

**Proposed Registration Decision** 

PRD2023-06

# Pentachlorophenol Treated Poles and Cross-Arms

(publié aussi en français)



This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications Pest Management Regulatory Agency Health Canada 2 Constellation Drive 8<sup>th</sup> floor, A.L. 2608 A Ottawa, Ontario K1A 0K9 Internet: canada.ca/pesticides pmra.publications-arla@hc-sc.gc.ca

Information Service: 1-800-267-6315 pmra.info-arla@hc-sc.gc.ca



ISSN: 1925-0878 (print) 1925-0886 (online)

Catalogue number: H113-9/2023-6E (print version) H113-9/2023-6E-PDF (PDF version)

#### © His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

### **Table of Contents**

Background	1
Overview	2
Proposed registration decision for Pentachlorophenol Treated Poles and Cross-Arms	2
What does Health Canada consider when making a registration decision?	2
What are Pentachlorophenol Treated Poles and Cross-Arms?	3
Health considerations	3
Environmental considerations	5
Value considerations	5
Measures to minimize risk	6
Next steps	8
Other information	8
Science evaluation	9
1.0 The active ingredient, its properties and uses	9
1.1 Identity of the active ingredient	9
1.2 Physical and chemical properties of the active ingredient and end-use product	0
1.3 Directions for use	1
2.0 Methods of analysis	1
2.1 Methods for analysis of the active ingredient	1
2.2 Method for formulation analysis	1
2.3 Methods for residue analysis	1
3.0 Impact on human and animal health	1
3.1 Hazard assessment	1
3.1.1 Toxicology summary	1
3.1.2 <i>Pest Control Products Act</i> hazard characterization	13
3.2 Toxicology reference values	5
3.2.1 Route and duration of exposure	5
3.2.2 Occupational toxicology reference values	5
3.2.3 Cancer assessment	5
3.3 Dermal absorption	6
3.4 Occupational and residential exposure assessment	6
3.4.1 Acute hazards of end-use product and mitigation measures	6
3.4.2 Occupational exposure and risk assessment	6
3.4.3 Exposure to the general public from treated wood	8
3.6 Health incident reports	8
4.0 Impact on the environment	8
4.1 Environmental risk characterization	8
4.1.1 Risks to terrestrial organisms	8
4.1.2 Risks to aquatic organisms	9
4.2 Environmental incident reports	9
5.0 Value	19

6.0	Pest co	ontrol product policy considerations	20
6.1	Assessment of the active ingredient under the toxic substances management policy 20		
6.2	Forn	nulants and contaminants of health or environmental concern	. 21
6.3	Dem	onstration of a critical need	22
7.0	Propos	ed regulatory decision	23
List o	fabbre	viations	26
Appe	ndix I	ix I Tables and figures	
Tab	le 1	Toxicology reference values for use in health risk assessment for	
		pentachlorophenol	28
Tab	ole 2	Short to Long-term exposure and risk assessment for treated pole installation	28
Tab	ole 3	Cancer risk assessment for treated pole installation	. 29
Refer	ences		. 30

### Background

Pentachlorophenol was registered for industrial uses as a heavy duty wood preservative in Canada until 4 October 2022. Health Canada's Pest Management Regulatory Agency (PMRA) announced the cancellation of all pentachlorophenol products (one technical grade active ingredient and two commercial end-use products) on 4 October 2022. A one-year phase-out period was authorized under the *Pest Control Products Act* to allow wood treatment facilities to deplete existing stocks of these cancelled products. Details regarding the conditions of authorization and events leading up to the cancellation can be found in REV2022-02, *Update on the Special Review of Pentachlorophenol*.

In general, articles that have been preserved with antimicrobials to protect them from microbial damage do not have to be registered under the *Pest Control Products Act*, as long as:

- the antimicrobial preservative (a pesticide) used to treat the article is registered or otherwise authorized under the *Pest Control Products Act* for that purpose; and
- the use is solely for the purpose of preventing degradation or damage to the product from microorganisms.

However, if the antimicrobial preservative is no longer registered or authorized under the *Pest Control Products Act*, the treated articles are no longer authorized. Since the authorization period of the pentachlorophenol products expires on 4 October 2023, the sale, import and installation of the treated wood would only be permitted to continue until the end of the phase-out period, 4 October 2023. Therefore, in order to continue use (i.e., installation) of already-treated utility poles and cross-arms in Canada beyond 4 October 2023, registration of the treated poles and cross-arms would be required.

Health Canada has reviewed an application to register Pentachlorophenol Treated Poles and Cross-Arms. Interested parties are encouraged to provide comments within 45 days of this publication.

### Overview

# **Proposed registration decision for Pentachlorophenol Treated Poles and Cross-Arms**

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration of Pentachlorophenol Treated Poles and Cross-Arms, for a finite period of three years (until 4 October 2026), for use in new line construction and replacement of damaged utility poles and/or cross-arms used in the transmission and distribution of electricity. These treated poles and cross-arms contain the active ingredient pentachlorophenol (plus related active chlorophenols) to prevent deterioration of the wood by wood-boring insects and fungi. This registration would allow for the continued possession, handling, transportation, storage, distribution, use (i.e., installation) and disposition of pentachlorophenol treated utility poles and cross-arms existing already in Canada as of 4 October 2023.

An evaluation of available scientific information found that, under the proposed conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Pentachlorophenol Treated Poles and Cross-Arms.

#### What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable<sup>1</sup> if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value<sup>2</sup> when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the

<sup>&</sup>lt;sup>1</sup> "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

<sup>&</sup>lt;sup>2</sup> "Value" as defined by subsection 2(1) of *the Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of the Canada.ca website.

Before making a final registration decision on Pentachlorophenol Treated Poles and Cross-Arms, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.<sup>3</sup> Health Canada will then publish a Registration Decision<sup>4</sup> on Pentachlorophenol Treated Poles and Cross-Arms, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

#### What are Pentachlorophenol Treated Poles and Cross-Arms?

Pentachlorophenol-treated utility poles and cross-arms are essential pieces of electrical grid infrastructure that have been treated with pentachlorophenol, an oil-borne heavy duty wood preservative. These utility poles and cross-arms are held in stock to maintain the grid's reliability through unpredictable weather events, to replace already installed poles and cross-arms at the end of their service life, and to advance new infrastructure projects.

#### Health considerations

## Can approved uses of Pentachlorophenol Treated Poles and Cross-Arms affect human health?

# Pentachlorophenol Treated Poles and Cross-Arms are unlikely to affect your health when used according to proposed label directions.

Potential exposure to pentachlorophenol may occur to workers installing treated poles and crossarms during the limited registration period. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are selected to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose level at which no effects are observed. The health

<sup>&</sup>lt;sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>&</sup>lt;sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

effects noted in animals occur at dose levels more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

Pentachlorophenol treated poles and cross-arms are composed of various species of wood impregnated with pentachlorophenol. Due to the solid nature of the treated article and low concentration of pentachlorophenol in the final treated product, the treated poles and cross-arms are not expected to pose acute chemical hazards to human health, including acute toxic effects via the oral, dermal or inhalation routes, skin or eye irritation, or an allergic skin reaction.

