of toxicity with other compounds.

4. Public Comments and Response

Through EPA's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for pentachlorophenol. During the 60-day public comment period ending on June 16, 2008, the Agency received comments on the revised risk assessments from several respondents: Parents for a Safer Environment, California Regional Water Quality Control Board, Pentachlorophenol Task Force, Chlorine Chemistry Division of the American Chemistry Council, Beyond Pesticides et al., Utility Solid Waste Activities Group, as well as several concerned consumers. All comments and EPA's comment response documents are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2004-0402.

B. Risk Management Decision

The Agency has concluded that continued use of wood preservatives containing pentachlorophenol would not meet the "no unreasonable adverse effects" criteria of FIFRA unless the mitigation measures and associated label changes presented in Table 5 and Table 7, respectively, are implemented and confirmatory data are submitted. Information is not currently available to quantify the amount of risk reduction; however, implementing these risk reduction measures will reduce potential worker exposure as well as potential environmental exposure to pentachlorophenol and its micro-contaminants. Additional PPE and engineering controls are needed to help reduce potential exposure and risk to workers, and the addition of a final vacuum is needed to help reduce potential environmental exposure and risk. The Agency will require confirmatory monitoring data to ensure that the measures below are protective.

Although the measures below are required at this time, in the future, registrants may request that EPA remove or reduce certain restrictions or mitigation measures based upon submission of acceptable toxicity and exposure studies that demonstrate risk exposure to pentachlorophenol is below EPA's level of concern.

Table 5 discusses the risk mitigation measures for wood preservatives containing pentachlorophenol. Engineering controls are specific to thermal and/or ambient treatments of pentachlorophenol. Additional mitigation measures are being implemented for thermal pentachlorophenol due to the potential for increased inhalation exposure.

Table 5. Risk Mitigation Measures for Wood Preservatives Containing Pentachlorophenol

Risk Estimates of Concern	Mitigation Measure(s)	Required Label Language
Occupational cancer and non-cancer risk estimates from inhalation exposure to pentachlorophenol	After treatment, personnel must not be located within 15 feet of the cylinder opening until the cylinder is ventilated and the door is completely open	"At the conclusion of the treatment, the cylinder must be ventilated by purging the post-treatment cylinder through fresh air exchange. The ventilation process is considered complete after a minimum of 2 volume exchanges based on the empty treatment cylinder volume. The exhaust pipe of the vacuum system or any air moving device utilized in conducting the air purge must terminate into a containment vessel such as a treating solution work tank or water/effluent tank. The ventilation process may be accomplished by one of the following methods: 1) activating an air purge system that operates while the cylinder door remains closed; or 2) using a device to open and hold open the cylinder door (no more than 6 inches) to allow adequate ventilation and activating the vacuum pump. If the second method is utilized, at the conclusion of the treatment, no personnel may be located within 15 feet of the cylinder when open (cracked) until the cylinder has been ventilated. In the event of equipment malfunction, or to place the spacer to hold the door open during venting, only personnel wearing specified PPE are permitted within 15 feet of the cylinder opening prior to ventilation. After ventilation is complete, the cylinder door may be completely opened."
Occupational cancer and non-cancer risk estimates from dermal exposure to pentachlorophenol	The treatment process must include a final vacuum to remove excess preservative from the wood	"The treatment process must include a final vacuum to remove excess preservative from the wood. The final vacuum must attain a vacuum equal to or greater than the initial vacuum. This vacuum must be held for an appropriate time period based on wood species, retention levels, and commodity treated to remove excess preservative from the wood."
	Automatic opening, closing, and locking devices (Elevated Temperature	"As of December 31, 2013, for elevated temperature pressure treatment with pentachlorophenol, automatic, remotely operated devices must be used to open, close, lock, and unlock cylinder doors."

