United States Environmental Protection Agency

Office of Prevention, Pesticides And Toxic Substances (7510P)

EPA 739-R-08-006
September 2008

Reregistration Eligibility Decision for Chromated Arsenicals

List A

Case No. 0132

Reregistration Eligibility Decision (RED) Document

for

Chromated Arsenicals

Approved by: ____________________
Frank Sanders
Director
Antimicrobials Division

Date: ____________

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Chromated Arsenicals Reregistration Team

Office of Pesticide Programs:

Benefits and Alternatives Analysis
Jonathan Becker
Steve Hopkins
Andrew Lee
Timothy Kiely
Skee Jones

Environmental Fate and Ecological Effects Risk Assessment
Rick Petrie
A. Najm Shamim
Siroos Mostaghimi

Health Effects Risk Assessment
Jonathan Chen
Doreen Aviado
Tim Dole
Tim McMahon
Timothy Leighton
Nader Elkassabany

Risk Management
Lance Wormell
Diane Isbell

Office of General Counsel:

Pesticides and Toxic Substances Law Office
Philip Ross

Office of Enforcement and Compliance Assistance:

David Stangel

Office of Solid Waste:

Ross Elliot

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
AWPA	American Wood-Preservers' Association
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EXAMS	Exposure Analysis Modeling System
EUP	End-Use Product
FCID	Food Commodity Intake Database
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter

mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for the wood preservatives containing arsenic and/or chromium ("chromated arsenicals") and is issuing its reregistration eligibility and risk management decisions. The risk assessments, which are summarized in this document, are based on review of registrant-submitted data supporting the use patterns of currently registered products, citations from the open literature, and additional information received through the public docket. The risk assessments have been revised, as needed, according to information received since they were last made available to the public in April through June 2008. After considering the risk assessments, available information about alternatives to chromated arsenicals for specific uses, public comments, and risk mitigation options, the Agency developed its reregistration eligibility and risk management decisions for wood preservative uses of chromated arsenicals. As a result of this review, EPA has determined that currently registered uses of chromated arsenicals are eligible for reregistration, provided that the prescribed risk mitigation measures are adopted and labels are amended accordingly, and required data are submitted. The reregistration eligibility decision and the associated risk mitigation measures are discussed fully in this document.

I. Introduction

This document is the Environmental Protection Agency's (EPA or "the Agency") reregistration eligibility determination (RED) for currently registered wood preservatives containing arsenic and/or chromium ("chromated arsenicals"). This document also summarizes the human health and environmental risks used to make the reregistration eligibility decision.

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 Food Quality Protection Act of 1996 (FQPA) and the Pesticide Registration Improvement Act of 2003 (PRIA) to set time frames for the issuance of Reregistration Eligibility Decisions. FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to 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 a 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.

The Agency made its reregistration eligibility determination for wood preservative uses of chromated arsenicals based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered wood preservative uses of chromated arsenicals are eligible for reregistration provided the requirements for reregistration identified in this reregistration eligibility decision (RED) are implemented.

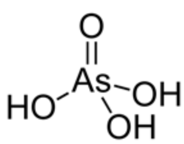
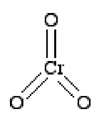
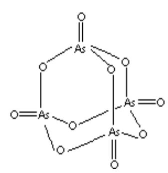
This document consists of six sections: Section I contains the regulatory framework for reregistration reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and ecological risk assessments; Section IV presents the Agency's reregistration eligibility and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents, and Data Call-In (DCI) information. The final risk assessment documents, related addenda, and public comments are not included in this document and are available in the Public Docket at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0250.

II. Chemical Overview

Case 0132, chromated arsenicals, includes heavy duty chemical wood preservatives containing copper and some combination of chromium and/or arsenic. These compounds are chromated copper arsenate (CCA), ammoniacal copper zinc arsenate (ACZA), ammoniacal copper arsenate (ACA), and acid copper chromate (ACC). According to the 2006 American

Wood-Preservers' Association (AWPA) Standards, ACA was "deleted in 2003, without prejudice, due to lack of use;" however, because one or more labels currently includes this use, ACA is included in this RED. Table 1 presents the registered active ingredients assessed in case 0132: arsenic acid, arsenic pentoxide, chromic acid, and sodium dichromate.

Table 1. Summary of Active Ingredients Assessed in Case 0132[1]

Parameter	Arsenic Acid	Chromium (VI) Oxide	Arsenic Pentoxide
PC Chemical Code	006801	021101	006802
CAS Number	7778-39-4	1333-82-0	1303-28-2
Molecular Formula	H_3AsO_4	CrO_3	As_2O_5
Chemical Name	Arsenic Acid	Chromium (VI) Oxide	Arsenic Oxide
Synonyms	Orthoarsenic acid	Chromic Acid	Arsenic acid anhydride
Structure	 commons.wikimedia.org	 www.meta-synthesis.com/.../matrix.php?id=1386	 www.answers.com/topic/arsenic-pentoxide

[1] One additional arsenic compound, arsenic trioxide (PC Code 007001), is currently registered as an insecticide for use in ant stake products. Because the potential exposure scenarios involve misuse of the product, significant human, environmental, or ecological exposure is not expected; therefore, quantitative risk assessments were not conducted.

Cupric oxide (PC Code 042401), the form of copper used in the treatment solutions for the wood preservatives containing arsenic and/or chromium, is outside the scope of this assessment. Non-antimicrobial uses of cupric oxide were addressed in a July 2006 RED (EPA 738-R-06-020); ecological effects of cupric oxide antimicrobial uses, including wood preservative uses of chromated arsenicals, will be addressed in a separate assessment at a future date. Similarly, zinc oxide (PC Code 088502), the form of zinc used as an active ingredient in the formulations of ACZA, is also outside the scope of this assessment because it has been addressed in the August 1992 RED for zinc salts (EPA-738-F-92-007).

Currently there are 11 end-use products (EUP) registered for pressure treatment of wood intended for above ground and ground contact, as well as in fresh water and marine environments, and 5 manufacturing use products (MUP) containing directions for further formulation into wood preservatives. Wood treated with these preservatives is specified for commercial, institutional, and limited residential/farm construction uses in indoor and outdoor sites. Chromated arsenical formulations intended for use as a wood treatment are Restricted Use Pesticides.

Table 2 presents a summary of the active Manufacturing Use Products (MUP) and End-Use Products (EUP) considered for reregistration.

Table 2. Active Registrations Considered in Case 0132[1]

EPA Reg. No.	Product Name	Product Type	Formulation
(935-83) 75449-2	Chromic Acid Flake	MUP (Formulator Use) TGAI (Technical Source) ***Product transfer 1/03 from Occidental Chemical Corp..***	99.85% Chromic Acid Flake (crystalline flakes)
3008-17	Osmose K-33-C (72%)	EUP	72% CCA-C: 24.5% Arsenic Pentoxide 13.3% Copper Oxide 34.2% Chromic Acid (liquid soluble concentrate)
3008-34	Osmose K-33 (60%)	EUP	60% CCA-C: 20.0% Arsenic Pentoxide 10.5% Copper Oxide 29.9% Chromic Acid (liquid soluble concentrate)
3008-60	Osmose ACC 50% Wood Preservative	EUP	50% ACC: 14.07% Copper Oxide 35.46% Chromic Acid (liquid soluble concentrate)
3008-66	Arsenic Acid 75%	MUP (Formulator Use)	75% Arsenic Acid (liquid)
3008-72	Osmose Arsenic Acid 75%	EUP	75% Arsenic Acid (liquid)
3008-78	Osmose Chromic Acid	MUP (Formulator Use)	99.9% Chromic Acid Flake (crystalline flakes)
(3098-16) 62190-27	Chemonite Part A	EUP (Component Product) ***Product transfer 3/08 from J.H.Baxter & Co.***	75% Arsenic Acid (liquid)
(10356-24) 10465-41	Chromic Acid	MUP (Formulator Use) ***Product transfer 1/99 within Chemical Specialties Inc. companies***	100% Chromic Acid (crystalline flakes)
10465-28	CCA Type-C Wood Preservative 60%	EUP	60% CCA-C: 20.10% Arsenic Pentoxide 11.4% Copper Oxide 28.5% Chromic Acid (liquid soluble concentrate)
10465-32	CSI Arsenic Acid	EUP	75% Arsenic Acid

EPA Reg. No.	Product Name	Product Type	Formulation
	75%		(liquid)
62190-7	(Koppers) Arsenic Acid 75%	EUP	75% Arsenic Acid (liquid)
62190-8	Wolman Concentrate 72%	EUP	72% CCA-C: 24.48% Arsenic Pentoxide 13.32% Copper Oxide 34.20% Chromic Acid (liquid soluble concentrate)
62190-14	Wolmanac Concentrate 60%	EUP	60% CCA-C: 20.40% Arsenic Pentoxide 11.10% Copper Oxide 28.5% Chromic Acid (liquid soluble concentrate)
62190-21	(Hickson) Arch Chromic Acid	MUP (Formulator Use) TGAI (Technical Source)	99.85% Chromic Acid Flake (crystalline flakes)
62190-23	Wolmanac ACC 50% Concentrate	EUP ***Registered 11/07***	50% ACC: 14.07% Copper Oxide 35.46% Chromic Acid (liquid soluble concentrate)
75832-1	FPRL ACC 50 Wood Preservative	EUP ***Registered 7/07***	50% ACC: 14.07% Copper Oxide 35.46% Chromic Acid (liquid soluble concentrate)
75832-3	Treaters Choice	EUP ***Registered 5/06***	50% ACC: 14.07% Copper Oxide 35.46% Chromic Acid (liquid soluble concentrate)
75832-4	Chromic Acid-A	MUP (Formulator Use) ***Registered 4/07***	99.7% Chromic Acid (Chromium Trioxide) (crystalline flakes)

[1] Two additional products containing arsenic trioxide (EPA Reg. No. 1663-15 and 1663-31) are included in Case 0132. As discussed above, because the potential exposure scenarios involve misuse of the product, quantitative risk assessments were not conducted.

No tolerance currently exists for the wood preservative uses of chomated arsenicals.

A. Chemical Information

Since the 1940s, wood has been pressure treated with chromated arsenicals in treatment cylinders, also called retorts, to protect wood from rotting due to insect and microbial agent attack and wood-boring marine invertebrates.

