Proposed Special Review Decision PSRD2020-03

Special Review of Pentachlorophenol and Its Associated End-use Products

Consultation Document

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing pentachlorophenol based on the regulatory decisions from the OECD member countries Switzerland, New Zealand, European Commission and Japan to prohibit all uses due to human health and environmental concerns. The special review was initiated in December 2013 (Canada, 2013a).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, Health Canada has evaluated the aspects of concern that prompted the special review of pest control products containing pentachlorophenol. The aspects of concern are relevant to the environment and human health (see Section 3.0).

2.0 Uses of Pentachlorophenol in Canada

Pentachlorophenol is currently registered for industrial uses as a heavy duty wood preservative in Canada.

When used as a wood preservative, pentachlorophenol is applied through pressure or thermal impregnation at specialized wood treatment facilities. The pentachlorophenol treated wood is used as utility poles, pilings, railway ties and outdoor construction materials. Pentachlorophenol treated wood is not permitted in Canada for use in residential construction, food/feed storage, animal housing, playground equipment, or any use where there is prolonged skin contact. Further, pentachlorophenol treated wood is not permitted for direct contact with drinking water, or where there is a potential to contaminate drinking water. All currently registered pest control products containing pentachlorophenol are considered in this special review (Appendix I).

Pentachlorophenol was re-evaluated in Canada in 2011 (Canada, 2010; Canada, 2011). Continued registration of pentachlorophenol was contingent on the adoption of additional control measures for wood treatment facilities as per the *Recommendations for the Design and Operation of Wood Preservation Facilities, Technical Recommendations Document* (TRD; Canada, 2004; Canada, 2013b). The TRD includes requirements to reduce the release of wood preservative chemicals into the environment and minimize exposure of workers to wood treatment chemicals. All Canadian facilities using pentachlorophenol must follow the requirements of the TRD.

As part of the re-evaluation, Health Canada, in consultation with stakeholders, developed a risk management plan (RMP) to identify and implement opportunities to lower potential exposures and further reduce risk.

3.0 Aspects of concern that prompted the special review:

Based on the information from Switzerland, New Zealand, the European Union and Japan, Health Canada has identified the following aspects of concern that prompted the special review:

- Environment
  - Persistence, mobility and bioaccumulation (presence in all environmental compartments);
  - Potential risk to aquatic organisms;
  - Potential risk to terrestrial vertebrates; and
  - Release to the environment of polychlorodibenzodioxins, polychlorodibenzofurans, hexachlorobenzene.

- Human health
  - Occupational exposure in wood treatment facilities; and
  - Exposure to the general public from treated wood.

4.0 Evaluation of the aspect of concern that prompted the special review

Following the initiation of the special review of pentachlorophenol, Health Canada requested information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. Canadian water monitoring data were received and were considered in the special review.

In order to evaluate the aspects of concern for pentachlorophenol, Health Canada has considered currently available relevant scientific information. This included information submitted by the registrant as part of the special review, information considered for the re-evaluation of pentachlorophenol in Canada, as well as any relevant information obtained since then (such as, Canadian and American monitoring data, information considered by other regulatory agencies such as the United States Environmental Protection Agency (USEPA), information considered by the Stockholm Convention on Persistent Organic Pollutants, and scientific knowledge obtained from the open literature). No information related to the aspects of concern was identified in the Canadian incident report database.

4.1 Aspects of concern related to the environment

4.1.1 Persistence and bioaccumulation:

Pentachlorophenol (PCP) in the environment can convert to the methylated major transformation product pentachloroanisole (PCA), which in turn can demethylate back to pentachlorophenol in some organisms. Given the interconversion between PCP and PCA in the environment, both the parent and the transformation product (PCA) were considered as part of the assessment against the following persistence and bioaccumulation criteria outlined in the Persistence and Bioaccumulation Regulations and the Toxic Substances Management Policy (TSMP) (Canada, 1995; Canada, 1999b). Both the Persistence and Bioaccumulation Regulations and the TSMP have similar criteria for persistence and bioaccumulation.

- **Persistence:** Environmental persistence refers to the length of time a substance resides in environmental media and is usually defined in terms of half-life. A substance is considered persistent when the persistence criterion is met in any one medium (soil, water, sediment, or air). A substance may also be considered as persistent in air if it is shown to be subject to atmospheric transport to remote regions such as the Arctic.

- **Bioaccumulation:** Bioaccumulation describes the process by which a substance accumulates in a living organism, either from the surrounding medium, or through food containing the substance. The potential of a substance to bioaccumulate can be expressed by the bioaccumulation factor (BAF), the bioconcentration factor (BCF), or the octanol-water partition coefficient (K_{ow}). Bioaccumulation factors are preferred over bioconcentration factors. In the absence of BAF or BCF data, the octanol-water partition coefficient (log K_{ow}) may be used. The numeric criterion of 5000 is applied to BCF and BAF values to provide evidence of bioaccumulation in freshwater, marine, and terrestrial organisms. However, since this criterion was developed from BCF values for freshwater fish, data obtained for other organisms are used with caution. The numeric criterion of 5 is applied to the log K_{ow} value.