International reviews and registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of pentachlorophenol to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the liver and the developing fetus. There was some evidence to suggest that pentachlorophenol damaged genetic material. Pentachlorophenol caused several tumours, including liver and adrenal gland tumours. There was an indication that the young were more sensitive than the adult animal. The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose level at which these effects occurred in animal tests.

#### Occupational risks from handling pentachlorophenol treated poles and cross-arms

# Occupational risks are not of health concern when Pentachlorophenol Treated Poles and Cross-Arms are used according to the proposed label directions, which include protective measures.

Workers installing pentachlorophenol treated poles and cross-arms, or conducting postinstallation (for example, maintenance) activities, can come in direct skin contact with pentachlorophenol residues. Therefore, the label specifies that anyone working with pentachlorophenol treated poles and cross-arms must wear personal protective equipment (PPE), including leather riggers gloves or leather linesman gauntlet gloves (or rubber if lines are charged), long sleeve shirt, bib, long pants, safety glasses, Canadian Standards Association (CSA) approved safety boots, hard hat and appropriate outer wear for seasonal or inclement weather (raincoat, winter lined coat or coveralls/bibs). Taking into consideration the label statements and the limited duration of the registration (3 years), the incremental increase in risks from potential pentachlorophenol exposure to these individuals are not of health concern.

#### Health risks in residential and other non-occupational environments

Risks to the general public were considered as part of the special review (PSRD2020-03, *Special Review of Pentachlorophenol and Its Associated End-use Products*, REV2022-02) and are not of health concern.

#### **Environmental considerations**

# What happens when Pentachlorophenol Treated Poles and Cross-Arms are introduced into the environment?

Pentachlorophenol can leach from treated poles and cross-arms to the soil adjacent to the treated wood. Pentachlorophenol may enter surface waters in limited quantities through movement of soils into surface waters through runoff, or if the treated pole is in contact with surface waters. As described in PSRD2020-03, pentachlorophenol in the environment can convert to the methylated transformation product pentachloroanisole under environmentally relevant conditions. Pentachloroanisole, in turn, can demethylate back to pentachlorophenol.

Exposures of terrestrial and aquatic organisms to pentachlorophenol and pentachloroanisole are expected to be minimal because of high sorption to soil and sediment and limited mobility in the environment. Potential risks to non-target terrestrial organisms are negligible as it is expected that exposures are limited to the soil adjacent to treated wood. The environmental risks to fish, aquatic invertebrates, and aquatic plants are also acceptable as low exposures are expected. If poles come in contact with water, any leached components are expected to remain mainly adsorbed to sediment near the pole. Furthermore, movement of pentachlorophenol into surface waters through soil runoff is expected to result in exposure concentrations below the level of concern.

Pentachlorophenol Treated Poles and Cross-Arms may contain TSMP (Toxic Substances Management Policy) Track 1 micro-contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. Risks of concern from the release of these contaminants into the environment are considered acceptable because their formation has been significantly reduced during the production process of pentachlorophenol.

#### Value considerations

Pentachlorophenol-treated utility poles and cross-arms are able to resist deterioration by woodboring insects and fungi. This has been demonstrated over the past several decades during which time various pentachlorophenol-borne products were registered and used in Canada. A variety of tree species are used in Canada as utility poles and cross-arms. Some of these, such as Douglasfir, are more effectively treated with an oil-borne preservative, such as pentachlorophenol.

#### What is the value of Pentachlorophenol Treated Poles and Cross-Arms?

# Pentachlorophenol-treated utility poles and cross-arms are part of a stock of electrical grid infrastructure that are crucial to maintain the electrical grid and to respond to severe weather events, ensuring Canadians have access to reliable electricity.

Pentachlorophenol-treated utility poles and cross-arms will provide a stock of preserved electrical infrastructure ready to replace damaged or end of service life poles and cross-arms as well as to advance new infrastructure projects.

The registration of pentachlorophenol-treated utility poles and cross-arms is intended to ensure people and essential services in Canada have access to reliable electricity following the phaseout of the use of pentachlorophenol. This will allow the continued use of existing stocks of treated utility poles and cross-arms while the wood preservation sector transitions to the use of an alternative heavy duty wood preservative.

#### Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Pentachlorophenol Treated Poles and Cross-Arms to address the potential risks identified in this assessment are as follows.

#### Key risk-reduction measures

#### Human health

To reduce the potential of workers coming into direct skin contact with pentachlorophenol, workers contacting pentachlorophenol treated poles and cross-arms must wear PPE, including leather riggers gloves or leather linesman gauntlet gloves (or rubber if lines are charged), long sleeve shirt, bib, long pants, safety glasses, CSA approved safety boots, hard hat and appropriate outer wear for seasonal or inclement weather (raincoat, winter lined coat or coveralls/bibs).

#### Environment

Pentachlorophenol Treated Poles and Cross-Arms is a Restricted Class product used for the purposes of transmission and distribution of electricity in Canada, for use in new line construction and replacement of damaged poles and cross-arms. The users of this product must adhere to legislation at applicable federal, provincial, territorial, and municipal levels. Additional industry guidelines for the protection of the environment are also followed. Legislation and guidelines may vary among different jurisdictions. For example, regional differences in soil types may require different installation methods and environmental protection measures. Therefore, label statements for protection of the environment will indicate that applicable legislation and industry guidelines for the protection of the protection of the environment must be followed, including for protecting soils and surface waters from contamination during all activities (including installation, storage, decommissioning, and disposal).

The following label statements are required:

- Under the Nature of Restriction and the Directions for Use:
  - This registration is granted under the *Pest Control Products Act* and does not exempt the user from any other legislative requirements. Use of treated poles and cross-arms must also be in accordance with any other applicable federal, provincial, territorial, and municipal legislation.
  - Use (installation), storage, decommissioning, and disposal of treated poles and cross-arms must be in accordance with applicable federal, provincial, territorial, and municipal legislation, including for environmental protection such as preventing contamination of soil and surface waters. Follow any additional industry guidelines for the protection of human health and the environment.
- Under Environmental Precautions:
  - Toxic to aquatic organisms. Refer to the Nature of Restriction and the Directions for Use in order to prevent contamination of soil and surface waters.
- Under Storage:
  - Store treated poles and cross-arms on pole storage or pole racking in a secured designated area.
  - Pole and cross-arm storage areas should be inspected on a regular basis for evidence of excessive releases of pentachlorophenol. Inspections should include confirmation that there is no visible ground staining resulting from pole and cross-arm storage. In the event excessive release is detected, follow industry guidelines, including using proper machinery, for the safe removal of the pole or cross-arm from storage for disposal and cleanup of soil.
- Under Disposal:
  - Dispose of unused or unwanted product in accordance with provincial/territorial regulations.
  - DO NOT BURN PENTACHLOROPHENOL-TREATED WOOD EXCEPT IN FACILITIES AUTHORIZED FOR DISPOSAL OF SUCH PRODUCTS. DO NOT USE PENTACHLOROPHENOL-TREATED WOOD AS A COMPOST OR MULCH.