Type of Pesticide: Fungicide, Insecticide, Miticide and Molluscicide

Use Sites: Arsenic and chromium compounds used as wood preservatives are Restricted Use Pesticides specified for commercial pressure treatment applications only (i.e., impregnated into forest products using a vacuum pressure system). Treated products include terrestrial uses (e.g., utility poles, cross ties, timbers, posts, lumber, and groundline-contact building components) and aquatic uses (e.g., piles/posts/timbers). Detailed information on currently approved use sites is presented in Appendix B of the Occupational Exposure Chapter for Inorganic Arsenicals and Chromium-based Wood Preservatives in Support of the Reregistration Eligibility Decision (RED) Document for the Chromated Arsenicals dated September 18, 2008.

Target Pests: Invertebrates: (Insects, Miscellaneous Invertebrates, and Related Organisms.)

- Wood Boring Insects
- Termites
- Ants
- Marine Borers (Limnoria & Teredo)

Plant Pathogenic Organisms: (Bacteria, Fungi, and Other Fouling Organisms.)

- Ascomycetes
- Wood Rot/Decay
- Wood Rot/Decay Fungi
- Wood Rot/Decay Fungi (Spores)
- Dry Rot
- Brown Rot
- White Rot

Types of Treatment: Pressure Treatment.

Equipment: Pressure Treating Cylinder/Vessel/Retort. Compounds are applied to untreated wood in high pressure treatment cylinders or retorts. Operation of treatment cylinders requires multiple people to perform a variety of tasks including, but not limited to, operating the treatment door, loading/removing wood from the treatment cylinder, and operating the treatment cylinder (i.e., applying the chemical). Roles of individual workers at treatment facilities are discussed in more detail in the Occupational Exposure Chapter dated September 18, 2008.

Timing: Prior to end use of wood.

Use Rates: Detailed use rate information is presented in Appendix B of the Occupational Exposure Chapter for Inorganic Arsenicals and Chromium-based Wood Preservatives in Support of the Reregistration

Eligibility Decision (RED) Document for the Chromated Arsenicals dated September 18, 2008.

B. Estimated Usage of Pesticide

This section summarizes the best estimates available for the wood preservatives containing arsenic and/or chromium. These estimates are derived from a variety of published and proprietary sources available to the Agency.

Based on EPA proprietary data and public literature, the Agency estimates that approximately 110 million pounds of CCA were used in 2002, although this number is likely less today based on the voluntary use changes implemented in 2003. The majority of chromated arsenicals is used to treat lumber and timber. In 2004, approximately 99% of treated lumber and timber in the U.S. was treated with chromated arsenicals. Chromated arsenicals are believed to account for approximately 44% of the treated poles market (the remaining percentage being treated with pentachlorophenol or creosote). In addition to the poles, lumber and timber, and the pilings market, CCA is also an important wood preserver for the plywood market. In 2004, an estimated 413 million square feet of plywood (assuming 3/8" thickness) was treated with CCA, accounting for over 99% of all treated plywood in the United States.

According to registrant-submitted data, there are currently approximately 150 wood treatment plants in the U.S. that use CCA to treat approximately 100 million cubic feet annually.

C. Disposal Information

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

1. Treated Wood

Discarded chromated arsenical-treated lumber is usually land disposed in either construction and demolition landfills, municipal solid waste landfills, or industrial non-hazardous waste landfills. Under the existing federal hazardous waste regulations, wastes containing certain constituents, such as arsenic, are defined as hazardous waste if a representative sample of that waste leaches arsenic above a certain threshold concentration, using a specified testing procedure. While it has been shown that some chromated arsenical-treated wood meets this definition, discarded arsenical-treated wood is generally not subject to regulation as a hazardous waste. This is because of an existing exemption at 40 CFR 261.4(b)(9), originally promulgated in the November 25, 1980 *Federal Register* (45 FR 78530). In addition, some amount of discarded chromated arsenical-treated wood is also exempt from hazardous waste regulation when it is "household waste," and therefore can often be discarded along with household trash (40 CFR 261.4(b)(1)). Therefore, the disposal of discarded chromated arsenical-treated wood is generally under the jurisdiction of state and local solid waste management authorities.

Currently, many state and local governments have specific regulations, guidelines, or recommendations for the management and disposal of discarded chromated arsenical-treated wood, either explicitly, or sometimes under the larger category of "treated wood." In addition, some states have developed, or are developing, legislation and regulations to prohibit or restrict activities such as burning chromated arsenical-treated wood, producing wood mulch using chromated arsenical-treated wood, and disposing of chromated arsenical-treated wood in 'unlined' construction and demolition landfills. Therefore, EPA recommends that persons contact their state and local authorities regarding specific policies or regulations concerning the disposal of chromated arsenical-treated wood.

EPA estimates that there will remain a supply of CCA- and other chromated arsenical-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 chromated arsenical-treated wood. In the meantime, EPA has recommended that the land disposal of this material take place in a manner that minimizes any possibility of releases of hazardous constituents to groundwater resources. Specifically, in a memorandum dated April 12, 2004[1], EPA recommended that if discarded chromated arsenical-treated wood is to be disposed in a landfill, the landfill should be designed to satisfy the standards for protecting groundwater in 40 CFR 258.40, which contain design and performance criteria applicable to municipal solid waste landfills. EPA's goal is to promote the sensible management of this material, by encouraging the use of landfills that meet these standards (whether through specific design criteria or through demonstrating compliance with performance standards) to ensure the utility of groundwater resources.

In addition, in a memorandum dated January 6, 2004 (http://www.epa.gov/oppad001/reregistration/cca/mulch.pdf), EPA clarified that chromated arsenical-treated wood used to produce wood mulch products (such as landscaping mulch) is not exempt from regulation as hazardous waste under 40 CFR 261.4(b)(9). This is because the intended end uses of the chromated arsenical-treated wood products are as building materials, not as mulch. For example, chromated arsenical-treated wood waste generated during construction using chromated arsenical-treated wood, is generated by persons using the wood for its intended end use, and therefore would not be regulated as hazardous waste under this exemption (unless of course this wood waste is then used to produce mulch). In contrast, persons who shred or chip waste chromated arsenical-treated lumber into wood mulch for uses such as in landscaping applications, are not using the treated wood for its intended end use. Therefore, the exemption at 261.4(b)(9) does not exempt wood mulch produced from discarded chromated arsenical-treated wood. This clarification is consistent with the Consumer Awareness Program (CAP) for consumers and users of chromated arsenical-treated lumber, which instructs consumers that they "...should never burn chromated arsenical-treated wood or use it as compost or mulch."

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[1] Springer, R., "Recommendation on the Disposal of Waste Lumber Preserved with Chromated Copper Arsenate (CCA)," EPA Memorandum, Office of Solid Waste, Washington, D.C., April 12, 2004.

The Agency is also aware that materials such as utility poles are sometimes sold for reuse after their original intended use has ended. The typical lifespan for a utility pole is many years, depending 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 arsenic and chromium 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 chromated arsenical-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 chromated arsenical-treated materials will be conducted during the Registration Review process for this case.

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 F035) can be found in the hazardous waste regulations at 40 CFR 261.31, and reads as follows:

> F035 - Wastewaters (except those that have not come in contact with process contaminants), process residuals, preservative drippage, and spent formulations from wood preserving processes generated at plants that use inorganic preservatives containing arsenic or chromium. This listing does not include K001 bottom sediment sludge from the treatment of wastewater from wood preserving plants that use creosote and/or pentachlorophenol.

Because chromated arsenical preservative is an "inorganic preservative containing arsenic or chromium," wastes generated from its use fall within the scope of this hazardous waste listing. Thus, wood treaters using chromated arsenical 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.

D. Regulatory History

Formulated wood preservative products containing arsenic and/or chromium compounds have been registered since the 1940's when pesticides were under the regulatory purview of the United States Department of Agriculture (USDA) and subsequently have been regulated by EPA under FIFRA since the 1970s. The wood preservative pesticides containing arsenic and/or chromium compounds are registered as technical source/manufacturing-use products or formulated industrial end-use product concentrates or mixtures intended for aqueous dilution to form CCA, ACZA, ACA and ACC treatment solutions.

Case 0132 was previously identified as "Chromated Arsenicals" in OPP's Spring 1998 "Status of Pesticides in Registration, Reregistration, and Special Review (Rainbow Report)" and included five additional active ingredients for which all products have since been cancelled and therefore are not eligible for reregistration and are not further addressed in this document: sodium arsenate (PC Code 013505) cancelled 2004, potassium dichromate (PC Code 068302) cancelled 2000, sodium pyroarsenate (PC Code 013401), cancelled 1991, sodium chromate (PC Code 068303) cancelled 1987, and ammonium arsenate (PC Code 013601) cancelled 1987.

The Agency required registrants to submit studies in response to Registration Standards issued in 1986 and 1988 (PB87-114088, and PB89-102842) for chromated arsenical compounds. Data from submitted studies along with more recent industry-sponsored studies were used to characterize the risks associated with the uses described in this document. Additional data required to be eligible for reregistration, including any previously required and unfulfilled data, are presented in this document.

In 2002, the U.S. registrants of CCA wood preservatives voluntarily proposed the withdrawal of certain uses, including virtually all residential uses, for their products. The Agency approved these changes effective December 31, 2003 and effectively restricted the use of CCA to the treatment of wood used primarily in industrial and agricultural applications. In addition, effective May 28, 2003, all non-pressure treatments for arsenical products (e.g., brush, dips) were also voluntarily withdrawn by registrants.

III. Summary of Risk Assessments

The purpose of this section is to summarize EPA's human health and ecological risk conclusions for wood preservative uses of chromated arsenicals to help the reader better understand EPA's risk management decisions. The final human health and ecological risk assessment dated September 18, 2008, risk assessment support documents, and other supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for chromated arsenicals. The full risk assessments and related supporting documents are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0250.

EPA developed this RED for the wood preservative uses of chromated arsenicals through a 6–Phase public participation process. The Agency uses public participation processes to involve the public in developing pesticide reregistration decisions. EPA released its preliminary and revised risk assessments for 60-day public comment in March 2004 and April 2008, respectively. Substantive comments – including requests to characterize uncertainties associated with metals risk assessment and incorporate results from available biomonitoring data – were incorporated into the final risk assessments which were used to make this reregistration eligibility decision.

A. Background on Wood Preservative and Metals Risk Assessment

1. Heavy Duty Wood Preservative Risk Assessment

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.