- In addition to persistence and bioaccumulation criteria, Health Canada considered the toxicity (CEPA-toxic equivalent), and "predominantly anthropogenic" nature of PCP to determine whether PCP meets the Track 1 criteria under the TSMP (Canada 1999b). Except where the expression "inherently toxic" appears, a substance is CEPA-toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health. Therefore substances regulated under the *Pest Control Products Act* and found to meet this criterion are considered "CEPA-toxic equivalent". The TSMP policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment is largely due to human activity relative to contributions from natural sources. When all four criteria are met, the chemical is identified as a Track 1 substance.

The TSMP is a federal policy developed to provide direction on the management of substances of concern that are released into the environment, take a long time to break down, and collect in living organisms. The TSMP calls for virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative (Track 1 substances). 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.

Assessment conclusion for PCP and PCA

The relationship between PCP and PCA in the environment necessitates that pentachlorophenol (PCP) and pentachloroanisole (PCA) are considered together. Health Canada concludes that PCP forms the transformation product PCA, and that PCA meets the criteria for a Track 1 substance (Appendix II).

Health Canada has reached these conclusions following a comprehensive examination of available information including several new environmental fate studies on PCP and PCA, and ecotoxicology studies on PCP submitted to Health Canada for the current special review.

This assessment also considered studies reviewed by the USEPA (USEPA, 2008a; USEPA, 2015, USEPA, 2019) and evidence from studies from the published literature reviewed by the POPRC (UNEP, 2013a; UNEP, 2013b).

- **Persistence:** The persistence criteria have not been met for PCP or PCA in soil, water, or sediment.

  PCP also does not meet the persistence criteria in air. PCP is not expected to volatilize from water to air at environmentally relevant pH values. PCP has rarely been detected in air in remote areas. There is little evidence that PCP will undergo long-range environmental transport, including atmospheric transport.

  Although the atmospheric transport criterion is likely not met for PCP, there is ample evidence (air monitoring data) that the major transformation product, PCA, will undergo atmospheric transport. Subsequent metabolism by some organisms can cause PCA to become demethylated and biotransformed back to PCP. Additionally, some biota may biotransform other chemicals to PCP (in other words, hexachlorobenzene (HCB); hexachlorocyclohexanes (HCH, also known as lindane); pentachloronitrobenzene (PNCB; quintozene)). Both of these processes would account for the presence of PCP in biota from remote areas. It should be noted that HCB and HCH are not currently registered in Canada. There are 2 PNCB technical grade active ingredients registered in Canada, however, it is not currently used in Canada as no end-use products are registered.

  The major transformation product, PCA, however, is considered to have met the criterion for persistence in air. PCA is expected to volatilize from water to air, and the modelled half-life for the reaction of PCA with atmospheric hydroxyl (OH) radicals was 9.8 days based on a 12-hour day. PCA has commonly been measured in air collected from the circumpolar Arctic across several decades, and it has also been measured in particles, sediment, snow, and soil sampled from remote areas. There is substantial evidence that PCA will undergo atmospheric transport.

  As the persistence criteria for PCA is met in one environmental medium (air), this major transformation product is considered to meet the TSMP Track 1 criterion for persistence.

- **Bioaccumulation**: PCP does not meet the criterion for bioaccumulation. The log K_{ow} value for PCP varies with pH. All values are less than 5 at environmentally relevant pH values. The large majority of laboratory derived BCF values for whole fish (wet-weight) are below 1000 (for example, an acceptable BCF study (bluegill sunfish) reported BCF values of 190–790). There are some BCF values reported above 5000 for other species, however, the BCF criterion under the TSMP was developed for freshwater fish. Therefore, data from other species are considered with caution.

  The major transformation product, PCA, meets the criterion for bioaccumulation. Model estimated log K_{ow} values for PCA are 5.30 and 5.7. An experimentally derived log K_{ow} is 5.45. An acceptable laboratory bioconcentration study (with bluegill sunfish) reported BCF values of 5420 and 6320. These are above the bioaccumulation criterion of 5000. A second laboratory study conducted with rainbow trout, but which did not follow the OECD guideline, also showed significant bioaccumulation from BCF values higher than 10 000. Field studies from the open literature support the potential for bioaccumulation under environmentally relevant conditions indicating significant uptake of PCA by fish in the environment, including in remote areas.

  Both PCP and PCA have been measured in upper trophic level organisms in remote areas. As described above (under persistence), PCA, will undergo atmospheric transport and has been shown to subsequently demethylate to PCP in some living organisms.

- **CEPA-toxic equivalent and predominant anthropogenic nature:** PCA is a major transformation product produced in the environment from PCP. Considering that PCA has been shown to transform to PCP in living organisms, PCA is considered as equally toxic to PCP. Both chemicals have the potential to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Both substances therefore meet the criterion for toxicity under *Canadian Environmental Protection Act* (CEPA).

  PCP and PCA, are not naturally occurring chemicals and all known releases are due to human activity. PCP and PCA therefore meet the criterion of predominantly anthropogenic.