#### Next steps

Before making a final registration decision on Pentachlorophenol Treated Poles and Cross-Arms, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

#### **Other information**

When the Health Canada makes its registration decision, it will publish a Registration Decision on Pentachlorophenol Treated Poles and Cross-Arms (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

### **Science evaluation**

#### **Pentachlorophenol Treated Poles and Cross-Arms**

In order to evaluate the pentachlorophenol treated pole and cross-arms products, Health Canada has considered currently available relevant scientific information. This included information submitted by the applicant, as well as information considered for the re-evaluation and special review of pentachlorophenol in Canada, including Canadian biomonitoring data, information considered by other regulatory agencies such as the United States Environmental Protection Agency (USEPA) and scientific information obtained from the open literature.

#### 1.0 The active ingredient, its properties and uses

#### **1.1** Identity of the active ingredient

Active substance	Pentachlorophenol plus related active chlorophenols		
Function	heavy duty wood preservative		
Chemical name			
1. International Union of Pure and Applied Chemistry (IUPAC)	pentachlorophenol plus related active chlorophenols		
2. Chemical Abstracts Service (CAS)	2,3,4,5,6-pentachlorophenol		
CAS number	87-86-5		
Molecular formula	C <sub>6</sub> HCl <sub>5</sub> O		
Molecular weight	266.3 g/mol		
Structural formula			
Purity of the active ingredient	96.0 %		

#### **1.2** Physical and chemical properties of the active ingredient and end-use product

Property			Result
Colour and physical state	pale to dark so	olid	
Odour	phenolic pene	trating	odour
Melting range	187–189°C		
Boiling point or range	Not required f	for a sol	id
Specific gravity at 22°C	1.98		
Vapour pressure at 25°C	4.15 mPa		
Ultraviolet (UV)-visible	<u>λ (nm)</u>	ε (L m	$ol^{-1} cm^{-1})$
spectrum	301	2130	
Solubility in water at 20°C	pН	g/L	_
	5	0.014	
	5	0.020	
	7	2.0	
	8	8.0	
	10	15.0	
Solubility in organic solvents at	Solvent		<u>solubility (g/L)</u>
25°C	methanol		180
	2-propanol		140
	ethanol		120
	acetone		50
	benzene		15
	ethylene glyco	ol	11
<i>n</i> -Octanol-water partition	pН	log Kov	<u>v</u>
coefficient ( $K_{ow}$ )	2	5	
	7	3	
Dissociation constant (p <i>K</i> <sub>a</sub> )	4.71		
Stability (temperature, metal)	Relatively stal	ble and	non-hygroscopic. Sublimes at 54°C.

#### Technical product—KMG Technical Penta Blocks

#### End-use product—Pentachlorophenol Treated Poles and Cross-Arms

Property	Result
Colour	not applicable
Odour	not applicable
Physical state	solid
Formulation type	solid
Label concentration	0.81%

Property	Result
Container material and description	not applicable
Density	0.425–0.772 g/cm <sup>3</sup>
pH of 1% dispersion in water	not applicable
Oxidizing or reducing action	not applicable
Storage stability	not applicable
Corrosion characteristics	not applicable
Explodability	not explosive

#### **1.3** Directions for use

Pentachlorophenol Treated Poles and Cross-Arms is a Restricted Class product used for the purposes of transmission and distribution of electricity in Canada, for use in new line construction and replacement of damaged poles and cross-arms. Utility poles are installed wherever power lines are required to be above ground. Cross-arms are members attached to the poles to support the power lines (wires). Poles and cross-arms may be installed year-round, as new construction lines are being run, or when replacing older or damaged poles and cross-arms.

#### 2.0 Methods of analysis

#### 2.1 Methods for analysis of the active ingredient

Methods provided for the analysis of the active ingredient and impurities in the technical product have been validated and assessed to be acceptable.

#### 2.2 Method for formulation analysis

A method for the determination of the active ingredient in the treated material was not required.

#### 2.3 Methods for residue analysis

Not applicable

#### 3.0 Impact on human and animal health

#### 3.1 Hazard assessment

#### **3.1.1** Toxicology summary

The toxicology assessment for this review relied largely on the approach taken for the special review of pentachlorophenol (PSRD2020-03; REV2022-02), which was based on a recent assessment by the USEPA (PMRA# 3111213). The toxicology reference values established by the USEPA were used as the basis on which potential risks to workers from exposure to Pentachlorophenol Treated Poles and Cross-Arms were assessed. The USEPA assessment and

reference values were adapted for the Canadian regulatory context by taking into consideration requirements under the *Pest Control Products Act* with respect to the protection of vulnerable populations. The toxicology reference values used in the current human health risk assessment are summarized in Appendix I, Table 1.

The active ingredient, pentachlorophenol, is classified as being highly acutely toxic via the oral route and of low acute toxicity via the dermal route. Due to an inability to generate respirable vapours or dust from technical grade pentachlorophenol and maintain a consistent chamber concentration, the requirement for an acute inhalation study was waived and pentachlorophenol was classified as highly toxic via the inhalation route based on preliminary data, the known irritating properties of pentachlorophenol, and its high vapour pressure. It is classified as moderately to severely irritating to the eye and moderately irritating to the skin. Pentachlorophenol did not demonstrate dermal sensitizing potential when tested in guinea pigs using the Buehler method.

Pentachlorophenol Treated Poles and Cross-Arms are not expected to pose acute chemical hazards to human health, including acute toxic effects via the oral, dermal or inhalation routes, skin or eye irritation, or an allergic skin reaction. The treated article consists of various species of wood impregnated with pentachlorophenol at a final concentration of 0.81%. Due to the solid nature of these treated articles, they are not expected to result in oral, inhalation or ocular exposure. Although dermal exposure to the treated article is possible, acute dermal systemic toxicity and irritation hazards from potential contact with pentachlorophenol are not expected given the low concentration of active ingredient in the final treated article.

In laboratory animals, pentachlorophenol has been shown to be rapidly and readily absorbed by oral, inhalation, and dermal routes of exposure. Metabolism of pentachlorophenol in rats shows that pentachlorophenol is biotransformed to tetrahydroquinone via 2,3,5,6-tetrachlorophenol as a main degradative pathway, and to trichlorohydroquinone via 2,3,4,6- tetrachlorophenol and 2,3,4,5-tetrachlorophenol via a minor pathway. Pentachlorophenol, tetrachlorophenol, and trichlorophenol can become conjugated with glucuronic acid or sulfate.

Studies involving repeated exposure of laboratory animals to pentachlorophenol have demonstrated the liver to be the major target organ of toxicity. The dog was the most sensitive species to the hepatotoxic effects from oral exposure to pentachlorophenol, with the lowest point of departure for liver effects observed in the 1-year oral toxicity study in dogs in which pentachlorophenol was administered via capsule. In that study, effects at the lowest dose tested included increased liver weight and alkaline phosphatase activity, increased incidences of granular cytoplasmic pigment accumulation in the liver, and increased incidence of lymphocytic mucosal inflammation in the stomach.