Risk Estimates of Concern	Mitigation Measure(s)	Required Label Language
	Pentachlorophenol)	
	Lock/unlock cylinder doors using automatic locking devices (Ambient Temperature Pentachlorophenol)	"As of December 31, 2013, for ambient temperature pressure treatment with pentachlorophenol, an automatic locking/unlocking device must be used to accomplish locking and unlocking of the cylinder door."
	Allow excess preservative to drain before removing charges from the treatment cylinder and prior to shipment	"After treatment, wood must be moved to a drip pad capable of recovering excess preservative until the wood is drip free."
Occupational cancer and non-cancer risk estimates from dermal exposure to pentachlorophenol	Personnel must wear personal protective equipment when handling treated wood/equipment, when cleaning the cylinder, and approaching cylinder prior to ventilation	"All personnel handling treated wood or handling treating equipment (including poles/hooks used to retrieve charge cables) that has come in contact with preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, and * socks plus industrial grade safety work boots with chemical resistant soles. All personnel cleaning or maintaining the treatment cylinder gasket/equipment or working with concentrate or wood treatment preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a full face shield. In the event of equipment malfunction, or for door spacer placement, all personnel located within 15 feet of the cylinder opening prior to cylinder ventilation must wear the following PPE: * washable or disposable coveralls over long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a properly fitting half mask elastomeric respirator with appropriate

Risk Estimates of Concern	Mitigation Measure(s)	Required Label Language
		cartridges and/or filters. Entry to confined spaces is regulated by Federal and/or State Occupational Safety and Health Programs. Compliance is mandated by law. Individuals who enter pressure treatment cylinders or other related equipment that is contaminated with the wood treatment preservative (e.g.,cylinders that are not free of the treatment preservative or preservative storage tanks) must wear protective clothing and/or equipment as required by Federal and/or State Occupational Safety and Health Compliance laws."
Occupational cancer and non-cancer risk estimates from dermal exposure to pentachlorophenol	Cylinder openings and door pits	"Cylinder openings and door pits must use grating and additional measures such as sumps, dams or other devices which prevent or remove spillage of the preservative."
	Personnel must not retrieve charge cables by hand	"Personnel must not directly handle the charge cables, poles or hooks used to retrieve charge cables, or other equipment that has contacted the preservative without wearing chemical resistant gloves."
	Personnel must not place or remove bridge rails by hand	"As of December 31, 2013, mechanical methods must be used to place/remove bridge rails."
	Personnel must not eat, drink, or smoke in work areas	"Eating, drinking, and smoking is prohibited in the treatment cylinder load-out area, drip pad area, and engineering control room of wood treatment facilities. EXCEPTION: Where treating operator control rooms are isolated from the treating cylinders, drip pad, and work tanks, eating, drinking, and smoking (depending on local restrictions) are permitted."
	Work clothing must be left at the treatment facility	"Personnel must leave aprons, protective coveralls, chemical resistant gloves, work footwear, and any other material contaminated with preservative at the treatment facility."
Aquatic organisms acute and chronic risk estimates from exposure to	Double vacuum for wood used in aquatic and other sensitive environments	"For treated wood that will be used in marine or other aquatic or sensitive environments, a double vacuum must be used. Following the pressure period and once the pentachlorophenol has been pumped back to the work tank, a vacuum shall be applied for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation) of vacuum to recover excess preservative. Then, depending on plant equipment: 1) vacuum for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation); or 2) steam material for one hour minimum and then pull not less than 22 inches of

Risk Estimates of Concern	Mitigation Measure(s)	Required Label Language
		Hg (560 KPa) (adjusted for elevation) vacuum for a minimum of one and a half hours. Maximum temperature during steaming shall not exceed 240 degrees F (115.5 degrees C), as specified in the Best Management Practices (Aug. 2006) issued by the Western Wood Preservers Association, Southern Pressure Treaters' Association, Timber Piling Council, and Wood Preservation Canada."

1. Dioxin/Furan Reduction

Label modifications stipulating use of a final vacuum for all pentachlorophenol treated wood and a double vacuum for wood used in aquatic and other sensitive environments will reduce the amount of pentachlorophenol, CDDs and CDFs on the surface of the treated wood, thus reducing the amount of chemical that can leach into the environment. In addition the Agency is requiring that a terrestrial field dissipation study be submitted to confirm the dioxin levels leaching to the soil, and plant and organisms around pentachlorophenol treated utility poles.

The Pentachlorophenol Task Force has submitted information outlining changes in pentachlorophenol manufacturing process. These changes have been made in an effort to lower the concentrations of CDDs, CDFs as contaminants in pentachlorophenol.