Overall conclusion: Health Canada concludes that PCP and PCA are Track 1 substances. PCP forms the transformation product PCA in significant amounts under environmentally relevant conditions, and PCA meets all of the Track 1 criteria under the TSMP. Currently available information does not indicate measures to prevent the formation of PCA from PCP. Under the TSMP: 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. Considering the relationship between PCP and PCA, and the abundance of environmental monitoring data, PCP and PCA distribution may be nearly ubiquitous in the northern environment.

A substance is considered a Track 1 substance when it meets a combination of critical values for common characteristics of chemicals known to have the greatest potential impact on the health of ecosystems, including humans over the long-term. As these substances have the potential to

accumulate in the environment and organisms over time, science may not always accurately predict the effects that a substance will have on the environment or human health. Additional risk mitigation measures are proposed for PCP, to manage the potential long-term risk (see Section 7.0).

4.1.2 Mobility

Mobility of PCP is assessed based on available information. In Canada, the most common use of pentachlorophenol treated wood is for the treatment of utility poles and cross-arms. Environmental releases of pentachlorophenol are expected to be minimal from wood treatment facilities. For in-situ utility poles, pentachlorophenol can move downward along the vertical axis of the pole and leach from the pole to the surrounding soil which could then potentially move to other environmental compartments.

Mobility of PCP in air is considered in Section 4.1.1.

PCP is moderately mobile in sandy loam, immobile in clay loam, moderately mobile in silt loam at low pHs, and mobile at high pH (USEPA, 2015). The new mobility studies reviewed under this special review showed similar results. PCP was immobile in sandy loam, loamy sand, clay loam and sediment when tested in soils with lower pH values (pH 5.1–6.2). In a loam soil with a slightly higher pH value (pH 7.1), PCP was slightly mobile. As part of the special review, Health Canada considered the Canadian groundwater monitoring information, and the available Canadian groundwater monitoring data show low detections of pentachlorophenol. Pentachlorophenol was detected in 10 groundwater samples out of a total of 483 samples (2% detection) collected in Ontario between the years 2002 and 2014. The maximum concentration detected in Canada was 0.25 µg/L. The maximum concentration detected in the United States was 9.6 µg/L. Available information indicated that exposure to pentachlorophenol in drinking water sourced from groundwater is expected to be minimal, and no additional risk reduction measures are proposed related to this aspect of concern.

4.1.3 Potential risk to aquatic species

Aquatic species may be exposed to PCP released from in-service treated wood. In Canada, the most common use of PCP treated wood is utility poles. PCP can move downward along the vertical axis of the pole and leach from the pole to the surrounding soil which could then move to surface water. The estimated environmental concentrations (EEC) of PCP in surface water were estimated using modelling and monitoring.

The modelling was based on conservative assumptions including 100% release of PCP from the utility pole; no downward movement into the soil; and no volatilization. Based on the modelling, the estimated expected peak environmental concentration in surface water was 0.176 µg/L (USEPA, 2008c). In addition to modelling, Health Canada considered surface water monitoring information.

Monitoring data for PCP in surface water were available from locations in Manitoba as well as from several locations throughout the United States. PCP was detected in 72 out of a total of 2272 surface water samples collected in Manitoba between the years 2000 and 2014 (3% detection). The maximum concentration detected in Canada was 3.6 µg/L. The maximum concentration detected in the United States was 11 µg/L.

Based on the concentrations of pentachlorophenol in surface water from Canadian monitoring information, environmental risk to fish, aquatic invertebrates and aquatic plants was considered acceptable (both acute and chronic).

Exposure of aquatic species to pentachlorophenol is expected to be minimal from releases at wood treatment facilities. In Canada, pentachlorophenol use at wood treatment facilities is strictly regulated including mandatory requirements for operational practices, equipment, monitoring systems, design requirements and management practices to minimize the exposure to workers and to the environment (Canada, 2013b). The requirements are designed to minimize losses of preservative chemicals in the environment, monitor systems, prevent and contain spills/drips, and recover and recycle any releases that occur. In addition to facility design elements, Canadian facilities are required to have environmental monitoring programs in place for soil, water and air and an emergency response plan in the event of an uncontrolled, unplanned or accidental release. Effluent containing pentachlorophenol cannot be released to sewer systems, lakes, streams, ponds, estuaries, oceans or other waters. Potential risk to aquatic organism from exposure to PCP is considered to be acceptable under the current conditions of use, and, no additional risk reduction measures are proposed.

4.1.4 Potential risk to terrestrial vertebrate species

Exposure to terrestrial vertebrate species is expected to be negligible based on the Canadian use pattern. With the control measures in place, exposure to non-target vertebrates is not expected at treatment facilities. Further, as per the current label directions, pentachlorophenol treated wood is not permitted to be used as animal feed storage or as animal housing. Exposure to non-target vertebrates from in-service treated wood is expected to be negligible. Under the conditions of use, potential risk to terrestrial vertebrates from exposure to PCP is considered to be acceptable, and, no additional risk reduction measures are proposed.