There was some evidence of neurotoxicity in the toxicity database, such as decreases in motor activity and rotarod performance in rats, but these occurred at higher dose levels than other toxic effects. Some studies suggest disruption of thyroid homeostasis, which is postulated to be due to interference with thyroid hormone regulation at the hypothalamic/pituitary level and possibly increased peripheral thyroid hormone metabolism.

In an oral 2-generation reproductive toxicity study in rats, effects in offspring occurred at a parentally toxic dose and included reduced survival, decreased organ weight, and delayed sexual maturation. Effects in parental animals included decreased body weight, liver pathology, and reduced sperm count and testis weight.

With respect to developmental effects resulting from prenatal exposure to pentachlorophenol, the USEPA concluded that most developmental toxicity studies showed no teratogenic effects, but some older studies showed toxic effects in the young that occurred at dose levels below those producing maternal toxicity. In the guideline oral developmental toxicity study in rabbits, no developmental toxicity was noted up to the highest dose tested, which elicited maternal toxicity in the form of reduced body weight gain. In a guideline developmental toxicity study in rats, fetal effects included reduced body weight and increased variations, as well as more serious effects such as increased resorptions and malformations such as hydrocephaly and diaphragmatic hernia. These effects occurred in the presence of maternal toxicity in the form of reduced body weight. Although the guideline developmental toxicity studies were carried out according to internationally accepted test protocols in place at the time of study conduct, the duration of dosing of maternal animals was shorter than is required by current test guidelines, resulting in reduced in-utero exposure of the developing fetus during certain critical stages of development.

In supplemental developmental toxicity studies in rats from the scientific literature that were summarized in the USEPA review, reduced fetal weight, increased resorptions, skeletal variations, malformations, and altered sex ratio were observed in the presence of maternal toxicity. In one of these studies, the serious findings of increased resorptions and misshapen centra, considered a malformation, appeared to occur in the absence of maternal toxicity and at a lower dose level than that at which serious findings were noted in the guideline study. Limitations in these studies identified by the USEPA precluded their direct application for risk assessment purposes, but the results of these studies were used to inform the level of concern with respect to pre- and post-natal toxicity.

In oral carcinogenicity studies, hepatocellular adenomas and carcinomas as well as adrenal gland benign and malignant pheochromocytomas were observed in male and female mice. Female mice also exhibited hemangiomas and hemangiosarcomas. Some evidence of carcinogenicity was also observed in male rats in the form of malignant mesotheliomas and nasal squamous cell carcinomas. The available evidence for gene mutations in bacterial systems suggests that pentachlorophenol is largely devoid of positive effects except for one published report, in which a positive response was noted. Pentachlorophenol was also observed to be weakly clastogenic, with chromosomal aberrations observed using Chinese hamster ovary cells in the presence of metabolic activation. In light of these findings, it was considered appropriate to use a linear lowdose extrapolation approach for the cancer risk assessment.

#### 3.1.2 Pest Control Products Act hazard characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to

threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.<sup>5</sup>

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the database contains the full complement of required studies including a 2generation reproductive toxicity study in rats, and developmental toxicity studies in rats and rabbits. Although the guideline developmental toxicity studies were carried out according to internationally accepted test protocols in place at the time of study conduct, the duration of dosing of maternal animals was shorter than is required by current test guidelines, resulting in reduced in-utero exposure of the developing fetus during certain critical stages of development. In addition, developmental toxicity studies in rats were available in the scientific literature.

With respect to potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the rabbit developmental toxicity study. In the rat, serious effects were noted in the young in several studies. In the 2-generation reproductive toxicity study in rats, reduced offspring viability and delayed sexual maturation was observed in the presence of parental toxicity. In the developmental toxicity studies in rats included in the USEPA assessment, resorptions, malformations, and altered sex ratio were observed at doses levels that resulted in decreases in maternal body weight gain. There was some evidence from one supplemental study that resorptions and a malformation occurred in the absence of maternal toxicity at a lower dose level than that at which serious effects were observed in the guideline study. However, limitations in the supplemental study precluded its direct use in the human health risk assessment.

Overall, the database is adequate for determining the sensitivity of the young. However, there is a high level of concern for prenatal toxicity based on the seriousness of the endpoints. Although concern for most of these effects is tempered by the fact that they were observed in the presence of maternal toxicity, the shorter dosing period used in the guideline developmental studies adds a level of uncertainty to the assessment. In addition, the serious findings in the supplemental literature studies in the absence of maternal toxicity added to the overall level of concern for prenatal toxicity. Therefore, the full 10-fold *Pest Control Products Act* factor (PCPA factor) was retained for exposure scenarios in which serious endpoints in the young were used to establish the point of departure for assessing risk. For all other exposure scenarios, the risk was considered well-characterized and the PCPA factor was reduced to 1-fold.

Although the PCPA factor is not relevant for the use pattern involving Pentachlorophenol Treated Poles and Cross-Arms, it is important to give consideration to the fact that the worker population could include pregnant and nursing women. In light of the serious findings noted in the young in several studies and the limitations in the available developmental toxicity studies, a

<sup>&</sup>lt;sup>5</sup> SPN2008-01. The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides.

10-fold uncertainty factor was applied to exposure scenarios in which serious endpoints in the young were used to establish the point of departure for assessing risk.

#### **3.2** Toxicology reference values

#### 3.2.1 Route and duration of exposure

For workers installing treated poles and cross-arms, occupational exposure to pentachlorophenol is characterized as short- to long-term (<30 days to 1 year) in duration and is predominantly by the dermal route.

#### 3.2.2 Occupational toxicology reference values

For the short- and intermediate-term dermal and inhalation occupational risk assessments, the developmental NOAEL of 30 mg/kg bw/day from the guideline oral developmental toxicity study in rats was selected. This NOAEL was based on increased resorptions, reduced fetal weight, malformations, and variations at the LOAEL of 80 mg/kg bw/day. These findings occurred in the presence of reduced body weight gain of maternal animals. The target margin of exposure (MOE) is 1000, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. As the worker population could include pregnant people, it is necessary to afford adequate protection of the fetus that may be exposed via its mother. In light of concerns regarding prenatal toxicity, as outlined in the Pest Control Products Act Hazard Characterization section, an additional 10-fold factor was applied to this endpoint to protect for a sensitive subpopulation, namely females 13-49 years of age.

For long-term dermal and inhalation occupational risk assessments, the LOAEL of 1.5 mg/kg bw/day from the 1-year oral toxicity study in dogs was selected. This LOAEL was based on increase liver weight and alkaline phosphatase activity, increased incidences of granular cytoplasmic pigment accumulation in the liver, as well as increased incidence of lymphocytic mucosal inflammation in the stomach. The target MOE is 300, which includes standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, and an uncertainty factor of 3-fold to account for the use of a LOAEL.