The Agency has conducted a preliminary review of these data and determined that there is potential for a reduction in the amount of CDDs and CDFs in the pentachlorophenol. However, the laboratory data analysis is incomplete, and the data submitted does not detail the methodology, including, the concentrations of each congener (C); fraction of each congener (R); and methods used to calculate TEQ.

Based on incomplete information concerning the manufacturing process, the Agency cannot quantify the reduction in the amount of CDDs and CDFs available for release from pentachlorophenol-treated wood. Therefore, the Agency is requiring additional data regarding the manufacturing process for pentachlorophenol. The data needs are identified in Section V of this document.

2. Management of Pentachlorophenol-treated Materials

The Agency is aware that materials such as utility poles or railroad ties may be sold for reuse after their original intended use has ended. The typical lifespan for a utility pole or railroad tie depends on climate, setting and other factors. These materials are often sold into a secondary market where they may be installed in residential settings for garden borders, etc. Because the lifespan of these treated materials is fairly long, the Agency believes that the pentachlorophenol leaching from the treated material is significantly less than when it was originally placed into service. The Agency has not conducted a risk assessment of these secondary uses of pentachlorophenol treated materials but has begun to evaluate these uses and has found that other options such as disposing of these materials in a landfill, or incinerating these materials for energy generation are also currently practiced. Further evaluation of the potential risks and benefits associated with these secondary uses of pentachlorophenol treated materials will be conducted during the Registration Review process for this active ingredient.

3. Registration Review of Pentachlorophenol

Through this reregistration action, the Agency is implementing mitigation measures discussed above to reduce exposure to workers in wood treatment facilities. In an effort to determine if these mitigation measures are effective in reducing exposure, the Agency is requiring that exposure monitoring studies be conducted at wood treatment facilities. In addition, the Agency may shorten the Registration Review cycle from the current 15 year time-frame. The Agency plans on conducting Registration Review for pentachlorophenol once the submission and review of new data is complete.

V. What Registrants Need to Do

The Agency has determined that wood preservative products containing pentachlorophenol are eligible for reregistration provided that the conditions and requirements for reregistration identified in this RED are implemented (see Section IV). The registrants will also need to amend product labeling for each product.

The database supporting the reregistration of pentachlorophenol wood preservatives has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, additional confirmatory data are required to support continued registration.

A. Manufacturing Use Products

1. Generic Data Requirements

The generic databases supporting the reregistration of pentachlorophenol for currently registered wood preservative uses has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, the confirmatory data presented in Table 9 are required. Generally, registrants will have 90 days from receipt of a generic data call-in (GDCI) to complete and submit response forms or request time extensions and/or waivers with a full written justification. Timeframes for submitting generic data will be presented in the GDCI.

Table 6. Generic Data Required to Support Pentachlorophenol Wood Preservative Registrations

EPA Guideline Number	Requirement Name
GLN 830.1550	Product Identity and Composition
GLN 830.1600	Description of Materials Used to Produce the Products
GLN 830.1620	Description of Production Process
GLN 830.1650	Description of Formulation Process
GLN 830.1670	Discussion of Formation of Impurities
GLN 835.6100	Terrestrial Field Dissipation (potential dioxin exposure in substrate and organism sampling around treated utility poles)
GLN 875.1100	Dermal Outdoor Exposure
GLN 875.1200	Dermal Indoor Exposure
GLN 875.1300	Inhalation Outdoor Exposure
GLN 875.1400	Inhalation Indoor Exposure
GLN 875.1600	Applicator Exposure Monitoring Data Reporting
GLN 875.1700	Product Use Information

For pentachlorophenol technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call-in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Diane Isbell at (703) 308-8154 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Diane Isbell
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
Diane Isbell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

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 regarding the 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. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

Generally, registrants will have 90 days from receipt of a PDCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. Registrants will have eight months to submit product-specific data.

For wood preservative end-use products containing the active ingredient pentachlorophenol, the registrants need to 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. Submit 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 10 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 Adam Heyward at (703) 308-6422 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk
Adam Heyward
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
Adam Heyward
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 10. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific 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.

Amended product labeling must be submitted no later than March 31, 2009. 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.