4.1.5 Release to the environment of polychlorodibenzodioxins, polychlorodibenzofurans, hexachlorobenzene

Polychlorinated dibenzodioxins, polychlorinated dibenzofurans and hexachlorobenzene can be unintentionally formed as contaminants in the production process of pentachlorophenol. The Government of Canada has reviewed these contaminants from all potential sources including wood preservation and concluded that these substances are “toxic" as defined under Sections 11(a) and 11(c) of the *Canadian Environmental Protection Act, Priority Substances List Assessment Report No. 1. Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans.* (Canada, 1990).

Polychlorinated dibenzodioxins, polychlorinated dibenzofurans and hexachlorobenzene are Track 1 substances under the TSMP as they are toxic, persistent, bioaccumulative and predominantly anthropogenic, and therefore, the levels of these products 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 these micro-contaminants identified in pentachlorophenol have been significantly reduced from the values reported in the 1997/1998 productions.

The control measures required for all wood preservation facilities in Canada minimize the release of micro-contaminants to the environment (Canada, 2013b). The management of levels of micro-contaminants during production of pentachlorophenol along with the risk reduction measures implemented during the treatment and use of treated wood, results in reduced environmental releases of these contaminants from the use of pentachlorophenol as a wood preservative. No additional risk reduction measures are proposed to address this aspect of concern.

4.2 Aspects of concern related to human health

Pentachlorophenol has low acute dermal toxicity, slight to mild dermal irritation, high acute oral toxicity and is severe eye irritant. Pentachlorophenol is not a dermal sensitizer. Repeat subchronic and chronic toxicity/carcinogenicity studies identify the liver to be the target organ. A q_1* of 4×10^{-1} mg/kg/day^{-1} was based on liver and adrenal tumours in mice (USEPA's Integrated Risk Information System (IRIS) program; USEPA, 2010, 2019). Most developmental toxicity studies on PCP show no teratogenic effects, but some older studies showed toxic effects of PCP in offspring that occurred at dose levels below those producing maternal toxicity.

4.2.1 Occupational exposure in wood treatment facilities

Workers can be exposed to pentachlorophenol in wood treatment facilities via the dermal and inhalation routes. In Canada, all wood treatment facilities are required to follow control measures to protect workers from exposure. Currently, the wood preservation industry is required to adhere to the technical recommendations document (TRD). The TRD establishes a benchmark for the design and operation of wood preservation facilities in order to minimize human exposures associated with these facilities. The pentachlorophenol pesticide label requires that facilities must observe and comply with all TRD recommendations.

Workers are required to wear specialized personal protective equipment (PPE) at all times when handling pentachlorophenol, treated wood or treatment equipment. The labels contain information on the minimum necessary protective equipment and practices associated with using the product. The level of protective equipment increases with increasing potential for exposure to pentachlorophenol. For high exposure scenarios, workers must wear organic solvent impermeable clothing, boots and gloves with a full-face respirator or secondary breathing apparatus.

The label outlines PPE requirements for various scenarios to ensure the proper level of protection is in place at all times. The label also outlines specific requirements for handling and maintaining protective equipment and good hygiene practices for workers in treatment facilities.

The TRD also stipulates engineering controls and operational requirements for material handling and building systems which completely automate or substantially reduce the potential for exposure to workers such as closed mix/load system and ventilation requirements.

The TRD recommendations are required in the Canadian facilities, but not in the United States. The USEPA recently released a draft assessment of PCP (USEPA 2019), which was also considered as part of this special review. The USEPA assessment considered 2018 biomonitoring and inhalation air monitoring data for PCP from an observational exposure study at five industrial wood treatment facilities, which monitored a total of 18 workers (including one site in Alberta, Canada which implemented the TRD recommendations). Urine samples were collected for a 24-hour period which ended just prior to the last shift of the week, and the PCP exposure levels were calculated from the PCP urine concentrations. The inhalation samples were collected over a full work shift. A full day of inhalation monitoring of the workers was conducted (7.8–10.5 hours per worker), with the biomonitoring conducted at the end of a full production week. The activities that the workers performed were grouped into two job groups: treatment operators and wood handlers. Occupational risk estimations indicated that short term non-cancer occupational exposure to workers in treatment facilities is shown to be acceptable (MOEs were 1800 to 13 000, target MOE = 100). The long term non-cancer risk was not shown to be acceptable (MOEs were 200 to 230, target MOE = 300). Based on the arithmetic mean exposure for all sites, all job groups and assuming 35 years of work per 78 year lifetime, cancer risk for workers in the treatment facilities is estimated as 1×10^{-3}, compared to Health Canada's generally acceptable level of 1.0×10^{-5} for occupational scenarios.

The observational study considered in the USEPA assessment is not available to Health Canada. Therefore, the registrant is required to submit the observational study considered in the USEPA draft assessment during consultation of this proposed special review decision to validate the assessment of occupational risk assessment under Canadian use conditions.