#### 3.2.3 Cancer assessment

In oral carcinogenicity studies, hepatocellular adenomas and carcinomas as well as adrenal gland benign and malignant pheochromocytomas were observed in male and female mice. Female mice also exhibited hemangiomas and hemangiosarcomas. Some evidence of carcinogenicity was also observed in male rats in the form of malignant mesotheliomas and nasal squamous cell carcinomas. A linear low-dose extrapolation (non-threshold) approach was deemed appropriate for the risk assessment, and a cancer potency factor  $(q_1^*)$  of  $4.0 \times 10^{-1}$  (mg/kg bw/day)<sup>-1</sup> was derived by the USEPA based on the combined incidences of hepatocellular adenomas or carcinomas and adrenal benign or malignant pheochromocytomas in male mice and is considered relevant to all routes of exposure. The USEPA approach to calculating the cancer potency factor was based on combining the potency estimates from each separate tumour type, since the USEPA considered that an approach based on counts of animals with one or more tumours could underestimate the overall risk when tumour types occur independently.

#### **3.3 Dermal absorption**

A chemical-specific dermal absorption study was not required as the occupational exposure assessment was based on a human biomonitoring study.

#### 3.4 Occupational and residential exposure assessment

#### 3.4.1 Acute hazards of end-use product and mitigation measures

#### 3.4.1.1 Pentachlorophenol Treated Poles and Cross-Arms

Pentachlorophenol Treated Poles and Cross-Arms are not expected to pose acute chemical hazards to human health, as discussed in Section 3.1. Therefore, no additional PPE are required beyond that set out earlier.

#### 3.4.2 Occupational exposure and risk assessment

#### 3.4.2.1 Installation of treated poles and cross-arms exposure and risk assessment

Individuals have the potential for exposure to pentachlorophenol when contacting treated poles and cross-arms. This includes both installation and post-installation activities (for example maintenance and service).

Exposure for workers conducting post-installation activities on treated poles and cross-arms installed during the limited registration period are expected to be similar to poles installed prior to the discontinuation of pentachlorophenol. While post-installation activities were not identified as an aspect of concern in the Special Review (PSRD2020-03), they were assessed qualitatively. Human health risks were considered to be acceptable based on the 2019 USEPA interim decision (EPA-HQ-OPP-2014-0653-0034, PMRA# 3111213). Given the conservative assumptions used in the cancer assessment, including the work duration assumptions (5 days a week, 50 weeks a year for 35 years), the PPE worn during post-installation activities, and the transition to other utility pole materials, PMRA considers that health risks are acceptable for utility linemen under the current conditions of use, which includes post-installation activities. Therefore, wood treated with pentachlorophenol that was installed/already in service was not required to be replaced/removed (REV2022-02).

Exposure for workers installing treated poles during the limited registration period was assessed quantitatively. Exposure estimates were determined using a chemical-specific biological monitoring study (PMRA# 3448300, 3448295, 3448296, 3448297, 3448298, 3448299). In this study, crews of Ontario Hydro workers were monitored using total pentachlorophenol in urine as a biological monitoring parameter. Spot urine samples were collected once per month, with samples being collected near the end of the work week. Preliminary monitoring occurred in 1988 where urine samples were collected from workers in January and August. For the main study,

monitoring took place over approximately 6 months at one site in 1989 (23 workers) and at three sites in 1990 (41 workers). Control groups consisted of administration workers.

In the 1988 preliminary data, levels of pentachlorophenol measured in August were 3 times higher than those measured in January. Since the urine samples were normalized by volume, rather than creatinine, they cannot be directly compared to the samples collected in 1989 and 1990.

For the main study (1989 and 1990 data combined), monthly mean urine concentrations ranged from 15.9 to 63.5  $\mu$ g pentachlorophenol/g creatinine. The lowest urine levels were observed in May and November and the highest urine levels were observed in August and September. The study author indicated that the higher urine concentrations during the summer months were related to the higher air temperature, which caused pentachlorophenol to leach out of the poles, increasing the concentration at the surface of the poles. Lower exposure is expected in the winter months given there would be less pentachlorophenol on the surface of the poles and workers wear additional clothing, as supported by the 1988 preliminary data. A yearly mean urine concentration of 17.9  $\mu$ g pentachlorophenol/g creatinine was estimated using urine levels from monitored months and the highest urine level from the monitored spring/fall months as a surrogate for the unmonitored winter months. This calculated value is conservative as urine concentrations in the spring/fall are higher than those expected in winter months.

Limitations were identified with this study, including limited information regarding the method validation and quality control/quality assurance procedures, as well as details regarding the specific work functions (for example, schedules, number of poles handled per day) and other personal information. However, as this was a biological monitoring study conducted in Canada and representative of the sub-population of interest, it was considered to be the best data available.

There are conservatisms with the use of data from this study. For example, the PPE currently worn by linemen is greater than what was worn when the biological monitoring study was conducted. Workers are currently required to wear a fire-resistant long-sleeved shirt and pants or coveralls in addition to additional clothing depending on the weather conditions and work activity (for example, rubber gloves with leather covers if installing poles in proximity to live lines). When the study was conducted, workers commonly wore short-sleeved shirts under coveralls or bibs. As additional PPE are currently worn by workers, exposure is expected to be lower than indicated by the biomonitoring study.

Consistent with biological monitoring studies where spot samples are collected, the total grams creatinine excreted per day were not reported. To estimate daily exposure, the spot samples were multiplied by an assumed total daily creatinine output of 2.04 g creatinine/day. This estimate of daily urinary excretion of creatinine was determined from a biomonitoring study where workers were monitored for a full day. The correction factor of 0.86 was also used to account for absorbed dose not excreted in the urine. This value is based on an oral pharmacokinetic study in humans (PMRA# 3448293). Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the selected toxicology reference value to obtain the margin of exposure (MOE); the target MOE is 1000 for short-intermediate-term and 300 for long-term exposure durations. All calculated MOEs are greater than the target MOEs for exposure durations and are therefore not of health concern (Appendix I, Table 2).

For occupational workers, a lifetime cancer risk of less than  $1 \times 10^{-5}$  is considered acceptable. Potential conservatisms with inputs into the risk calculation should also be considered. If the cancer risk is greater than  $1 \times 10^{-5}$ , it does not necessarily mean the risk of excess cancer in the general population is of concern. However, cancer risks greater than  $1 \times 10^{-5}$  require measures to mitigate risk.

Estimated cancer risks for installation of treated poles for the limited registration period (3 years) are less than  $1 \times 10^{-5}$  and are therefore not of health concern (Appendix I, Table 3). As noted above, there are conservatisms with this exposure assessment, including information that workers in this study wore less personal protective equipment than current standards.

When considering lifetime cancer risk, the incremental increase in cancer risk from installing treated poles for an additional 3 years is acceptable and is not expected to significantly contribute to the background cancer risk for workers conducting post-installation activities on pentachlorophenol treated poles and cross-arms over their lifetime.

#### 3.4.3 Exposure to the general public from treated wood

Risks to the general public, including from drinking water, were considered by the special review (Sections 4.1.2 and 4.2.2, PSRD2020-03; REV2022-02) and are considered to be acceptable.