Thus, pesticides applied using treatment cylinders present challenges for risk assessment because limited data are available to estimate worker exposure. The Agency acknowledges these challenges and considered these and other factors when making its reregistration and risk management decisions.

2. Metals Risk Assessment

In addition to the challenges associated with assessing risk from heavy duty wood preservatives, EPA recognizes that metals in and of themselves present unique risk assessment issues.

In March 2007, EPA's Office of the Science Advisor issued a guidance document entitled, "Framework for Metals Risk Assessment" (EPA 120/R-07/001). The document, which acknowledges these issues, is not a prescriptive guide on how any particular type of assessment should be conducted within an EPA program office; rather, it is intended to outline key metal principles and how they should be considered in existing human health and ecological risk assessment practices to foster consistency across EPA programs and regions. One principle is to assess risk from metals, where possible, based on the toxicity of and exposure to the metallic compounds rather than the individual metals. As applied to the chromated arsenicals, this would mean assessing risk from the individual preservatives in the wood (i.e., CCA, ACZA, ACA, ACC) rather than the metals used to treat the wood (i.e., arsenic and chromium).

Throughout the public participation process for the chromated arsenicals, both prior to and after the release of the Framework for Metals Risk Assessment document, EPA openly communicated its intention to evaluate toxicity and exposure for Case 0132 based on the individual metals (i.e., arsenic and chromium). Accordingly, EPA completed its preliminary and revised risk assessments using this approach. In response to EPA's revised risk assessments, EPA received requests from stakeholders to follow Agency guidance set forth in the Framework for Metals Risk Assessment document. Accordingly, EPA's reregistration eligibility decision team for the chromated arsenicals revisited this issue in June 2008.

These discussions revealed that very little information is currently available regarding the toxicity, exposure, environmental fate, and ecological effects of the individual chromated arsenical wood preservative compounds. Arsenic and chromium, on the other hand, have been the subject of numerous toxicity, exposure, environmental fate, and ecological effects studies as well as independent scientific panel reviews including the FIFRA Scientific Advisory Panel and EPA Scientific Advisory Board. As a result, the Agency refers to the following section excerpted from the March 2007 Metals Risk Assessment document:

> EPA may conduct metals risk assessments using approaches that differ from those described in the Framework for many reasons… Specific approaches [outlined in the document] may become outdated or may otherwise require modification to reflect the best available science and others may be addressed only qualitatively until additional information becomes available. Application of this Framework in future metals risk assessments will be based on EPA decisions that its approaches are suitable and appropriate.

Because a relatively small body of research is available on the individual chromated arsenical wood preservative compounds compared to that available for arsenic and chromium, and because the Framework for Metals Risk Assessment document allows for metals risk assessment using approaches that differ from those described in the document, the risk assessments were finalized using the approach in the preliminary and revised risk assessments (i.e., assessing chromated arsenical wood preservatives uses based on the toxicity and exposure of arsenic and chromium). EPA considers this approach to be suitable, appropriate, and based on the best available science. In the future, upon submission of additional data for each chromated arsenical compound, EPA may modify this approach.

B. Human Health Risk Assessment

EPA has conducted a human health risk assessment for wood preservative uses of chromated arsenicals to support the reregistration eligibility decision. EPA evaluated the submitted toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision. However, confirmatory data are needed (see Section V). A summary of the human health findings and conclusions is presented below; the full risk assessments are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0250.

The Agency's use of human studies in the chromated arsenicals risk assessments 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.

1. Toxicity Profile

The toxicological databases for chromium and arsenic are adequate to support a reregistration eligibility decision for the wood preservative uses of chromated arsenicals; copper is beyond the scope of this document and will be addressed in a separate RED. Arsenic and chromium are considered toxicologically unique and were evaluated separately.

The Agency notes that treatment solutions contain different chemical forms of arsenic and chromium. The chemical forms of greatest toxicological concern to the Agency are pentavalent arsenic (As^{+5}) and hexavalent chromium (Cr^{+6}). Because these forms of arsenic and chromium are many times more toxic than other forms in the treatment solutions, the Agency only estimated risks from exposure to pentavalent arsenic and hexavalent chromium. Because estimated risks for chromated arsenical wood preservatives assume that 100% of the exposure will be to the most toxic forms of arsenic and chromium, these estimates are considered conservative and are considered to represent any additional risks posed by other chemical forms of arsenic and chromium in the treatment solutions.

a. Acute Toxicity Profile

i. Arsenic Acute Toxicity Profile

Inorganic arsenic has high acute toxicity via the oral, dermal, and inhalation routes (Category I and II). It is an eye irritant (Category I), a dermal irritant (Category III), and not a skin sensitizer. Table 3 presents the acute toxicity profile for inorganic arsenic (arsenic acid 7.5%).

Table 3. Acute Toxicity Profile for Inorganic Arsenic

Guideline Reference No.	Study Type	MRID/ Data Accession No.	Results	Toxicity Category
870.1100	Acute Oral	404090-01	Mouse LD_{50} = 141 mg/kg = 160 mg/kg M+F = 150 mg/kg	II

		26356	Rat LD_{50} = 76 mg/kg = 37 mg/kg M+F = 52 mg/kg	I
870.1200	Acute Dermal	26356	Rabbit LD_{50} = 1750 mg/kg = 2300 mg/kg	II
870.1300	Acute Inhalation	404639-02	Mouse LC_{50} = 1.153 mg/L = 0.79 mg/L M+F = 1.040 mg/L	II
870.2400	Primary Eye Irritation	26356	Rabbit 3/6 animals died by day 7. The 3 surviving animals were sacrificed on day 9 because of severe ocular irritation and corrosion.	I
870.2500	Primary Skin Irritation	26356	Rabbit At 30 minutes, all animals showed moderate to severe erythema and slight to severe edema. All animals died prior to the 24 hour observation.	I
870.2600	Dermal Sensitization	406462-01	Guinea Pig Not a Sensitizer	

ii. Chromium Acute Toxicity Profile

Chromium VI has high acute toxicity via the oral, dermal, and inhalation routes (Category I). It is an eye irritant (Category I), a dermal irritant (Category I), and a strong skin sensitizer. Table 4 presents the acute toxicity profile for chromium VI (chromic acid).

Table 4. Acute Toxicity Profile for Chromium VI

Guideline	Study Type [Substance]	MRID/Literature	Results	Toxicity Category
81-1 (OPPTS 870.1100)	Acute Oral/Rat [Chromic Acid, 100% a.i.]	434294-01	LD_{50} = 56 mg/kg = 48 mg/kg M+F = 52 mg/kg	I
81-2 (OPPTS 870.1200)	Acute Dermal/Rabbit [Chromic Acid,	434294-02	LD_{50} = >48 mg/kg = 48 mg/kg M+F = 57 mg/kg	I

	100% a.i.]			
81-3 (OPPTS 870.1300)	Acute Inhalation/Rat [Chromic Acid, 100% a.i.]	434294-03	LC_{50} = 0.263 mg/L = 0.167 mg/L M+F = 0.217 mg/L	I
81-4 (OPPTS 870.2400)	Primary Eye Irritation [Various Cr(VI) compounds]	Literature	Waiver Corrosive	I
81-5 (OPPTS 870.2500)	Primary Dermal Irritation [Various Cr(VI) compounds]	Literature	Waiver Corrosive	I
81-6 (OPPTS 870.2600)	Dermal Sensitization /Guinea Pig [Various Cr(VI) compounds]	Literature	Strong sensitizer	

b. Toxic Effects and Carcinogenicity

i. Arsenic Toxic Effects and Carcinogenicity

Inorganic arsenic is acutely toxic, and ingestion of large doses leads to gastrointestinal symptoms, disturbances of cardiovascular and nervous system functions, and eventually death. The effects seen after short-term arsenic exposure (appearance of edema, gastrointestinal or upper respiratory symptoms) differ from those after longer exposure (symptoms of skin and neuropathy).

Inorganic arsenic is known to be carcinogenic in humans by the oral and inhalation routes of exposure. An oral cancer slope factor of 3.67 $(mg/kg/day)^{-1}$ was used to estimate risks from oral and dermal exposures and a cancer slope factor of 5.0 $(mg/kg/day)^{-1}$ was used to estimate risks from inhalation exposures. The oral cancer slope value was reviewed by the FIFRA Science Advisory Board (SAB) in 2005 and supported in its 2007 final report. This value is consistent with the slope factor used by EPA's Office of Water for the arsenic maximum contaminant level (MCL).

ii. Chromium Toxic Effects and Carcinogenicity

In acute toxicity animal studies, administration of chromium VI (as chromic acid) by the oral, dermal, and inhalation routes resulted in significant acute toxicity including lethality. Human reports of death after ingestion of chromium show lethality at similar exposure levels. Chromium VI is a significant eye and skin irritant, and severe allergic reactions consisting of redness and swelling of the skin have also been noted in exposed animals and humans. Studies in experimental animals have demonstrated blood and liver effects from repeated oral exposure to chromium VI.

Chromium VI is known to be carcinogenic to humans by the inhalation route of exposure and is considered likely to be carcinogenic to humans by the oral route of exposure. An oral cancer slope factor of 0.79 (mg/kg/day)$^{-1}$ was used to estimate risk. Although exposure to children is not expected based on the current use patterns, because limited data suggest that older children may have increased sensitivity to chromium VI, the Agency applied Age Dependent Adjustment Factors (ADAF) to the potency factor.

c. Toxicological Endpoints

i. Inorganic Arsenic Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for inorganic arsenic are presented in Table 5.