4.2.2 Exposure to the general public from treated wood

The potential for residential exposure to pentachlorophenol is limited since treated wood is not sold to the general public or used in residential construction. Despite the limited use, the general public may be exposed to pentachlorophenol in the environment as a result of contaminated sites and historical global use. The Canadian Health Measures Survey (CHMS) conducted between 2009 and 2011 detected PCP in urine of only 3.45% of a nationally representative sample (N = 2551) of Canadians aged 3–79 years from 18 sites across Canada (Canada, 2013d). Due to poor detection rates, geometric mean concentrations were not calculated for the total population or different age groups, and the 95th percentile concentration was available only for the 60–79 years age group (1.7 µg/g creatine adjusted). In addition, in northern Canada, PCP has been measured in blood sampled from Inuit in Nunavik (AMAP, 2009; AMAP, 2015; Canada, 2018)

Exposure to the general public from treated wood was based on the USEPA (2019) assessment. Biological monitoring information was used to assess the aggregate exposure to the general population. Biological monitoring measures the total exposure to pentachlorophenol from all sources (drinking water, incidental oral, inhalation and dermal), including any exposure to pentachlorophenol from volatilization and leaching from treated wood.

The United States National Health and Nutrition Surveys (NHANES, 2003–2004) measured urine levels of pentachlorophenol in the United States population aged 6 and older. The United States Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP, 2007) study includes exposure to pentachlorophenol for children less than 6 years of age. These data provide a broad view of pentachlorophenol exposure from all sources. The USEPA noted that there are uncertainties related to these surveys, such as the contribution from other sources of PCP exposure that are not attributable to PCP pressure treated wood and incidental exposures from directly contacting treated poles may or may not be included in these surveys. It is also assumed that exposure frequency occurs daily (in other words, 365 days per year) at the levels monitored in these surveys and that the daily exposures continue for the entire lifetime. Based on the assessment, there was no non-cancer risks of concern to the general public (long term MOEs ranged from 2400–130 000; target MOE = 300). Cancer risk is estimated as 7.9×10^{-6} based on the mean exposure concentration (USEPA, 2019), compared to Health Canada's generally acceptable level of 1.0×10^{-6} for the general public. A comparison of American and Canadian survey data of PCP levels in urinary samples of adults indicated that Canadian levels fall within the American reported levels considered in the 2019 USEPA assessment.

5.0 Incident reports

As of 20 May 2020, there was no information related to pentachlorophenol in the Canadian incident report database.

6.0 Outcome of the evaluation of the aspects of concern

Based on the assessment of available information, pentachlorophenol and its transformation product pentachloroanisole are identified as Track 1 substances under the TSMP. Therefore, cancellation of all uses is proposed to address the potential long-term risk of these substances.

Evaluation of the available scientific information indicated that under the current conditions of use of pentachlorophenol, potential risks to aquatic organisms and terrestrial vertebrates are considered to be acceptable. No additional risk reduction measures are proposed to address the aspects of concern related to potential risks to aquatic organisms and terrestrial vertebrates, mobility and release of to the environment of polychlorodibenzodioxins, polychlorodibenzofurans, and hexachlorobenzene.

Evaluation of the available scientific information related to the human health aspects of concern indicated that under the current conditions of use of pentachlorophenol, potential risk to human health is not shown to be acceptable. No additional risk mitigation measures related to human health are proposed at this time as cancellation of all uses is proposed based on the concerns related to TSMP.

However, the observational occupational exposure study conducted in wood treatment facilities under the current conditions of use is required to be submitted during the consultation period to validate the assessment of occupational risk assessment under Canadian use conditions.

7.0 Risk management considerations

Wood treatment facilities are currently required to be in compliance with Environment and Climate Change Canada's TRD which recommend routine workplace and environmental monitoring.

Currently available information does not indicate that there are available measures that could be put in place to prevent the formation of PCA from PCP, particularly from treated wood.

Information from the recent USEPA draft assessment indicated that potential risks to human health are not shown to be acceptable.

While PCP does not meet all the screening criteria for a Track 1 substance, taking into account its transformation product pentachloroanisole (PCA), PCP does meet the criteria for a Track 1 substance under the TSMP. A substance is considered a Track 1 substance when it meets a combination of critical values for common characteristics of chemicals known to have the greatest potential impact on the health of ecosystems, including humans over the long-term. As these substances accumulate in the environment and organisms over time, science may not always accurately predict the effects that a substance will have on the environment or human health, and, the environmental risk assessment and mitigation measures may not address all the potential long-term risk posed by persistent and bioaccumulative substances.

As outlined in the TSMP, the social, economic and technical considerations would be taken into account in the risk management decision of PCP. Therefore, registrants and other stakeholders may consider submitting information during consultation period that may inform the implementation of the proposed decision (for example, social, economic and technical considerations such as the extent of leaching of PCP from treated utility poles under Canadian environment).

8.0 Proposed special review decision for pentachlorophenol

Evaluation of the available scientific information indicated that pentachlorophenol (PCP) and its transformation product pentachloroanisole are identified as Track 1 substances under the TSMP. Therefore, to address the potential long-term risk from these substances, Health Canada is proposing the following risk mitigation measures:

- Cancellation of all uses of pentachlorophenol.

Under the current conditions of use of PCP, potential risks to aquatic organisms and terrestrial vertebrates are considered to be acceptable. The assessment of the aspect of concern related to the release of micro-contaminants indicated that no additional control measures to minimize the release of micro-contaminants to the environment is required.