#### 3.5 Health incident reports

As of 10 May 2023, no human or domestic animal incidents involving pentachlorophenol had been submitted to the PMRA.

### 4.0 Impact on the environment

#### 4.1 Environmental risk characterization

Based on the environmental fate characteristics of pentachlorophenol and pentachloroanisole as described in PSRD2020-03, exposures of terrestrial and aquatic organisms to pentachlorophenol and pentachloroanisole are expected to be minimal because of high sorption to soil and sediment and limited mobility in the environment.

#### 4.1.1 Risks to terrestrial organisms

The assessment of Pentachlorophenol Treated Poles and Cross-Arms is based on the currently used methodology in the 2013 Organisation for Economic Cooperation and Development (OECD) Emission Scenario Document (ESD) for Wood Preservatives. Based on the ESD suggestion that the exposure area in soil extends 10 cm from the perimeter of installed treated

wood, exposures of terrestrial organisms are expected to be limited to the soil adjacent to treated wood. Any potential risks to non-target terrestrial organisms from installed Pentachlorophenol Treated Poles and Cross-Arms are expected to be negligible.

#### 4.1.2 Risks to aquatic organisms

The assessment of environmental risk from the use of heavy duty wood preservatives has shown that, in general, ground-based structures made from pressure-treated wood that is properly treated and fixed or stabilized are unlikely to cause any major environmental hazard. The potential risk is greater from treated wood that is submerged in water. However, as the leached components remain mainly adsorbed in sediment at the base of the treated structure, the risk to organisms in the water column is below the level of concern (PRVD2010-03, *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)*; RVD2011-06, *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)*; RVD2011-06, *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)*; RVD2011-06, *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)*; RVD2011-06, *Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)*.

Additionally, ecological risk characterization conducted in USEPA 2019 determined risk quotients by comparing estimated environmental concentrations of pentachlorophenol in surface water (as the result of leaching of pentachlorophenol from utility poles into soil, followed by runoff into surface water) with acute and chronic ecotoxicity endpoint values for fish, aquatic invertebrates, and aquatic plants. The determined risk quotient values were below the levels of concern as described in USEPA 2019. The environmental risks to aquatic organisms are considered acceptable.

#### 4.2 Environmental incident reports

As of 10 May 2023, no environmental incidents involving pentachlorophenol had been submitted to the PMRA.

#### 5.0 Value

Pentachlorophenol-treated utility poles and cross-arms are able to resist deterioration by woodboring insects and fungi. This has been demonstrated over the past several decades, during which time pentachlorophenol was registered in Canada for use as a heavy-duty wood preservative for utility poles and cross-arms.

The inventory of approximately 70,000 pentachlorophenol-treated utility poles currently in stock across Canada are crucial to respond to emergencies and to ensure people and essential services in Canada have reliable access to electricity. If these pentachlorophenol-treated utility poles and cross-arms could not be installed after 4 October 2023, per REV2022-02, they would have to be disposed of properly. Consequently, the removal of 70,000 poles from existing stockpiles could have a significant impact in the short- to medium-term on the ability to maintain electrical infrastructure, respond to emergency situations related to severe weather events and to advance new infrastructure projects, such as bringing electricity and internet to rural and indigenous

communities. Disruptions in the delivery of electricity to communities would result in numerous safety risks and economic hardships ranging from unreliable electrical and internet service in hospitals and households, to businesses unable to conduct daily operations (PMRA# 3441722).

There are four registered alternatives to pentachlorophenol for the pressure treatment of utility poles and cross-arms in Canada: copper azole (CA)-type preservatives, chromated copper arsenate (CCA)-type preservatives, ammoniacal copper zinc arsenate (ACZA)-type preservatives, and creosote. Of these, three are water-borne (copper azole, CCA and ACZA) and one is oil-borne (creosote). The selection of the wood preservative used may be influenced by the wood species to be treated and the intended location of use once treated. A variety of tree species are used in Canada as utility poles and cross-arms. One of the most widely used species, Douglas-fir, is more effectively treated with an oil-borne product, such as pentachlorophenol. Although water-borne preservatives are registered for the treatment of Douglas-fir (i.e., copper azole, CCA and ACZA-type preservatives), the industry does not recommend treating Douglas-fir utility poles with copper azole. Although target retention rates are specified for pressure treatment of Douglas-fir with CCA and ACZA, industry has indicated that these are difficult to achieve.

As the treatment of wood with pentachlorophenol is not permitted after 4 October 2023, treatment plants may need to shift to the use of a registered water-borne alternative. This shift will take time (6–24 months, PMRA# 3462510) and will be accompanied by additional pressures to source pine and cedar as replacements for Douglas-fir. As a result, there is a need for pentachlorophenol-treated utility poles and cross-arms for companies to be able to respond to emergencies and ensure Canadians have continued reliable access to electricity.

The PMRA has determined that the use of pentachlorophenol-treated utility poles and cross-arms has acceptable value. The supporting information which includes use-history information, survey of alternatives and social and economic impacts related to the use of pentachlorophenol-treated utility poles and cross-arms demonstrates that their use meets a critical need. The registration of pentachlorophenol-treated utility poles and cross-arms will allow Canadians to have access to reliable electricity following the phase-out of the use of pentachlorophenol, through the use of existing stocks of treated utility poles and cross-arms until the sector can adjust to using other registered alternatives.

#### 6.0 Pest control product policy considerations

#### 6.1 Assessment of the active ingredient under the toxic substances management policy

The *Toxic Substances Management Policy* (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, i.e., those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity, and toxic as defined under the *Canadian Environmental Protection Act* or its equivalent. Virtual elimination of Track 1 substances is a long-term goal, and the TSMP recognizes that social, economic and technical considerations

must be taken into account in any management decision. Where a Track 1 substance results from the degradation or transformation of a parent substance in the environment, the parent substance may also be considered for Track 1. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, pentachlorophenol and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03<sup>6</sup> and evaluated against the Track 1 criteria.

The interconversion between pentachlorophenol and pentachloroanisole in the environment necessitated that both the parent and the transformation product, pentachloroanisole, were considered during the special review in PSRD2020-03. Health Canada reached the conclusion that pentachlorophenol and its transformation product, pentachloroanisole, are Track 1 substances under the TSMP that may cause long-term risks in the environment.

Please refer to PSRD2020-03, Table 3 - Toxic substances management policy (TSMP) considerations for pentachlorophenol (PCP) and pentachloroanisole (PCA): comparison to TSMP Track 1 criteria, for further information on the TSMP assessment.

#### 6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*<sup>7</sup> The list is used as described in the PMRA Science Policy Note SPN2020-01<sup>8</sup> and is based on existing policies and regulations, including the Toxic Substances Management Policy and Formulants Policy,<sup>9</sup> and taking into consideration the Ozone-depleting Substances and Halocarbon Alternatives Regulations under the *Canadian Environmental Protection Act*, 1999, (substances designated under the Montreal Protocol).