Table 7. Required Label Changes for Manufacturing and End-Use Wood Preservative Products Containing Pentachlorophenol

Description	Pentachlorophenol: Required Labeling Language	Placement on Label
	Manufacturing-Use Products	
For all Manufacturing Use Products	"Only for formulation as a preservative for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and PR Notice 93-10 and 95-1	"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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority have been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

Description	Pentachlorophenol: Required Labeling Language	Placement on Label
	End-Use Products	
PPE Requirements Established by the RED	"Personal Protective Equipment (PPE)" "All personnel handling treated wood or handling treating equipment (including poles/hooks used to retrieve charge cables) that has come in contact with preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, and * socks plus industrial grade safety work boots with chemical resistant soles. All personnel cleaning or maintaining the treatment cylinder gasket/equipment or working with concentrate or wood treatment preservative must wear the following PPE: * washable or disposable coveralls or long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a full face shield. In the event of equipment malfunction, or for door spacer placement, all personnel located within 15 feet of the cylinder opening prior to cylinder ventilation must wear the following PPE: * washable or disposable coveralls over long-sleeved shirt and long pants, * chemical resistant gloves, * socks plus industrial grade safety work boots with chemical resistant soles, and * a properly fitting half mask elastomeric respirator with appropriate cartridges and/or filters. Entry to confined spaces is regulated by Federal and/or State Occupational Safety and Health Programs. Compliance is mandated by law. Individuals who enter pressure treatment cylinders or other related equipment that is contaminated with the wood treatment preservative (e.g.,cylinders that are not free of the treatment preservative or preservative storage tanks) must wear protective clothing and/or equipment as required by Federal and/or State Occupational Safety and Health Compliance laws."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Pentachlorophenol: Required Labeling Language	Placement on Label
User Safety Requirement	"Personnel must leave aprons, protective coveralls, chemical resistant gloves, work footwear, and any other material contaminated with preservative at the treatment facility." "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them." "Eating, drinking, and smoking are prohibited in the treatment cylinder load-out area, drip pad area, and engineering control room of the wood treatment facilities." EXCEPTION: Where treating operator control rooms are isolated from the treating cylinders, drip pad, and work tanks, eating, drinking, and smoking (depending on local restrictions) are permitted."	Precautionary Statements: Hazards to Humans and Domestic Animals Immediately following the PPE requirements
User Safety Recommendations	"USER SAFETY RECOMMENDATIONS" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Description	Pentachlorophenol: Required Labeling Language	Placement on Label
Other Application Restrictions (Risk Mitigation)	"At the conclusion of the treatment, the cylinder must be ventilated by purging the post-treatment cylinder through fresh air exchange. The ventilation process is considered complete after a minimum of 2 volume exchanges based on the empty treatment cylinder volume. The exhaust pipe of the vacuum system or any air moving device utilized in conducting the air purge must terminate into a containment vessel such as a treating solution work tank or water/effluent tank. The ventilation process may be accomplished by one of the following methods: 1) activating an air purge system that operates while the cylinder door remains closed; or 2) using a device to open and hold open the cylinder door (no more than 6 inches) to allow adequate ventilation and activating the vacuum pump. If the second method is utilized, at the conclusion of the treatment, no personnel may be located within 15 feet of the cylinder when open (cracked) until the cylinder has been ventilated. In the event of equipment malfunction, or to place the spacer to hold the door open during venting, only personnel wearing specified PPE are permitted within 15 feet of the cylinder opening prior to ventilation. After ventilation is complete, the cylinder door may be completely opened."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"After treatment, wood must be moved to a drip pad capable of recovering excess preservative until the wood is drip free."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"The treatment process must include a final vacuum to remove excess preservative from the wood. The final vacuum must attain a vacuum equal to or greater than the initial vacuum. This vacuum must be held for an appropriate time period based on wood species, retention levels, and commodity treated to remove excess preservative from the wood."	Directions for Use