Table 5. Summary of Inorganic Arsenic Toxicological Endpoints

Exposure Scenario	LOAEL/NOAEL, MOE, CSF	Endpoint	Reference
Acute Dietary	This risk assessment is not required.		
Chronic Dietary	This risk assessment is not required.		
Incidental Short- and Intermediate- Term Oral	LOAEL= 0.05 mg/kg/day MOE = 30	Based on edema of the face, gastrointestinal, upper respiratory, skin, peripheral and neuropathy symptoms	Franzblau et al.(1989) and Mizuta et al. (1956)
Dermal Short- and Intermediate-Term [a] [b]	LOAEL= 0.05 mg/kg/day MOE = 30	Based on edema of the face, gastrointestinal, upper respiratory, skin, peripheral and neuropathy symptoms	Franzblau et al.(1989) and Mizuta et al. (1956)
Dermal Long-Term [a] [b]	NOAEL= 0.0008 mg/kg/day MOE = 3	Based on hyperpigmentation, keratosis and possible vascular complications.	Tseng et al. (1968) and Tseng (1977)
Inhalation Short- and Intermediate-Term[c]	LOAEL= 0.05 mg/kg/day MOE = 30	Based on edema of the face, gastrointestinal, upper respiratory, skin, peripheral and neuropathy symptoms	Franzblau et al.(1989) and Mizuta et al. (1956)
Inhalation, Long-Term	NOAEL= 0.0008 mg/kg/day MOE = 3	Based on hyperpigmentation, keratosis and possible vascular complications.	Tseng et al. (1968) and Tseng (1977)
Carcinogenicity - Inhalation (Inhalation Risk)	CSF = 15.1 [d] (mg/kg/day)$^{-1}$ for general population	Lung cancer	Chronic epidemiological inhalation study on humans
	CSF = 5.0 [e] (mg/kg/day)$^{-1}$ for 8 hour working day		
Carcinogenicity - Oral Ingestion	CSF= 3.67 [f] (mg/kg/day)$^{-1}$	Internal organ cancer (liver, kidney, lung and bladder) and skin	Chronic epidemiological oral study on humans

(Oral and Dermal Risks)		cancer	

(a). MOE = Margin of Exposure; NOAEL = No observed adverse effect level; LOAEL = Lowest observed adverse effect level; CSF=Cancer slope factor

(b). The dermal absorption factor = 6.4%. (Note: The FIFRA Scientific Advisory Panel recommended use of a lower value of 2-3%. The occupational assessment in the risk assessment uses 6.4 percent dermal absorption because the handlers and workers are exposed to the arsenic residue from the aqueous solution during mixing, loading, and handling or are exposed to newly treated or "wet" wood which has arsenic residues on the surface of the wood).

(c). For inhalation exposure, a default absorption factor of 100% is used. Route-to-route extrapolation is used to estimate the exposed dose.

(d). Inhalation unit risk (IUR) is derived from a 24 hour exposure inhalation unit risk with a value of 4.3 x 10^{-3} ($\mu g/m^3)^{-1}$. To convert the IUR to a cancer slope factor in units of $(mg/kg/day)^{-1}$ for the general population = IUR ($\mu g/m^3)^{-1}$ x 1/70 kg x 20 m^3/day x 1 mg/1,000 µg (EPA, 1989).

(e). For workers working 8 hour per day, the inhalation cancer slope factor (CSF) derived from the 24 hour IUR for general population, is adjusted for an 8 hour work day. CSF for 8-hr work day = general population CSF of 15.1 $(mg/kg/day)^{-1}$ x (8hrs/24 hrs) = 5.0 $(mg/kg/day)^{-1}$.

ii. Hexavalent Chromium Toxicological Endpoints

The toxicological endpoints used in the human health risk assessment for hexavalent chromium are presented in Table 6.

Table 6. Summary of Hexavalent Chromium Toxicological Endpoints

Exposure Scenario	LOAEL/NOAEL, MOE, CSF	Endpoint	Reference
Acute Dietary	This risk assessment is not required.		
Chronic Dietary	This risk assessment is not required.		
Incidental Short- and Intermediate- Term Oral	NOAEL[a] = 0.5 mg/kg/day of chromic acid [0.12 mg/kg/day of Cr(VI)] MOE = 100	based on the increased incidence of maternal mortality and decreased body weight gain at LOAEL of 2.0 [0.48 mg/kg/day of Cr (VI)]	Developmental/Rabbit Tyl, 1991
Dermal Exposure[b] Systemic Effects (All Durations)	Because dermal irritation and dermal sensitization are the primary concern through the dermal exposure route, no toxicological end-point is selected for use in assessing dermal exposure risks to chromium.		
Dermal Exposure Dermal Effects (All Durations)	CCDS[a] = 92 ng Cr(VI)/cm^2 MOE = 1	Based on the MET_{10} (10% response level) which was determined by the FIFRA SAP to be adequate and sufficiently conservative.	Proctor, D.; Gujral, S.; Fowler, J. 2006
Inhalation Exposure (All Durations)	LOAEL[a] = 0.002 mg/m^3; (or 2.3 x 10^{-4} mg/kg/day) MOE = 30	based on nose and throat symptoms observed at the 0.002 mg/m^3 level	Linberg and Hedenstierna, 1983.

Carcinogenicity - Inhalation (Inhalation Risk)	CSF = 40.6 [c](mg/kg/day)$^{-1}$ (For general Population) CSF = 13.5 [d](mg/kg/day)$^{-1}$ (For 8 hour working day)	Lung tumors	IRIS
Carcinogenicity - Oral Ingestion (Oral and Dermal Risks)	CSF = 0.79 [e] (mg/kg/day)$^{-1}$ with age dependent adjustments factors (ADAFs) applied.	Female Mice - Small Intestine (Duodenum, Jejunum or Ileum) adenomas and/or carcinomas combined	NTP (2007a),

(a). MOE = Margin of Exposure; NOAEL = No observed adverse effect level; and LOAEL = Lowest observed adverse effect level. CCDS = Concentration of Concern for Dermal Sensitization.

(b). The dermal absorption factor for Cr(VI) = 1.3% for handler dermal contact with chromated arsenical pesticides.

(c) The 24 hours inhalation unit risk is 1.16 x 10^{-2} (μg/m^3)$^{-1}$ which can also be expressed as 0.0116 m^3/μg. To convert the air concentration to a dose to yield units of kg-day/mg or (mg/kg/day)$^{-1}$ the unit risk is expressed mathematically as 0.0116 m^3/μg x day/20 m^3 x 1000 μg/mg x 70 kg = 40.6 (mg/kg/day)$^{-1}$ (EPA, 1989).

(d) For workers working 8 hour per day, the inhalation cancer slope factor (CSF) derived from the 24 hour CSF for the general population, is adjusted for an 8 hour work day . CSF for 8-hr work day = general population CSF of 40.6 (mg/kg/day)$^{-1}$ x (8hrs/24 hrs) = 13.5 (mg/kg/day)$^{-1}$.

(e) CARC (2008) classified hexavalent chromium, Cr(VI), as "Likely to be Carcinogenic to Humans" based on the presence of oral and tongue tumors and/or carcinomas for rats in both sexes, and the presences of adenoma and carcinoma in both sexes of mice at doses that were adequate but not excessive to assess the carcinogenicity. There are clear evidence that Cr(VI) is mutagenic. The decision is also qualitatively supported by the human epidemiological study. The Committee recommended using a linear low-dose extrapolation approach (Q1*) for estimating the human cancer risk based on the most potent tumor type (Kidwell, 2008).

2. Dietary Exposure and Risk from Food and Drinking Water

Based on the current use patterns, dietary exposure is not expected from the wood preservative uses of chromated arsenicals; therefore, a dietary risk assessment was not performed.

Using current treatment practices, under certain environmental conditions small amounts of arsenic and/or chromium may leach from treated wood into surrounding water bodies. This is not expected to result in food exposure (e.g., fish grown for food) because aquatic organisms tend to eliminate arsenic and chromium with little bioaccumulation. Arsenic and chromium leaching from wood is not expected to result in drinking water exposure because metals released from the chromated arsenical-treated wood tend to migrate to sediment – typically within 10 meters of the treated wood – as opposed to dissolving or suspending in water where it would be available for consumption.

In addition, while minimal leaching is expected, this potential will be further minimized through implementation of EPA's risk mitigation strategy (see Section IV of this document). Primarily developed to address potential human health risk estimates of concern, certain measures such as pulling a final vacuum will ensure that the potential for dietary exposure is virtually eliminated.

3. Residential Exposure and Risk

As restricted use pesticides that all also require highly specialized application equipment, chromated arsenicals are neither permitted to be purchased nor expected to be applied by potential residential users. The few remaining treated commodities that may be found in residential settings (e.g., shakes/shingles, permanent wood foundations) are not expected to result in any measurable residential exposure. Therefore, residential exposure is not expected from the wood preservative uses of chromated arsenicals and a residential risk assessment was not performed.

One end-use product containing arsenic trioxide in granular form is currently registered with EPA for potential use in residential settings. This product is a ready-to-use plastic ant stake. Because the potential exposure scenarios involve misuse of the product, significant human, environmental, or ecological exposure is not expected; therefore, quantitative risk assessments were not conducted. However, ant stakes containing arsenic trioxide for use in residential settings have characteristics that, based upon human toxicological data (see Table 5), could result in accidental injury or illness which child-resistant packaging could reduce. Therefore, the Agency is requiring the registrant to supply a certification that the product as packaged meets the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995), and that the product as packaged will continue to meet the effectiveness, compatibility, and durability standards of 40 CFR 157.32.

For additional information on potential residential exposure from existing structures treated with CCA, refer to "A Probabilistic Risk Assessment for Children Who Contact CCA-Treated Playsets and Decks" (US EPA, April 16, 2008), available at http://www.regulations.gov in public docket EPA-HQ-OPP-2003-0250.

4. Aggregate Exposure and Risk

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.

Based on the current use patterns, no dietary, residential, or other non-occupational exposure is expected from the wood preservative uses of chromated arsenicals; therefore, an aggregate risk assessment was not performed.

5. Occupational Exposure and Risk

Because chromated arsenicals are currently registered for use in occupational settings, occupational handlers have the potential to be exposed to arsenic and/or chromium through mixing, loading, or applying the pesticide, or through handling or fabricating the treated wood. These exposures could result in potential cancer and non-cancer risks. Therefore, EPA estimated cancer and non-cancer risks to occupational handlers as a result of inhalation and dermal exposure to arsenic and chromium from products containing chromated arsenicals. EPA performed these assessments for individuals working at treatment facilities and, where appropriate, for individuals working at wood fabrication facilities.

This document presents information summarized from the document entitled, "Occupational Exposure Chapter for Inorganic Arsenicals and Chromium-based Wood Preservatives in Support of the Reregistration Eligibility Decision (RED) Document for the Chromated Arsenicals" dated August 28, 2008. The risk estimates of concern presented below are not inclusive of all potential risks for CCA, ACZA, ACA, and ACC. Rather, the summary information presented in this document is provided to demonstrate that estimated risks for chromated arsenicals in general exceed EPA's levels of concern and, consequently, must be managed through mitigation and associated label changes (see Section IV of this document). Therefore, detailed risks for each compound are not presented in this document.