Pentachlorophenol Treated Poles and Cross-Arms may contain low levels of polychlorinated dibenzodioxins, polychlorinated dibenzofurans, and chlorinated benzenes, which are TSMP Track 1 micro-contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. These substances can be unintentionally formed as contaminants in the production process of pentachlorophenol. As described in

<sup>&</sup>lt;sup>6</sup> DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy* 

<sup>&</sup>lt;sup>7</sup> SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

<sup>&</sup>lt;sup>8</sup> PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the Pest Control Products Act.

<sup>&</sup>lt;sup>9</sup> DIR2006-02, Formulants Policy and Implementation Guidance Document

PSRD2020-03, the levels of these micro-contaminants must be as low as can be achieved by the application of the best available technology from the manufacturing perspective. Health Canada's review of the 2006 and 2013 analytical data indicated that the TSMP Track 1 micro-contaminants identified in pentachlorophenol have been significantly reduced from the values reported in the 1997/1998 productions. Risks of concern from the release of micro-contaminants into the environment were considered acceptable because their formation has been significantly reduced during the production process of pentachlorophenol (REV2022-02). As the levels of these micro-contaminants have been reduced in pentachlorophenol used to treat wood, the levels of these micro-contaminants in Pentachlorophenol Treated Poles and Cross-Arms are expected to be low and are considered acceptable.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

#### 6.3 Demonstration of a critical need

Pentachlorophenol is considered a Track 1 substance under the Toxic Substances Management Policy, and therefore can only be registered in exceptional circumstances (for example, emergency or critical need situations), and with the imposition of conditions of registration designed to minimize the risks associated with its use (DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*). A product is deemed to be critically needed if it is to control a new pest problem or one for which registered products are no longer effective or acceptable in international markets, and the inability to manage the pest problem effectively would lead to severe economic hardship to the potential user.

The continued installation of pentachlorophenol-treated utility poles and cross-arms has been found to meet a critical need for the following reasons:

- Pentachlorophenol has been proven to be effective at preventing wood deterioration by wood-boring insects and fungi for pressure treatment of utility poles and cross-arms as evidenced by the registration and use in Canada for many decades.
- Currently, the last date of use of pentachlorophenol-treated utility poles and cross-arms is 4 October 2023. Until that date, utility poles and cross-arms can continue to be treated with pentachlorophenol and installed.
- There are approximately 70,000 pentachlorophenol-treated utility poles in stock in Canada, as of February 2023. As utility poles can continue to be treated with pentachlorophenol up until 4 October 2023, the number of pentachlorophenol-treated poles in stock in Canada may increase up until that date.

- It is estimated by industry that approximately 50,000–60,000 utility poles are installed annually.
- Pentachlorophenol has four registered alternatives which include copper azole (CA)-type preservatives, chromated copper arsenate (CCA)-type preservatives, ammoniacal copper zinc arsenate (ACZA)-type preservatives, and creosote. Of these, the latter is oilborne while the former are all water-borne. Oil-borne preservatives are best used to treat specific wood types such as Douglas-fir, a species used in abundance for utility poles in Canada.
- In the short- to medium-term, there would be additional pressures on pine and cedar as replacements for Douglas-fir, for CCA treatment (a water-borne preservative) to replace the stock of approximately 70 000 pentachlorophenol-treated poles.
- Over the past several decades, the sector has shifted away from using creosote, the only registered oil-borne alternative to pentachlorophenol and the sector is reluctant to revert back to creosote (PMRA# 3450234). Treatment plants would need to shift to the use of water-borne alternatives, which would take 6–24 months to accomplish.
- The inability to use the stocks of pentachlorophenol-treated poles and cross-arms will result in various safety and economic hardships, specifically, a reduced ability to maintain electrical infrastructure, respond to emergency situations related to severe weather events and advance new infrastructure projects, such as bringing electricity and internet to rural and indigenous communities.

#### 7.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration of Pentachlorophenol Treated Poles and Cross-Arms, containing the active ingredient pentachlorophenol (plus related active chlorophenols) to resist deterioration by woodboring insects and fungi of the wood to be used in new line construction and replacement of damaged or end of service life utility poles and/or cross-arms used in the transmission and distribution of electricity. This proposed registration is for a finite period of three years (until 4 October 2026).

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control product is acceptable for this finite period. In addition, the continued installation of the remaining stocks of pentachlorophenol-treated utility poles and cross-arms meets a critical need.

This proposed registration of Pentachlorophenol Treated Poles and Cross-Arms will allow the continued possession, handling, transportation, storage, distribution, use (i.e., installation) and disposition of pentachlorophenol treated utility poles and cross-arms already in Canada as of 4 October 2023 for a period of three years (until 4 October 2026). Below are the specific conditions pertaining to the registration of this treated product:

- After 4 October 2023, treatment of wood with pentachlorophenol products and import of pentachlorophenol treated wood are prohibited.
- During the registration period, from 4 October 2023 to 4 October 2026, possession, handling, transportation, storage, distribution, use and disposition of existing pentachlorophenol treated utility poles and cross-arms in Canada is permitted. It is important to define that "use" for this product refers to the installation of pentachlorophenol treated poles and cross-arms by utility companies for the specific purpose of transmitting and distributing electricity and telecommunications. Sale or use of the pentachlorophenol treated poles and cross-arms for any other purpose is prohibited.
- Once the registration period ends (i.e., after 4 October 2026), distribution, including sale for the purpose of installation (use), and use (i.e., installation) of pentachlorophenol treated poles and crossarms is prohibited.
- After 4 October 2026, possession of installed pentachlorophenol treated poles and cross-arms is permitted.
- After 4 October 2026, transfer of ownership of installed pentachlorophenol treated poles and cross-arms is permitted. No other form of distribution is permitted.
- After 4 October 2026, handling, transportation, and storage of endof-life/damaged pentachlorophenol treated poles and cross-arms is permitted for the purpose of disposal (in accordance with provincial/territorial regulations).
- After 4 October 2026, all unused pentachlorophenol treated poles and cross-arms must be disposed of in accordance with provincial/territorial regulations.
- The pentachlorophenol treated poles and cross-arms installed during this registration period (or prior) will not be required to be replaced/removed after 4 October 2026.

• Any installed/in service pentachlorophenol treated poles and crossarms that need to be replaced/removed at any time must be disposed of in accordance with provincial/territorial regulations.