While no additional data is required related to the environmental aspects of concerns, registrants and other stakeholders, during consultation period, may consider submitting information that may inform the implementation of the proposed special review decision.

Evaluation of the available scientific information related to the human health aspects of concern indicated that under the current conditions of use of pentachlorophenol, potential risk to human health is not shown to be acceptable. No additional risk mitigation measures related to human health are proposed at this time as cancellation of all uses of PCP is proposed based on the concerns related to TSMP. However, the observational occupational exposure study conducted in wood treatment facilities under the current conditions of use is required to be submitted during the consultation period.

This proposed special review decision is a consultation document.[1] 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 (please see contact information on the cover page of this document).

9.0 Additional data requirements

- Occupational exposure monitoring study conducted in wood treatment facilities under the current conditions of use.
- While no additional data is required related to the environmental aspects of concerns, registrants and other stakeholders, during the consultation period, may consider submitting information that may inform the implementation of the proposed special review decision (for example, social, economic and technical considerations such as the rate of leaching of PCP from treated utility poles in the Canadian environment and the subsequent rate of PCA formation in the surrounding soil, to provide an estimate of total percent PCA formed).

10.0 Next steps

Before making a special review decision on pentachlorophenol, Health Canada will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on pentachlorophenol. Health Canada will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and Health Canada's response to these comments.

[1] "Consultation statement" as required by Subsection 28(2) of the *Pest Control Products Act*.

List of abbreviations and symbols

%	percent
a.i.	active ingredient
BAF	bioaccumulation factor
BCF	bioconcentration factor
CEPA	*Canadian Environmental Protection Act*
K_{ow}	octanol water partition coefficient
mg	milligram
pH	a measure of the concentration of protons in solution
PMRA	Pest Management Regulatory Agency
PCPA	*Pest Control Products Act*
POPRC	Persistent Organic Pollutants Review Committee
OECD	Organisation for Economic Co-operation and Development
TSMP	Toxic Substances Management Policy
µg	micrograms
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency

Appendix I Registered products containing pentachlorophenol as of 20 may 2020

Registration number	Marketing class	Registrant	Product name
22024	Technical	KMG-Bernuth Inc.	KMG Technical Penta Blocks
26110	Commercial	KMG-Bernuth Inc.	Dura Treat 40
28838	Commercial	KMG-Bernuth Inc.	KMG Penta Blocks

Appendix II

Table 1 Fate and behaviour in the terrestrial environment from new studies submitted under the special review

Property	Test substance	Value	Transformation products	Comments	PMRA#
Biotransformation					
Aerobic Soil Soil 1: sandy loam, pH 6.6, 2.3% OC Soil 2: sandy clay loam, pH 7, 2.4% OC Soil 3: clay loam, pH 6.5, 5.4% OC Soil 4: silty clay loam, pH 7.6, 5.3% OC	PCP	DT_{50} (days): Soil 1: 2.77 Soil 2: 1.88 Soil 3: 2.99 Soil 4: 4.92	Major: PCA, unextracted residues, carbon dioxide Minor: carbon dioxide, unidentified transformation products, unidentified volatile organic compounds, and unextracted residues	Non-persistent in aerobic soil	2917839
Aerobic Soil Soil 1: sandy loam, pH 6.8, 2.0% OC Soil 2: sandy clay loam, pH 6.5, 2.5% OC Soil 3: clay loam, pH 6.7, 6.0% OC Soil 4: silty clay loam, pH 7.6, 4.0% OC	PCA	DT_{50} (days):Soil 1: 6.57 Soil 2: 6.14 Soil 3: 6.53 Soil 4: 9.28	Major: PCP, unextracted residues, carbon dioxide Minor: carbon dioxide, unidentified transformation products, unidentified volatile organic compounds, and unextracted residues	Non-persistent in aerobic soil	2917840
Anaerobic soil Soil 1: sandy loam, pH 6.7, 2.4% OC Soil 2: sandy clay loam, pH 6.6, 2.6% OC Soil 3: clay loam, pH 6.7, 5.9% OC	PCP	DT_{50} (days): Soil 1: 7.93 Soil 2: 4.83 Soil 3: 3.18 Soil 4: 5.28	Major: PCA, 2,3,4,5-tetrachlorophenol (TeCP), 3,4,5-trichlorophenol (TCP), 3,5-dichlorophenol (3,5-DCP), unextracted residues, and carbon dioxide	Non-persistent in anaerobic soil	2917841