To estimate potential risks, the Agency developed dermal and inhalation exposure scenarios. For cancer risks, these include only lifetime exposure duration (working for 35 years). For non-cancer risks, these include short-term (1 day to 1 month), intermediate-term (1 to 6 months), and long-term (> 6 months) exposure durations. Table 7 presents the representative occupational uses assessed for wood preservative uses of chromated arsenicals.

Table 7. Representative Chromated Arsenicals Occupational Exposure Scenarios

Exposure Scenario	**Risks Assessed**			
	Dermal		Inhalation	
	Arsenic	Chromium[1]	Arsenic	Chromium
Applying chromated arsenicals at a pressure treatment plant using a treatment cylinder	✓	NA	✓	✓
Performing post-treatment tasks at a pressure treatment plant (e.g., handling treated wood)	✓	NA	✓	✓
Performing construction fabrication using treated wood (i.e., inhalation of sawdust)	NA[2]		✓	✓

NA = Not Assessed.

[1] A dermal assessment was not conducted for chromium. Dermal irritation and sensitization are the primary concerns for hexavalent chromium dermal exposures and assumed to be mitigated through occupational use of required PPE.

[2] Significant dermal exposure to sawdust from treated wood is not expected through proper use of personal protective equipment (gloves) required by tags on chromated arsenical-treated wood.

Significant exposure is not expected due to mixing/loading 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 EPA 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 in the studies used to estimate exposure, one person often performed more than one job function. Therefore, estimated risks presented for any single job function may overestimate exposure and risk because that individual may have performed multiple job functions during the exposure study.

- **Treatment Operator (TO):** TOs operate and monitor application system valves and controls, opened and closed cylinder doors, and supervise the insertion and removal of charges (loads of dried, debarked poles or untreated ties) of poles from the treatment cylinders. TOs could also clean cylinder doors and gaskets; handle charge leads inside cylinders; position bridge rails; adjust drip pad track switches; clean treatment system filters; pressure wash treatment areas; end-mark treated charges; and operate the forklift to insert or remove a charge.

- **Treatment Assistant (TA):** TAs operate self-propelled vehicles (i.e., open-cab forklifts) used to load wood products onto and off of trams, move charges in and out of treatment cylinders and to and from load-out areas. TAs could perform certain out-of-cab tasks such as collecting tank samples and performing test boring and lab analysis of treatment solutions in wood.

- **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 perform lead and chain handling and operate 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. Occupational Cancer Risk at Treatment Facilities

The Agency estimated the probability of developing cancer as a result of inhalation and dermal exposure to arsenic and chromium from chromated arsenical wood preservatives. Occupational cancer risks are presented as a probability of developing cancer (e.g., one-in-a-million or 1×10^{-6}). In general, EPA's level of concern for cancer risk is 1×10^{-4} to 1×10^{-6}. EPA notes that the cancer risks for workers exposed at the OSHA permissible exposure limits (PEL) for inorganic arsenic and hexavalent chromium are in the 1×10^{-3} range (2.4×10^{-3} for inorganic arsenic and 6.6×10^{-3} for hexavalent chromium) assuming 8 hours per day exposure for 250 days per year and 35 years per lifetime.

i. Occupational Inhalation Cancer Risk

Lifetime inhalation cancer risks from exposure to pentavalent arsenic were generally in the one-in-ten-thousand (1×10^{-4}) and one-in-a-hundred-thousand (1×10^{-5}) range. The highest estimated risk was for the Tram Setter job function (5.5×10^{-4}).

Lifetime inhalation cancer risks from exposure to hexavalent chromium were also generally in the one-in-ten-thousand (1×10^{-4}) and one-in-a-hundred-thousand (1×10^{-5}) range. The highest estimated risk was for the Treatment Assistant job function (3.0×10^{-4}).

See Section IV of this document for EPA's risk management strategy.

ii. Occupational Dermal Cancer Risk

Lifetime dermal cancer risks from exposure to pentavalent arsenic were generally in the one-in-a-thousand (1×10^{-3}) range. The highest estimated risk was for the Treatment Operator job function (2.8×10^{-2}).

A dermal assessment was not conducted for chromium. Dermal irritation and sensitization are the primary concerns for hexavalent chromium dermal exposures and assumed to be mitigated through personal protective equipment and other exposure reduction measures.

See Section IV of this document for EPA's risk management strategy.

b. Occupational Non-Cancer Risk at Treatment Facilities

The Agency estimated non-cancer effects as a result of inhalation and dermal exposure to arsenic and chromium from chromated arsenical wood preservatives. Occupational non-cancer risks are presented as margins of exposure (MOE). EPA's level of concern for non-cancer risks depends on the scenario assessed.

i. Occupational Inhalation Non-Cancer Risk

For pentavalent arsenic, short-term and intermediate-term occupational inhalation non-cancer risk did not exceed the Agency's level of concern. However, one long-term exposure scenario (Treatment Operator job function; MOE = 1) exceeded EPA's level of concern of MOE $\leq$ 3.

For hexavalent chromium, the Agency's level of concern for inhalation exposure is MOEs $\leq$ 30 for short-term, intermediate-term, and long-term exposures. In general, several short-term and intermediate-term exposure scenarios exceeded EPA's level of concern (MOE range: 9 to 23) and several long-term exposure scenarios exceeded EPA's level of concern (MOE range: 5 to 24). The highest short-/intermediate-term estimated risk was for the Treatment Operator job function (MOE = 9). The highest long-term estimated risk was for the Forklift Operator job function (MOE = 5).

See Section IV of this document for EPA's risk management strategy.

ii. Occupational Dermal Non-Cancer Risk

For pentavalent arsenic, the Agency's level of concern for dermal exposure is MOEs less than or equal to 30 for short-term and intermediate-term exposures and MOEs less than or equal to 3 for long-term exposure. In general, several short-term and intermediate-term exposure scenarios exceeded EPA's level of concern (MOE range: 2 to 24) and several long-term exposure scenarios exceeded EPA's level of concern of MOEs $\leq$ 1.

A dermal assessment was not conducted for chromium. Dermal irritation and sensitization are the primary concerns for hexavalent chromium dermal exposures and assumed to be mitigated through occupational use of required PPE.

See Section IV of this document for EPA's risk management strategy.

c. Occupational Cancer and Non-Cancer Risk for Construction Using Treated Wood

A limited assessment was conducted for post-application inhalation exposures to pentavalent arsenic and hexavalent chromium from wood dust during construction fabrication of treated wood. Significant dermal exposure to sawdust from treated wood is not expected through proper use of personal protective equipment (gloves); therefore, risk from dermal exposure was not assessed.

i. Occupational Inhalation Cancer Risk

For pentavalent arsenic, lifetime inhalation cancer risks from sawing/sanding treated wood were in the one-in-a-thousand (1×10^{-3}) and one-in-ten-thousand (1×10^{-4}) range. For hexavalent chromium, lifetime inhalation cancer risks from sawing/sanding treated wood were in the one-in-ten-thousand (1×10^{-4}) range.

See Section IV of this document for EPA's risk management strategy.

ii. Occupational Inhalation Non-Cancer Risk

For pentavalent arsenic, short-term and intermediate-term non-cancer risk did not exceed the Agency's level of concern for inhalation exposure. For long-term exposure, sanding and sawing tasks yielded MOEs of 2 which exceed the Agency's level of concern (MOE $\leq$ 3).

For hexavalent chromium, several short-term and intermediate-term scenarios yielded non-cancer risks that exceeded the Agency's level of concern for inhalation exposure. Risk estimates included MOEs ranging from 1 to 9 which exceed the Agency's level of concern (MOE $\leq$ 30).

See Section IV of this document for EPA's risk management strategy.

6. Incident Reports

Only limited incident reports are associated with exposure to end-use products containing chromated arsenicals. In contrast, a large body of literature exists on the health effects (acute and chronic) in humans of exposure to the components of chromated arsenicals, particularly arsenic and, to a lesser degree, chromium and copper.

Itching, burning rashes, neurological symptoms, and breathing problems associated with handling unmarked CCA-treated wood have been reported. Sap draining from CCA treated wood stairs has been reported as a potential source of dermal and inhalation exposure leading to dermatitis and development of film on the teeth. At least one individual reported “ruined” nerves in feet and legs which he attributed to exposure to saw dust and fumes from cutting and routing CCA-treated lumber.

C. Environmental Fate and Ecological Risk Assessment

EPA has conducted an environmental fate assessment and an ecological hazard assessment for chromium and arsenic to support the reregistration eligibility decision for wood preservative uses of chromated arsenicals. Copper is outside the scope of this assessment: non-antimicrobial uses of cupric oxide were addressed in a July 2006 RED (EPA 738-R-06-020) and antimicrobial uses of cupric oxide, including wood preservative uses of chromated arsenicals, will be addressed in a separate action at a future date.

EPA evaluated the submitted environmental fate and ecological studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision. A summary of the ecological hazard and environmental fate findings and conclusions is presented below; the full risk assessments are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0250.

1. Environmental Fate

Field and laboratory studies have demonstrated that under certain circumstances copper, arsenic, and/or chromium can leach from treated wood into the surrounding soil or water. In general, most leaching takes place in the first few days and the extent and rate of leaching being highest for copper and lowest for chromium. Available field and laboratory studies suggest that leaching of metals is highly variable and is dependent on environmental conditions.

For aquatic uses, these environmental conditions include pH, salinity (fresh water, sea water, estuaries, natural and synthetic, sterile buffered water), temperature, moisture content of the treated wood, wood type, and wood texture. For terrestrial uses, these include soil pH, type, texture, and organic content. Studies on sorption into soils from utility poles, have shown that the release of metals into soils/sediments from the base of treated wood, decks or utility poles or from the pressure treatment facilities, do not show a high degree of migration, either to groundwater or to the surface. In most cases, after migration of the metals a few meters down into soil, these metals attain the background level concentration of soil.

Chromium is released into water and soil as trivalent chromium, but the concentration of trivalent chromium is the lowest of the three metals, partly attributed to the fixation process in the wood structure. Arsenic is leached into soil and water as pentavalent arsenic. However, few open literature studies report short depuration rates.