#### List of abbreviations

%	percent
μg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
CSA	Canadian Standards Association
DF	dry flowable
DNA	deoxyribonucleic acid
DT <sub>50</sub>	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT <sub>90</sub>	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC25	effective concentration on 25% of the population
EC <sub>50</sub>	effective concentration on 50% of the population
ER25	effective rate for 25% of the population
σ σ	gram
ha	hectare(s)
HDT	highest dose tested
Ησ	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K <sub>d</sub>	soil-water partition coefficient
KF	Freundlich adsorption coefficient
km	kilometre
Koc	organic-carbon partition coefficient
Kow	n-octanol-water partition coefficient
L	litre
$LC_{50}$	lethal concentration 50%
LD50	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR50	lethal rate 50%
mg	milligram
mĹ	millilitre
MAS	maximum average score
MOE	margin of exposure

mPa	millipascal
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PCP	pentachlorophenol
PHI	preharvest interval
p <i>K</i> a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
$q_1^*$	cancer potency factor
RSD	relative standard deviation
SC	soluble concentrate
t <sub>1/2</sub>	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

#### Appendix I Tables and figures

## Table 1 Toxicology reference values for use in health risk assessment for pentachlorophenol

Exposure scenario	Study	Point of departure and endpoint	Target MOE <sup>1</sup>
Short- and intermediate-term dermal and inhalation	Oral developmental toxicity study in the rat	NOAEL = 30 mg/kg bw/day Increased resorptions, reduced fetal weight, and skeletal malformation	1000
Long-term dermal and inhalation	1-year oral toxicity study in the dog	LOAEL = 1.5 mg/kg bw/day Increased liver weight and alkaline phosphatase activity; increased incidence of granular cytoplasmic pigment accumulation in the liver.	300
Cancer $q_1^* = 4.0 \times 10^{-1} (mg/kg bw/day)^{-1}$ based on combined incidence of hepatocellular adenomas or carcinomas, and adrenal benign or malignant pheochromocytomas in male B6C3F1 mice			

MOE (margin of exposure) refers to a target MOE for occupational assessments. All exposure scenarios are based on absorbed doses from biological monitoring studies which measure the absorbed dose from oral, dermal and inhalation exposure.

#### Table 2 Short to Long-term exposure and risk assessment for treated pole installation

Scenario	PCP in urine (μg PCP/g creatinine)	Daily dose <sup>c</sup> (µg/kg bw/day)	Short/ Intermediate-term MOE <sup>d</sup> Target = 1000	Long-Term MOE <sup>e</sup> Target = 300
Install	Installation of poles and cross-arms treated with pentachlorophenol			ophenol
Peak exposure	63.5 <sup>a</sup>	1.94	15,900	N/A
Typical	17.9 <sup>b</sup>	0.55	N/A	2,800
exposure				

PCP = pentachlorophenol; MOE = margin of exposure

<sup>a</sup> For short- to intermediate-term exposure, the highest monthly peak urine concentration was selected from the biomonitoring study to address potential peak exposures.

<sup>b</sup> For the long-term assessment, the yearly mean value was selected from the biomonitoring study to address longer term exposures.

<sup>c</sup> Daily Dose (mg/day) = [PCP in Urine (μg PCP/g creatinine) \* Creatinine Excretion (2.04 gram/day)] /PCP Urinary Excretion (86%) \* BW (80 kg)

<sup>d</sup> Short and Intermediate-term MOE = NOAEL (30 mg/kg bw/day)/ Daily Dose (mg/kg bw/day). Target MOE=1000.

<sup>e</sup> Long-term MOE = LOAEL (1.5 mg/kg bw/day)/ Daily Dose (mg/kg bw/day). Target MOE=300

#### Table 3 Cancer risk assessment for treated pole installation

Average daily dose <sup>a</sup> (mg/kg bw/day)	Lifetime average daily dose <sup>b</sup> (mg/kg bw/day)	Cancer risk <sup>c</sup>
0.00028	1.07E-05	4 E-06
	verage daily dose <sup>a</sup> (mg/kg bw/day) 0.00028	Average daily doseaLifetime average daily(mg/kg bw/day)doseb (mg/kg bw/day)0.000281.07E-05

<sup>a</sup> Average Daily Dose = Typical exposure Daily Dose from Table 2 (mg/kg/day) \* (192 days worked / 365 days per year). The typical number of days workers may install poles per year (192) was determined from use information.

<sup>b</sup> Lifetime average daily dose = Average daily dose × (3-year limited registration period/ 78-year lifetime)

<sup>c</sup> Cancer risk = lifetime average daily dose × cancer potency factor (0.4 mg/kg bw/day<sup>-1</sup>)

#### References

#### A. List of studies/information submitted by registrant

#### 1.0 Human and animal health

PMRA
------

document number	Reference
3441723	2023, Use Description Scenario, DACO: 5.2
3443775	2023, 2023-0852_DACO-5.2_Clarification_Response_9March2023, DACO: 5.2

#### 2.0 Value

#### PMRA

document number	Reference
3441721	2023, Use History, DACO: 10.2.4
3441722	2023, Social and Economic Impact, DACO: 10.4
3441723	2023, Use Description Scenario, DACO: 5.2
3450234	2023, Response to PMRA on the Viability of Creosote as an Alternative Oil-Borne Wood Preservative, DACO: 10.2.4

#### B. Additional information considered

#### i) Published information

1.0 Chemistry

#### PMRA

document number	Reference
2917388	Environment Canada, 2013, Recommendations for the Design and Operation of Wood Preservation Facilities, 2013 - Technical Recommendations Document, DACO: 5.14,8.6

#### 2.0 Human and Animal Health

PMRA document number	Reference
3111213	United States Environmental Protection Agency, 2019, Registration Review Draft Risk Assessment for Pentachlorophenol, DACO: 12.5
3448300	Thind, K.S. et al, 1991, Occupational Exposure of Electrical Utility Linemen to Pentachlorophenol - American Industrial Hygiene Association Journal, Volume 52, Number 12, Pages 547 to 552, DACO: 5.5
3448293	Werner H. Braun et al, 1979, The Metabolism/Pharmacokinetics of Pentachlorophenol in Man, and a Comparison with the Rat and Monkey - Toxicology and Occupational Medicine, Proceedings of the Tenth Inter-American Conference on Toxicology and Occupational Medicine, Key Biscayne (Miami), Florida, October 22-25, 1978, DACO: 5.14

#### 3.0 Environment

#### PMRA

document number	Reference
3111213	United States Environmental Protection Agency, 2019, Registration Review Draft Risk Assessment for Pentachlorophenol, DACO: 12.5

#### 4.0 Value

#### PMRA

document

number	Reference
3458730	Wood Preservation Canada, 2018, Process Based Specification for CCA Treatment of Coastal Douglas-Fir Wood, DACO: 10.6
3459196	CSA Group, CSA 080 Series:21, DACO: 10.6

#### ii) Unpublished information

#### 1.0 Human and animal health

PMRA document number	
	Reference
3448295	1990, Assessment of Linemen Exposure to Pentachlorophenol – EE Data, DACO: 5.5

3448296	1990, Assessment of Linemen Exposure to Pentachlorophenol – NS Data, DACO: 5.5
3448297	1990, Assessment of Linemen Exposure to Pentachlorophenol – P Data Including Creatine Adjustment, DACO: 5.5
3448298	1990, Assessment of Linemen Exposure to Pentachlorophenol – P Data, DACO: 5.5
3448299	1990, Assessment of Linemen Exposure to Pentachlorophenol - PS Data, DACO: 5.5

#### 2.0 Value

#### **PMRA**

document	
number	Reference
3462510	2023, Stella-Jones letter to the Health Minister, DACO: 10.6