Property	Test substance	Value	Transformation products	Comments	PMRA#
Soil 4: silty clay loam, pH 7.5, 5.5% OC			Minor: 3,5-DCP, TCP, TeCP, PCA, carbon dioxide, unidentified transformation products, and unextracted residues		
Anaerobic soil Soil 1: sandy loam, pH 6.8, 2.0% OC Soil 2: sandy clay loam, pH 6.5, 2.5% OC Soil 3: clay loam, pH 6.7, 6.0% OC Soil 4: silty clay loam, pH 7.6, 4.0% OC	PCA	DT_{50} (days): Soil 1: 25.1 Soil 2: 21.2 Soil 3: 22.0 Soil 4: 35.8	Major: PCP, 3,4,5-TCP, 3,5-DCP, unextracted residues, and carbon dioxide Minor: TeCP, carbon dioxide, unidentified transformation products, unidentified volatile organic compounds, and unextracted residues	Slightly persistent in anaerobic soil	2923375
Mobility					
Adsorption/desorption in soil Soil 1: sandy loam, pH 6.2, 1.7% OC Soil 2: loamy sand, pH 4.9, 0.8% OC Soil 3: clay loam, pH 5.1, 3.3% OC Soil 4: loam, pH 7.1, 4.6% OC	PCP	K_d (L/kg): Soil 1: 86.61 Soil 2: 95.54 Soil 3: 335.4 Soil 4: 101.5 K_{oc}: Soil 1: 5095 Soil 2: 11 943 Soil 3: 10 165 Soil 4: 2206	N/A	Immobile to slightly mobile Mobility is related to pH. Mobility increases with increasing pH.	2917843
Adsorption/desorption in soil Soil 1: silty clay loam, pH 7.6, 4.7% OC Soil 2: sandy loam, pH 6.7, 1.7% OC	PCA	K_d (L/kg): Soil 1: 855.2 Soil 2: 255.2 Soil 3: 111.8 Soil 4: 686.4 K_{oc}:	N/A	Immobile	2917842

Property	Test substance	Value	Transformation products	Comments	PMRA#
Soil 3: loamy sand, pH 4.7, 0.8% OC Soil 4: clay loam, pH 5.1, 3.4% OC		Soil 1: 18 195 Soil 2: 15 011 Soil 3: 13 980 Soil 4: 20 188			
Wood leaching study	PCP	Loss of 13–22% of the initial PCP. No PCA was detected in wood exposed to soil over a period of 12 weeks, at least in the middle part of treated stakes.	N/A	N/A	2917844 with clarifications in 2917845

Table 2 Fate and behaviour in the aquatic environment from new studies submitted under the special review

Study type	Test material	Value	Transformation products	Comments	PMRA#
Abiotic transformation					
Phototransformation in water	PCA	DT_{50} (days): 33.8	Major: ROI-3 (not explicitly identified; suspected degradate of 2,3-dichloromaleic anhydride) Minor: ROI-2 (identified as 2,3-dichloromaleic anhydride), ROI-1 (not explicitly identified), and others (not explicitly identified)	Not expected to be a major route of transformation.	2801308

Study type	Test material	Value	Transformation products	Comments	PMRA#
Partitioning					
Adsorption/desorption in sediment River sediment: pH 5.6, 5.8% OC	PCP	K_d (L/kg): 2574 K_{oc}: 44 380	N/A	Immobile	2917843
Adsorption/desorption in sediment River sediment: pH 6.6, 4.3% OC	PCA	K_d (L/kg): 1427 K_{oc}: 33 178	N/A	Immobile	2917842
Bioaccumulation					
Bioconcentration	PCA	$BCF_{k\,GL}$: 5420 (low concentration) 6320 (high concentration) $BCF_{SS,L}$: 5780 (high concentration) Depuration half-life: 3.85 days (low concentration) 4.33 days (high concentration)	N/A	Steady state was not reached at the low concentration	2801304

Table 3 Toxic substances management policy (TSMP) considerations for pentachlorophenol (PCP) and pentachloroanisole (PCA): comparison to TSMP track 1 criteria.

TSMP Track 1 criteria	TSMP Track 1 criterion value	PCP	PCA
CEPA toxic or CEPA toxic equivalent	Enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.	Yes	Yes
Predominantly anthropogenic	Concentration in the environment is largely due to human activity relative to contributions from natural sources	Yes	Yes

TSMP Track 1 criteria	TSMP Track 1 criterion value		PCP	PCA
Persistence	Soil	Half-life ≥ 182 days	No Half-life 2 days to < 10 weeks	No Half-life 6 days to 5 weeks
	Water, sediment	Half-life ≥ 182 days (water) Half-life ≥ 365 days (sediment)	No Half-life < 4 weeks (water) Half-life < 20 weeks (sediment)	No Limited data are available.
	Air	Half-life ≥ 2 days or evidence of atmospheric transport	No Half-life < 2 days (direct photolysis) Half-life 19.43 days (with hydroxyls; modelled) Will ionize in water at environmentally relevant pH and unlikely to volatilize. Little evidence will undergo atmospheric transport.	Yes Direct photolysis unknown. Half-life 9.8 days (with hydroxyls; modelled) Likely to volatilize from water. Substantial evidence of atmospheric transport. Measured in air, particles, sediment, snow, and biota from remote areas.
	Other	• Evidence that PCA is formed from PCP in significant quantities under environmentally relevant conditions.		
Bioaccumulation	Log K_{ow}	≥ 5	No < 5 (at environmentally relevant pH)	Yes 5.45 (measured) 5.30 (modelled) 5.7 (calculated)
	BCF	≥ 5000	No < 1,000	Yes > 5,000
	Other	• Detected in higher trophic organisms in remote areas.		