Chromium and arsenic in water exist as: hydrated species (coordinated with water), hydroxy species, bound to inorganic anions like FeF_6^{-3}, bonded to organic ligands to form metal complexes or as organometallics (containing C-Metal bonds). Fate and transport processes, and interaction with aquatic and benthic organisms by these chemical species will vary from one of type of organism to another. Because metals tend to attain background level concentrations in soil and water and because the metals tend to change forms (speciate), it is often difficult to identify the source(s) of the contamination in water and soil.

2. Ecological Risk

Based on the high degree of variability in available data and the inability to predict metals speciation and bioavailability in aquatic environments, EPA did not conduct a quantitative ecological hazard assessment. However, based on the current use patterns and the Agency's current understanding of chromium and arsenic environmental fate, it is unlikely that chromium and/or arsenic leaching from chromated arsenical-treated wood would result in significant water or soil contamination. Therefore, there appears to be a relatively low likelihood of significant ecological exposure to arsenic and/or chromium from chromated arsenical-treated wood.

Chromated arsenicals can be used to treat freshwater or marine piling, bulkheads, and bracing timbers underneath non-residential docks, decks, and walkways. The results of the terrestrial risk assessment indicate that the potential for adverse acute effects to birds and mammals from exposure to average concentrations of arsenic acid or chromic acid in soil is low. Average residue levels are not expected to result in chronic impacts to birds. Average soil concentrations are considered more likely to represent the exposure level for mobile receptor species such as birds and mammals than maximum soil concentrations. A quantitative assessment of the risks to birds and mammals to arsenic acid or chromic acid from direct contact (feet, feathers, oral) with chromated arsenicals-treated lumber was not conducted but is considered to be minimal. Non-residential structures built from chromated arsenicals-treated lumber (bracing, bulkheads, pilings, support poles) are not expected to pose an adverse risk to non-target birds or mammalian species due to very limited surface area exposure and greatly reduced surface area wood volume (absent dimensional lumber).

Arsenic and chromium are typically found in most soils and sediments in the U.S. at background levels that approximate those leaching from chromated arsenicals-treated wood. Water-column concentrations of these metals in aquatic habitats would likely be much lower than the values obtained in leaching studies conducted in small laboratory vessels due to dispersion in the water body by tidal flow and wave action, and the degree of partitioning into biota and sediment. Risk quotients (RQ) were not calculated because of the high degree of variability in available data and the inability to predict metals speciation and bioavailability in aquatic environments.

The bioavailability of arsenic and chromium is considered to be relatively constant regardless of chromated arsenicals-treated wood contribution due to steady background environmental levels. Aquatic organisms eliminate arsenic and chromium with little bioaccumulation. Published studies on the effects of chromated arsenicals-treated wood on aquatic organisms indicate that the metals released from the treated wood are localized within sediments, typically within 10 meters of the treated wood. Of the three metals, copper is considered the most toxic to aquatic organisms. Metals are released at higher concentrations from new wood than from old wood, and benthic levels are higher in poorly flushed tidal areas close to the treated wood. Leachates from pilings in well flushed tidal areas do not appear to have adverse effects on the benthic community. Benthic community impacts may occur from copper leachate in aquatic areas having high treated wood usage that are poorly flushed.

Some research indicates that making sure that wood is properly conditioned (complete the fixation reaction) prior to installation in water; and collection of sawdust during construction/maintenance would help reduce the impact of chromated arsenicals metals in the environment. It is not known if the combination of metals in treated wood is antagonistic or synergistic upon exposure to terrestrial or aquatic organisms. The uptake of arsenic, chromium, and copper by plants; and subsequent impacts on the food chain are also not well understood.

3. Risk 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.

As stated previously, based on the high degree of variability in available data and the inability to predict metals speciation and bioavailability in aquatic environments, EPA did not conduct a quantitative ecological hazard assessment. However, based on the current use patterns and the Agency's current understanding of chromium and arsenic environmental fate, it is unlikely that chromium and/or arsenic leaching from chromated arsenical-treated wood would result in significant water or soil contamination. Therefore, there appears to be a relatively low likelihood of significant ecological exposure to arsenic and/or chromium from chromated arsenical-treated wood. A quantitative endangered species assessment, if appropriate, will be conducted at a later date. Copper is also outside the scope of this assessment and antimicrobial uses of cupric oxide, including wood preservative uses of chromated arsenicals, will be addressed in a separate action at a future date.

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 arsenic and/or chromium as active ingredients. 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 chromated arsenicals (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 chromated arsenicals 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) current data gaps and confirmatory data needs are addressed. Accordingly, should a registrant fail to implement any of the requirements for reregistration identified in this document, the Agency may take regulatory action to address the potential risk concerns from the use of chromated arsenicals.

1. Regulatory Rationale

The Agency has determined that wood preservative uses of chromated arsenicals are eligible for reregistration provided that the registrants implement the conditions in this RED including amended labeling and the requirements for 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 chromated arsenicals 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 risks from pesticides applied using treatment cylinders and from pesticides containing metals and metal compounds. Therefore, the risks presented in this document may overestimate risk. Notwithstanding, EPA has identified the following risk estimates of concern associated with the continued use of wood preservatives containing arsenic and/or chromium:

- occupational cancer and non-cancer risk from inhalation exposure to arsenic and chromium, and

- occupational cancer and non-cancer risk from dermal exposure to arsenic.

Without the adoption of additional protective measures to reduce exposure, continued use would not meet the "no unreasonable adverse effects" criteria of FIFRA.

b. Summary of Benefits and Alternatives

A detailed discussion of chromated arsenical benefits and alternatives is presented in the document entitled, "REVISED: A Qualitative Economic Impact Assessment of the Use of Alternatives to CCA as a Wood Preservative" dated September 25, 2008.

i. Alternatives

Chemical alternatives to chromated arsenical wood preservatives include pentachlorophenol, creosote, copper and zinc naphthenates, ammoniacal/alkaline copper quaternary (ACQ), copper azole (CBA), sodium borates (SBX), and copper HDO (CX-A); in addition, the individual chromated arsenicals were evaluated as alternatives (e.g., ACZA was evaluated as an alternative to CCA). 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 arsenic and/or chromium, 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 arsenic and/or chromium, 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. Arsenic and chromium, on the other hand, have been the subject of numerous toxicity, exposure, environmental fate, and ecological effects studies as well as independent scientific panel reviews. 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 chromated arsenicals 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, certain alternatives are known to promote corrosion of metal fasteners whereas this issue has not been observed with chromated arsenicals. If metal fasteners were not necessary for a particular project, these alternatives might offer advantages over chromated arsenicals; however, if metal fasteners were necessary, these compounds could not be considered legitimate 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 chromated arsenical; 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 chromated arsenicals). 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 chromated arsenicals, 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, chromated arsenicals 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 chromated arsenical-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 risk estimates of concern for workers exposed to chromated arsenicals at wood treatment plants and wood construction fabrication facilities. 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 risks and benefits, EPA has determined that wood preservative uses of chromated arsenicals 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 needs are addressed.

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 arsenic and chromium. 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 arsenic or chromium. EPA has not assumed that the arsenic or chromium 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 the chromated arsenicals. During the 60-day public comment period ending on June 16, 2008, the Agency received comments on the revised risk assessments from five respondents: Southern Pressure Treaters' Association and the Western Wood Preservers Institute, American Chemistry Council, Utility Solid Waste Utility Group, Beyond Pesticides, and Forest Products Research Laboratory. Although the overall conclusions stated in the previous risk assessments did not change, as a result of comments received EPA added additional characterization and uncertainties discussions to its risk assessments. All comments and EPA's official responses are available at http://www.regulations.gov in docket number EPA-HQ-OPP-2003-0250.

B. Risk Management Decision

The Agency has concluded that continued use of wood preservatives containing arsenic and/or chromium would not meet the "no unreasonable adverse effects" criteria of FIFRA unless the mitigation measures and associated label changes presented in Table 8 and Table 10, 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 worker exposure to arsenic and chromium. The Agency will require confirmatory monitoring data to ensure that the measures set forth below are protective.

Although the measures below are deemed necessary at this time, in the future, registrants may request that EPA remove or reduce certain restrictions or mitigation measures upon submission of acceptable toxicity and exposure studies that demonstrate risk estimates from exposure to arsenic and/or chromium are below EPA's level of concern.

Table 8. Risk Mitigation Measures for Wood Preservatives Containing Arsenic and/or Chromium[1]

Risk Estimates of Concern	Mitigation Measure(s)	Required Label Language
Occupational cancer and non-cancer risk estimates from inhalation exposure to arsenic and chromium	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 arsenic	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."
	Lock/unlock cylinder doors using automatic locking devices	"As of December 31, 2013, 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."

	Personnel must wear personal protective equipment when handling treated wood/equipment, cleaning the cylinder; approaching the cylinder prior to ventilation, or entering the cylinder.	"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 rinsing 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 within 15 feet of the cylinder opening prior to 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 NIOSH-approved cartridge or canister respirator approved for inorganic arsenic and chromium. 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."
	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 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."
	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."

[1] In the future, registrants may request that EPA remove or reduce certain restrictions or mitigation measures upon submission of acceptable toxicity and exposure studies that demonstrate risk estimates to arsenic and chromium are below EPA's level of concern.

V. What Registrants Need to Do

The Agency has determined that wood preservative products containing arsenic and/or chromium are eligible for reregistration provided that the 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 chromated arsenical 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 arsenic and chromium 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 9. Generic Data Required to Support Chromated Arsenical Wood Preservative Registrations

EPA Guideline Number	Requirement Name
875.1100	Dermal Outdoor Exposure
875.1200	Dermal Indoor Exposure
875.1300	Inhalation Outdoor Exposure
875.1400	Inhalation Indoor Exposure
875.1600	Applicator Exposure Monitoring Data Reporting
875.1700	Product Use Information
850.2300	Avian reproduction study for chrome
850.1735	Freshwater invertebrate sediment toxicity for arsenic
850.1735	Freshwater invertebrate sediment toxicity for chromium
850.1740	Marine invertebrate sediment toxicity using arsenic
850.1740	Marine invertebrate sediment toxicity using chromium
850.4400	*Lemna gibba* aquatic plant toxicity using chromium
850.5400	*Skeletonema costatum* aquatic plant toxicity using arsenic
850.5400	*Selenastrum capricornutum* aquatic plant toxicity using chromium
850.5400	*Anabaena flos-aquae* aquatic plant toxicity using chromium
850.5400	*Skeletonema costatum* aquatic plant toxicity using chrome
850.5400	*Navicula pelliculosa* aquatic plant toxicity using chrome
850.4225	Seedling Emergence terrestrial plant toxicity using arsenic
850.4225	Seedling Emergence terrestrial plant toxicity using chrome

EPA Guideline Number	Requirement Name
850.4250	Vegetative Vigor terrestrial plant toxicity using arsenic
850.4250	Vegetative Vigor terrestrial plant toxicity using arsenic

Submission of the guideline studies above would allow for refined acute and chronic risk assessments for human health as well as non-target and listed aquatic organisms. Currently, insufficient toxicity data are available to calculate acute and chronic risks to sediment dwelling organisms or to plants in either freshwater or saltwater environments. The registrant may wish to conduct the studies on a complex of various metals leaching from treated wood according to the expected proportion of each metal in the water column or sediment. Before conducting any testing on the complex, the registrant should consult with the Agency.