Description	Pentachlorophenol: Required Labeling Language	Placement on Label
Other Application Restrictions (Risk Mitigation)	"For treated wood that will be used in marine or other aquatic or sensitive environments, a double vacuum must be used. Following the pressure period and once the pentachlorophenol has been pumped back to the work tank, a vacuum shall be applied for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation) of vacuum to recover excess preservative. Then, depending on plant equipment: 1) vacuum for a minimum of one and a half hours at not less than 22 inches of Hg (560 KPa) (adjusted for elevation); or 2) steam material for one hour minimum and then pull not less than 22 inches of Hg (560 KPa) (adjusted for elevation) vacuum for a minimum of one and a half hours. Maximum temperature during steaming shall not exceed 240 degrees F (115.5 degrees C), as specified in the Best Management Practices (Aug. 2006) issued by the Western Wood Preservers Association, Southern Pressure Treaters' Association, Timber Piling Council, and Wood Preservation Canada."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, for elevated temperature pressure treatment with pentachlorophenol, automatic, remotely operated devices must be used to open, close, lock, and unlock cylinder doors."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, for ambient pentachlorophenol treatments, an automatic locking/unlocking device must be used to accomplish locking and unlocking of the cylinder door."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"Cylinder openings and door pits must use grating and additional measures such as sumps, dams or other devices which prevent or remove spillage of the preservative."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"Personnel must not directly handle the charge cables, poles or hooks used to retrieve charge cables, or other equipment that has contacted the preservative without wearing chemical resistant gloves."	Directions for Use
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, mechanical methods must be used to place/remove bridge rails."	Directions for Use

Appendix A: Use patterns Eligible for Reregistration
Pentachlorophenol

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(10) **Wood preservatives**				
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members	Ready to use Reg: 61483-1 Reg: 61483-58 Reg: 61483-59	Pressure treatment In a commercial vessel capable of physically impregnating the wood and providing adequate penetration and retention	If temperature or time is used as the treating parameter, treat for 12 to 48 hours or until effective penetration is achieved	**Restricted use pesticide** *Due to fetotoxicity and oncogenicity in laboratory animals* For retail sale and use only by certified applicators or by persons under their direct supervision and only for those uses covered by certified applicator's certification This product is intended for exterior use. Is not intended for home and farm use, must not be used for pressure or thermal treated logs used in the construction of log homes except laminated beams or building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied. Urethane,
(Exterior use only) Lumber, timber's, posts, poles, and other wooden members	Soluble Concentrate Reg: 61483-62 Reg: 61483-2 Reg: 61483-3	Pressure treatment In a commercial vessel capable of physically impregnating the wood and providing adequate penetration and retention	Add one part of product to nine parts of fuel oil, kerosene, or other hydrocarbon with the desired volatility, and mix well If temperature or time is used as the treating parameter, treat for 12 to 48 hours or until effective penetration is achieved	**Restricted use pesticide** *Due to fetotoxicity and oncogenicity in laboratory animals* For retail sale and use only by certified applicators or by persons under their direct supervision and only for those uses covered by certified applicator's certification This product is intended for exterior use. Is not intended for home and farm use, must not be used for pressure or thermal treated logs used in the construction of log homes except laminated beams or building components which are in ground contact andare subject to decay or insect infestation and where two coats of an appropriate sealer are applied. Urethane, shellac, latex, epoxy, enamel and varnish are acceptable sealers for pentachlorophenol treated wood

APPENDIX B: Pentachlorophenol Case (2505)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Pentachlorophenol. These requirements apply to Pentachlorophenol in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

   (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

3. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition		Open Literature
830.1600	61-2	Description of Beginning Materials and Manufacturing Process		41002701
830.1670	61-3	Discussion of Formation of Impurities		41002701
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		Open Literature
830.1670	61-2b	Formation of Impurities		Open Literature
830.1700	62-1	Preliminary Analysis		40999402, 41002702
830.1750	62-2	Certification of Limits		40999402, 41002702
830.1800	62-3	Analytical Method		41002702
830.6300	63-0	Reports of Multiple phys/chem Characteristics		40999403, 41002703
830.6302	63-2	Color		Open Literature
830.6303	63-3	Physical State		Open Literature
830.6304	63-4	Odor		Open Literature
830.7200	63-5	Melting Point		Open Literature
830.7220	63-6	Boiling Point		Open Literature
830.7300	63-7	Density		Open Literature
830.7840 830.7860	63-8	Solubility		Open Literature
830.7950	63-9	Vapor Pressure		Open Literature