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A. List of studies/information submitted by the registrant

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PMRA reference number	Reference
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2917849	2018, Pentachlorophenol: A Life Cycle Toxicity Test with the Midge (Chironomus dilutus) Using Spiked Sediment, DACO: 9.9
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B. List of additional information (not submitted by the registrant)

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B.2 Unpublished information

PMRA document number	Reference
2462786	British Columbia Ministry of Health. 2014. Monitoring data for pentachlorophenol in British Columbia drinking water distribution systems shared by Health Canada's Water Quality & Science Bureau following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received September 16, 2014, DACO: 8.6

PMRA document number	Reference
2463609	California Department of Pesticide Regulation (DPR). 2014. Surface Water Protection Program data for pentachlorophenol, downloaded October 6, 2014. https://www.google.com/fusiontables/DataSource?snapid=S954602gmYX, DACO: 8.6
2462710	Environment Canada. 2014. Air monitoring data of pentachloroanisole (PCA) in air at the Canadian High Arctic Station of Alert. Submitted following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data submitted September 24, 2014, DACO: 8.6
2469164	Environment Canada. 2014. Summary of detailed air monitoring data for pentachloroanisole (PCA) at the Canadian High Arctic Station of Alert, Nunavut. See PMRA 2462710 for general monitoring data for PCA at this station, DACO: 8.6
2462793	Government of Alberta. 2014. Email summarizing monitoring data for pentachlorophenol in Alberta municipal drinking water sources shared by Health Canada's Water Quality & Science Bureau following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Email received September 16, 2014, DACO: 8.6
2914809	Hung, Hayley, 2013, Air Monitoring of Pentachloroanisole (PCA) at Alert, Nunavut, Canada. Environment Canada, Annex F.
2472666	Ministère du Développement durable, de l'Environnement, et de la Lutte contre les changements climatiques. 2014. Monitoring data on pentachlorophenol in Quebec treated water and distributed water collected by water distribution systems between 2001 and 2013 as part of obligations of the 'Règlement sur la qualité de l'eau potable (RQEP). Data submitted following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received November 6, 2014, DACO: 8.6
2472670	Ministère du Developpement durable, de l'Environnement, et de la Lutte contre les changements climatiques. 2014. Monitoring data on pentachlorophenol in Quebec raw water, treated water and water in distribution systems collected between 2005 and 2014 as part of the drinking water surveillance program (Programme de surveillance de la qualité de l'eau potable). Data submitted following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received November 6, 2014, DACO: 8.6
2931385	Muir, D. 2013. Environment Canada. Information submitted in response to Annex E of the Convention.

PMRA document number	Reference
2462787	New Brunswick Department of Health. 2014. Monitoring data on pentachlorophenol in New Brunswick drinking water supplies shared by Health Canada's Water Quality & Science Bureau following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received September 16, 2014, DACO: 8.6
2171036	Ontario Ministry of the Environment. 2010. Unpublished groundwater monitoring data from Ontario's Provincial Groundwater Monitoring Network. Received September 2011, DACO: 8.6
2462788	Ontario Ministry of the Environment and Climate Change. 2014. Monitoring data on pentachlorophenol in Ontario drinking water supplies shared by Health Canada's Water Quality & Science Bureau following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received October 2, 2014, DACO: 8.6
2463575	Ontario Ministry of the Environment and Climate Change. 2014. Monitoring data on pentachlorophenol in Ontario groundwater from the provincial monitoring network of the Ontario Ministry of the Environment and Climate Change, Environmental Monitoring and Reporting Branch. Data submitted following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received October 6, 2014, DACO: 8.6
2462790	Saskatchewan Water Security Agency. 2014. Monitoring data on pentachlorophenol in Saskatchewan drinking water supplies shared by Health Canada's Water Quality & Science Bureau following the PMRA's September 2014 monitoring data request for the special review of pentachlorophenol. Data received September 16, 2014, DACO: 8.6
2463608	United States Environmental Protection Agency. 2014. Monitoring data for pentachlorophenol and pentachloroanisole in water, sediment and soil downloaded from the US EPA Storage and Retrieval (STORET) data warehouse on October 6, 2014. http://ofmpub.epa.gov/storpubl/dw_pages.querycriteria, DACO: 8.6
2463657	United States Geological Survey. 2014. USGS National Water Quality Assessment (NAWQA) program surface water, treated water, groundwater and sediment monitoring data for pentachlorophenol, from 2000 to 2014. Downloaded October 6, 2014. http://cida.usgs.gov/nawqa_public/apex/f?p=136:1:0, DACO: 8.6

PMRA document number	Reference
2463658	United States Geological Survey. 2014. USGS National Water Quality Assessment (NAWQA) program surface water, sediment and animal tissue monitoring data for pentachloroanisole, from 2000 to 2014. Downloaded October 6, 2014. http://cida.usgs.gov/nawqa_public/apex/f?p=136:1:0, DACO: 8.6
2462784	Water Quality Management Section, Manitoba Conservation and Water Stewardship. 2014. Monitoring data on pentachlorophenol in Manitoba surface water. Submitted in response to the PMRA's September 2014 monitoring data request as part of the special review for pentachlorophenol. Data submitted September 12, 2014, DACO: 8.6