An alternative to dedicated laboratory studies might be focused field studies (850.1950) that document the amounts of various metals leaching from treated wood, and their impacts on aquatic life in freshwater, estuarine, and marine environments. The registrant should consult with the Agency to develop suitable protocols for field studies.

For chromated arsenical 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 Lance Wormell at (703) 603-0523 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Lance Wormell
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
Lance Wormell
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.

One end-use product containing arsenic trioxide in granular form is currently registered with EPA. This product is a ready-to-use ant stake for use in residential and other settings. Because the potential exposure scenarios involve misuse of the product, significant human, environmental, or ecological exposure is not expected; therefore, quantitative risk assessments were not conducted. However, ant stakes containing arsenic trioxide for use in residential settings have characteristics that, based upon human toxicological data (see Table 5), the Agency determines pose potential for serious hazard of accidental injury or illness which child-resistant packaging could reduce. Therefore, the Agency is requiring the registrant supply a certification that the product as packaged meets the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20, as published in 60 FR 37710 (July 21, 1995), and that the product as packaged will continue to meet the effectiveness, compatibility, and durability standards of 40 CFR 157.32.

<u>For wood preservative end-use products containing the active ingredients arsenic and/or chromium</u>, 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) 308-6411 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 10. Required Label Changes for Manufacturing and End-Use Wood Preservative Products Containing Arsenic and/or Chromium

Description	Chromated Arsenicals: 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 Agency Label Policies	"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 has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

Description	Chromated Arsenicals: 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 rinsing 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 within 15 feet of the cylinder opening prior to 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 NIOSH-approved cartridge or canister respirator approved for inorganic arsenic and chromium." "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	Chromated Arsenicals: 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	Chromated Arsenicals: 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)	"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
Other Application Restrictions (Risk Mitigation)	"As of December 31, 2013, an automatic locking/unlocking device must be used to accomplish locking and unlocking of the cylinder door."	Directions for Use

Description	Chromated Arsenicals: Required Labeling Language	Placement on Label
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)	"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: Chromated Arsenical Uses Eligible for Reregistration (Case 0132)

All currently labeled uses are eligible for reregistration provided that the prescribed risk mitigation measures are adopted and labels are amended accordingly, and required data are submitted. EPA is currently in the process of incorporating new American Wood Protection Association standards and online use guidance documents into this appendix. The Agency is working with the regulated community and other regulatory agencies to ensure this appendix accurately reflects current uses and plans to issue the completed Appendix A as part of an addendum or amendment to this RED in late 2008.

APPENDIX B: Inorganic Arsenic and Inorganic Chromium (Case 0132, PC Codes 006801, 006802, 021101)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Chlorine Dioxide and Sodium Chlorite. These requirements apply to Chlorine Dioxide and Sodium Chlorite 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 establishments 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	10	40992001 40992002 41034001
830.1600 830.1620 830.1650	61-2a	Starting Materials	10	40992001 40992002 40992008 41034001
830.1670	61-2b	Manufacturing Process	10	40992001 40992002 40992008 41034001
830.1670	61-3	Formation of Impurities	10	40992001 40992002 41034001
830.1750	62-2	Certification of Limits	10	40992008
830.6302	63-2	Color	10	Open Literature
830.6303	63-3	Physical State	10	Open Literature
830.6304	63-4	Odor	10	Not Applicable
830.7200	63-5	Melting Point	10	Not Applicable
830.7220	63-6	Boiling Point	10	Open Literature
830.7300	63-7	Density	10	Open Literature
830.7840 830.7860	63-8	Solubility	10	Open Literature
830.7950	63-9	Vapor Pressure	10	Not Applicable
.830.7550	63-11	Partition Coefficient (Octanol/Water)	10	Not Applicable

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.7000	63-12	pH	10	42418702 42418703
830.6313	63-13	Stability	10	Open Literature
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test, Bobwhite Quail	10	40409013 41719201 41621104
850.2200	71-2	Avian Dietary Toxicity Test, Bobwhite Quail	10	121618 41719202 41621101
850.2200	71-2	Avian Dietary Toxicity Test, Mallard Duck	10	41621102 40409012
850.2300	71-4	Avain Reproduction	10	Data gap, Chrome only
850.1075	72-1	Fish Acute Toxicity – Freshwater, Rainbow Trout	10	41620003 41621105
		Fish Acute Toxicity – Freshwater, Rainbow Trout		EPA 2002a, supplemental study
		Fish Acute Toxicity – Freshwater, Bluegill Sunfish		40409014 41658401 41950601
850.1010	72-2	Aquatic Invertebrate Acute Toxicity, Daphnia	10	41620001 41621103
850.1075	72-3a	Fish Acute Toxicity—Saltwater, Sheepshead Minnow	10	41620004 41703601

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1025	72-3b	Oyster acute toxicity test (shell deposition)	10	Waived
850.1035	72-3c	Mysid acute toxicity test	10	41620002 41703602
850.1300	72-4b	Daphnia Chronic Toxicity Test	10	42001601 41881501
850.1400	72-4	Fish early-life stage toxicity test	10	41802201 41974901
850.4400	122-2	Aquatic plant toxicity	10	Data gap
850.4225	123-1a	Seedling Emergence	10	Data gap
850.4250	123-1b	Vegetative Vigor	10	Data gap
		Acute algal dose-response toxicity – marine diatom	10	42278801, arsenic only. 2233, supplemental. Data gap for chrome
		Acute algal dose-response toxicity – freshwater diatom	10	42290903, arsenic only. Data gap for chrome
		Acute algal dose-response toxicity – bluegreen cyanobacteria	10	42278802, arsenic only. 3960, supplemental, Data gap for chrome
850.5400	123-2	Acute algal dose-response toxicity - duckweed	10	42290901, arsenic only. Data gap for chrome
850.3020	141-1	Honey bee acute contact toxicity	10	40351301 Data gap for chrome
850-1735		Freshwater invertebrate sediment toxicity	10	Data gap

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
850-1740		Marine invertebrate sediment toxicity	10	Data gap
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	10	26356 40409001 43429401
870.1200	81-2	Acute Dermal - Rabbit	10	26356 43429402
870.1300	81-3	Acute Inhalation - Rat	10	40463902 43429403
870.2400	81-4	Primary Eye Irritation - Rabbit	10	26356 Open Literature
870.2500	81-5	Primary Dermal Irritation - Rabbit	10	26356 Open Literature
870.2600	81-6	Dermal Sensitization	10	40646201 Open Literature
870.3700	83-3	Developmental Toxicity – Non-rodent	10	42171201
870.4200???	83-2???	Toxicity/carcinogenicity– Mouse, Rat.	10	47325703 47325704
ENVIRONMENTAL FATE				
835.2110	161-1	Hydrolysis	10	Open Literature
835.4100	162-1	Aerobic Soil Metabolism	10	Open Literature
835.4400	162-3	Anaerobic Aquatic Metabolism	10	Open Literature
835.1240	163-1	Special Leaching Study	10	43249201

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.1730	165-4	Bio-accumulation in Fish	10	Open Literature
OCCUPATIONAL AND RESIDENTIAL EXPOSURE				
875.2800	133-3	Dermal Exposure, Post application	10	46644701
875.1200	233	Dermal Indoor Exposure, Applicator	10	46884001 46922901 46930701
875.1400	234	Inhalation Indoor Exposure, Applicator	10	45502101 46720801
875.1600	236	Applicator Exposure Monitoring Data Reporting	10	44759504

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 03/17/2004 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:

- Notice of Availability of the Preliminary Risk Assessment for Wood Preservatives Containing Arsenic and/or Chromium Reregistration Eligibility Decision, (03/17/2004*)*.

Preliminary Risk Assessment and Supporting Science Documents:

- Wood Preservatives Containing Arsenic and/or Chromium: Risk Assessment and Science Support Branch's Revised Preliminary Risk Assessments and Science Chapters In Support of the Reregistration Eligibility Decision, 02/27/2004, Norman Cook, PhD.
- Case Overview, Case 0132, Antimicrobials Division, 03/11/2004.
- Product Chemistry, Case 0132, Antimicrobials Division, 03/11/2004.
- Residue Chemistry Science Chapter, Case 0132, Antimicrobials Division, 03/11/2004.
- Human Exposure, Risk Assessment Science Support Branch, February 18, 2004
- Worker Exposure Study Review: *Assessment of Potential Inhalation and Dermal Exposure Associated with Pressure-Treatment of Wood with Arsenical Products*, Submitted September 24, 2001 by the American Chemistry Council's Arsenical Wood Preservatives Task Force. 5/21/2002, Doreen Aviado, Biologist.
- Hazard Identification and Toxicology Endpoint Selection, Case 0132, Antimicrobials Division, February 18, 2004, Timothy F. McMahon, Ph.D. and Jonathan Chen, Ph.D..
- Incident Report, Case 0132, Antimicrobials Division, February 2, 2004, Jonathan Chen, Ph.D..
- Occupational Risk Characterization, Case 0132, Risk Assessment and Science Support Branch, Feb 18, 2004, Jonathan Chen, Ph.D..
- Environmental Fate, Case 0132, Risk Assessment and Science Support Branch, Antimicrobials Division, 03/11/2004.
- Environmental Risk RED Chapter, Case 0132, Risk Assessment and Science Support Branch, Antimicrobials Division, 03/11/2004.