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)		Open Literature
830.7000	63-12	pH		Open Literature
830.6313	63-13	Stability		Open Literature
830.6314	63-14	Oxidizing/Reducing Action		Open Literature
830.6315	63-15	Flammability		Open Literature
830.6316	63-16	Explodability		Open Literature
830.6317	63-17	Storage Stability		Open Literature
830.6319	63-19	Miscibility		Open Literature
ECOLOGICAL EFFECTS				
850.4400	122-2	Aquatic plant growth		42633704, 42633705, 42633706
850.4400	123-2	Aquatic vascular plant dose-response toxicity- *Lemna* sp.		42633704, 42633705, 42633706
850.220	71-2	Avian Dietary Toxicity		42633702
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat		00101715
870.1200	81-2	Acute Dermal - Rabbit		00101715
870.1300	81-3	Acute Inhalation - Rat		waiver
870.2400	81-4	Primary Eye Irritation - Rabbit		00101715
870.2500	81-5	Primary Dermal Irritation - Rabbit		00101715
870.2600	81-6	Dermal Sensitization		42594301
870.3250	82-3	Sub chronic Dermal Toxicity		43091702

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.4100	83-1 (a)	Chronic Toxicity		43982701
870.4200	83-2(a)	Carcinogenicity in Mice		NTP, 1989
870.4300		Combined Chronic Toxicity / Carcinogencity in Rats		NTP, 1999
870.3700	83-3	Developmental Toxicity in Rabbits		43091701, 43091702
870.3700	83-3	Developmental Toxicity -Rat		43091702
870.3800		2-Genaration Reproduction Toxicity in Rats		44464101
870.5265		Salmonella thyphimurium reverse mutation assay		NTP study
870.5395		Erythrocyte micronucleus assay		43911301
870.6200		Neurotoxicity screening battery		Open literature
870.8700		Immunotoxicity		Open literature

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the August 26, 2004 preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments 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 www.regulations.gov

These documents include:

- Pentachlorophneol Preliminary Risk Assessment; Notice of Availability, 11/30/2004

Preliminary Risk Assessment and Supporting Science Documents:

- Pentachlorophenol: Preliminary Risk Assessment for the Reregistration Eligibility Decision, PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004
- Product Chemistry Science Chapter on Pentachlorophenol PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004.
- Pentachlorophenol Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004, Timothy F. McMahon, Ph.D.
- Pentachlorophenol Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 063001, Case 2505, Antimicrobials Division 11/19/2004
- Pentachlorolphenol Occupational/Residential Exposure Assessment. PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004, Siroos Mostaghini, PhD. Senior Scientist
- Environmental Fate Assessment of Pentachlorlophenol for the Reregistration Eligibility Decision (RED). PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004
- Ecological Hazard and Environmental Risk Assessment:Pentachlorophenol PC Code 063001, Case2505, Antimicrobials Division, 11/19/2004, Richard C. Petrie Argonomist, Team Leader 3

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

- Pentachlorophenol: Revised Risk Assessment for the Reregistration Eligibility Decision, PC Code 063001, Case 2505, Antimicrobials Division 8/29/2008 Timothy F. McMahon, Ph.D. Senior Toxicologist/Risk Assessor
- Product Chemistry Science Chapter on Pentachlorophenol PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004.
- Pentachlorophenol Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 063001, Case 2505, Antimicrobials Division, 3/16/2008, Timothy F. McMahon, Ph.D.
- Pentachlorophenol Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 063001, Case 2505, Antimicrobials Division 11/19/2004
- Pentachlorolphenol Occupational/Residential Exposure Assessment. PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004, Siroos Mostaghini, PhD. Senior Scientist
- Environmental Fate Assessment of Pentachlorlophenol for the Reregistration Eligibility Decision (RED). PC Code 063001, Case 2505, Antimicrobials Division, 11/19/2004.
- Ecological Hazard and Environmental Risk Assessment:Pentachlorophenol PC Code 063001, Case2505, Antimicrobials Division, 11/19/2004, Richard C. Petrie Argonomist, Team Leader 3.

Appendix D. Citations Supporting the Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

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

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

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

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

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

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

1. MRID Studies

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3. Other Supporting Documents

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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 Pentachlorophenol 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 for:

Pentachlorophneol (Case 2505) PC Code: 063001

Appendix G. Batching of Pentachlorophenol Products for Meeting Acute Toxicity Data Requirements for Reregistration

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.