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

- Occupational Exposure Chapter for Inorganic Arsenicals and Chromium-based Wood Preservatives in Support of the Reregistration Eligibility Decision (RED) Document for the Chromated Arsenicals (RED Case 0132). 8/28/2008, Doreen Aviado, Biologist, Team Two, Timothy Dole, Industrial Hygienist, Team One.
- Hazard Identification and Toxicology Endpoint Selection for Inorganic Arsenic and Inorganic Chromium. 8/25/ 2008, Jonathan Chen, Ph.D. and Timothy F. McMahon, Ph.D.
- Human Health Risk Assessment and Ecological Effects Assessment for the Reregistration Eligibility Decision (RED) Document of Inorganic Arsenicals and/or Chromium-based Wood Preservatives. Risk Assessment and Science Support Branch, 9/18 2008, Doreen Aviado, Biologist.
- Ecological Hazard and Risk Assessment for the Reregistration Eligibility Decision (RED) Document. Case 0132, PC Codes 006802, 021101. 08/27/2008, Richard C. Petrie, Agronomist, Team 3 Leader.
- Amended Environmental Fate and Transport Risk Assessment for the RED Process on the Inorganic Arsenicals and Chromated Wood Preservatives. 8/20/2008, A. Najm Shamim, PhD., Chemist
- Amended Product Chemistry Chapter for the RED Process on the Inorganic Arsenicals and Chromated Wood Preservatives. 8/20/2008, A. Najm Shamim, PhD., Chemist

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 Chromated Arsenicals 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

MRID #	Citation
26356	PBI-Gordon Corporation (1976) Reproduction: Technical. Summary of studies 241576-C and 241576-AG. (Unpublished study received Jan 2, 1980 under 2217-641; CDL:241576-AF).
121618	Goldenthal, E.; Wazeter, F.; Dean, W. (1974) Dietary Toxicity (LC-50) Study in Bobwhite Quail: 316-004. (Unpublished study received Apr 9, 1974 under 7401-184; prepared by International Research and Development Corp., submitted by Voluntary Purchasing Group, Inc., Bonham, TX; CDL:128273-A)
40351301	Hoxter, K.A., and M. Jaber. 1987. Arsenic Acid: An Acute Contact Toxicity Study with the Honey Bee (*Apis mellifera*). Conducted by Wildlife International for Pennwalt Corporation.
40409001	Glaza, S. (1987) Acute Oral Toxicity Study of Arsenic Acid: 75% w/w in Mice: Final Report: Laboratory Project ID: 70602444. Unpublished study prepared by Hazleton Laboratories America, Inc. 36 p.

40409012 Fletcher, D.W. 1987. 8-Day Dietary Study with Arsenic Acid as Desiccant L-10 in Mallard (*Anas platyrhynchos*) Ducklings. Conducted by Bio-Life Associates for Pennwalt Corporation.

40409013 Fletcher, D.W. 1987. 21-Day Acute Oral Toxicity Study with Arsenic Acid as Desiccant L-10 in Bobwhite Quail. Conducted by Bio-Life Associates for Pennwalt Corporation.

40409014 Suprenant, D.C. 1987. Acute Toxicity of Arsenic Acid (Desiccant L-10) to Bluegill (Lepomis macrochirus). Conducted by Springborn Life Sciences, Inc., for Pennwalt Corporation.

40463902 Terrill, J. (1987) Acute Inhalation Toxicity Study with Arsenic Acid in the Mouse: HLA Study No. 153-136. Unpublished study prepared by Hazleton Laboratories America, Inc. 35 p.

40646201 Glaza, S. (1988) Dermal Sensitization Study of Arsenic Acid 75% in Guinea Pigs (Closed Patch Technique): Final Report: Project ID: HLA 80206225. Unpublished study prepared by Hazleton Laborato- ries. 22 p.

40992001 Muchow, Teri. 1989. Arsenic Acid Product Chemistry Data. Guideline Reference No. 61-1. Guideline Reference No. 61-2. Guideline Reference No. 61-3. Unpublished study prepared by Research Division, Osmose Wood Preserving, Inc. January 25, 1989.

40992002 Muchow, Teri. 1989. Sodium Arsenate Product Chemistry Data. Guideline Reference No. 61-1. Guideline Reference No. 61-2. Guideline Reference No. 61-3. Unpublished study prepared by Research Division, Osmose Wood Preserving, Inc. January 25, 1989.

40992008 Muchow, Teri. 1989. Osmose K-33-C (50 %) Wood Preservative. EPA Reg. No. 3008-36. Product Chemistry Data. Guideline Reference No. 61-2. Guideline Reference No. 62-2. Guideline Reference No. 62-2. Unpublished study prepared by Research Division, Osmose Wood Preserving, Inc. January 20, 1989.

41034001 Muchow, Teri. 1989. Chromic Acid Product Chemistry Data. Guideline Reference No. 61-1. Guideline Reference No. 61-2. Guideline Reference No. 61-3. Unpublished study prepared by Electrochemical, Detergent & Specialty Product Group Development Center, Occidental Chemical Corporation. January 26, 1989.

41034002 Muchow, Teri. 1989. Sodium Bichromate Product Chemistry Data. Guideline Reference No. 61-1. Guideline Reference No. 61-2. Guideline Reference No. 61-3. Unpublished study prepared by Electrochemical, Detergent & Specialty Product Group Development Center, Occidental Chemical Corporation. January 25, 1989.

41620001 LeLievre, M. 1990. Arsenic Acid: Static Acute Toxicity Test Using *Daphnia magna*. Conducted by Springborn Laboratories, Inc. for Chemical Manufacturers Association.

41620002 LeLievre, M. 1990. Arsenic Acid: Static Acute Toxicity Test with Mysid Shrimp, *Mysidopsis bahia*. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41620003 LeLievre, M. 1990. Arsenic Acid: 96-hour Static Acute Toxicity Test with Rainbow Trout, *Oncorhynchus mykiss*. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41620004 LeLievre, M. 1990. Arsenic Acid: 96-hour Static Acute Toxicity Test with Sheepshead Minnow, *Cyprinodon variegatus*. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41621101 Hoxter, K.A. 1990. Eight Day Dietary Toxicity LC50 Test with Bobwhite Quail (*Colinus virginianus*). Conducted by Wildlife International for Chemical Manufacturers Association.

41621102 Hoxter, K.A. 1990. Eight-Day Dietary Toxicity LC50 Test with Mallard Duck, *Anas platyrhynchos*. Conducted by Wildlife International for Chemical Manufacturers Association.

41621103 LeLievre, M. 1990. Chromic Acid: Static 48-hour Acute Toxicity Using *Daphnia magna*. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41621104 Hoxter, K.A. 1990. Chromic Acid: Avian Acute Oral Toxicity Using *Colinus virginianus*. Conducted by Wildlife International for Chemical Manufacturers Association.

41621105 LeLievre, M. 1990. Chromic Acid: 96-hour Static Acute Toxicity Test Using Rainbow Trout, *Oncorhynchus mykiss*. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41658401 LeLievre, M. 1990. Chromic Acid: 96-hour Static Acute Toxicity Using Bluegill Sunfish (*Lepomis macrochirus*). Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41703601 LeLievre, M. 1990. Chromic Acid: 96-hour Static Acute Toxicity Test Using Sheepshead Minnow (*Cyprinodon variegatus*). Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41703602 LeLievre, M. 1990. Chromic Acid: Static Acute Toxicity Test Using Mysid shrimp (*Mysidopsis bahia)*. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41719201 Campbell, S., K.A. Hoxter, and G.J. Smith. 1990. Arsenic Acid (76.1%) Encapsulated: An Acute Oral Toxicity Study with the Northern Bobwhite (Colinus virginianus).Conducted by Wildlife International for Chemical Manufacturers Association.

41719202 Long, R.D., J. Foster, K.A. Hoxter and G.J. Smith. 1990. Arsenic Acid: A Dietary LC50 Study with the Northern Bobwhite (*Colinus virginianus*). Conducted by Wildlife International for Chemical Manufacturers Association.

41802201 Machado, M.W. 1991. Arsenic Acid: Toxicity Test with Fathead Minnow (*Pimephales promelas*) Embryos and Larvae.. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41881501 McNamara, P.C. 1991. Chronic Acid: Chronic Toxicity to Daphnids (*Daphnia magna*) Under Flow-Through Conditions. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41950601 Machado, M.W. 1991. Arsenic Acid: Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Conditions.. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

41974901 Machado, M.W. 1991. Chromic Acid: Toxicity Test with Fathead Minnow (*Pimephales promelas*) Embryos and Larvae. . Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

42001601 McNamara, P.C. 1991. Arsenic Acid: Chronic Toxicity to Daphnids (*Daphnia magna*) Under Flow-Through Conditions. Conducted by Springborn Laboratories, Inc., for Chemical Manufacturers Association.

42171201 Tyl, R.; Marr, M.; Myers, C. (1991) Developmental Toxicity Evaluation of Chromic Acid Administered by Gavage to New Zeal- and White Rabbits: Final Report: Lab Project Number: 60C-4808- 30/40. Unpublished study prepared by Research Triangle Institute. 204 p.

42418702 Desai, Laxman S. 1991. Physical and Chemical Characteristics. pH Determination. Guideline 63-12. CCA-C 50 % Concentrate. Unpublished study prepared by Toxicon Corporation for Hickson Corporation. Laboratory Project ID/Study Number 91GR-0016A. September 30, 1991.

42418703 Desai, Laxman S. 1991. Physical and Chemical Characteristics. pH Determination. Guideline 63-12. CCA-C 70 % Concentrate. Unpublished study prepared by Toxicon Corporation for Hickson Corporation. Laboratory Project ID/Study Number 91GR-0016B. Se

43249201 Stanley, J.S. 1994. Task III- CCA-C: Chromated Arsenical Treated Wood Aqueous Leaching Study. Midwest Research Institute. May 27, 1994. . Unpublished.

43429401 Shults, S.; Gelin, M.; Wilson, N.; et al. (1989) Acute Oral Toxicity (LD50) Study in Rats With Chromic Acid: Lab Project Number: 1628-87-0071-TX-001: 87-0071: T-222-1. Unpublished study prepared by Ricerca, Inc. 104 p.

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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 Inorganic Arsenicals and Chromium-based Wood Preservatives 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 for Inorganic Arsenicals and Chromium-based Wood Preservatives at a later date.

Appendix G. Batching of Inorganic Arsenicals and Chromium-based Wood Preservatives Products for Meeting Acute Toxicity Data Requirements for Reregistration.

Batching information, if applicable, will be completed at a later date.

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

A data call-in will be issued at a later date.