Government of Canada / Gouvernement du Canada

Risk Management Scope

for

Certain Substituted Phenols, specifically:

Chemical Abstracts Service Registry Numbers (CAS RNs):
118-82-1
128-37-0
36443-68-2
61788-44-1

Environment and Climate Change Canada

Health Canada

January 2024

Canada

Summary of proposed risk management

This document outlines the risk management options under consideration for 4 of the 15 substances in the Substituted Phenols Group, which have been proposed to be harmful to the environment.

In particular, the Government of Canada is considering **regulatory and/or non-regulatory options for industrial formulation activities involving four substances in the Substituted Phenols Group**. For CAS RN 128-37-0 and 36443-68-2 that are proposed toxic and meet the persistence but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 2000), regulatory or non-regulatory initiatives are being considered that could set out **release limits, best practices or other requirements to limit releases of these substances**. For two substituted phenols that are proposed toxic and meet the criteria for both persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000) (CAS RNs 118-82-1 and 61788-44-1), **regulatory or mandatory initiatives** are being considered such as **regulations** to phase out manufacture, use, sale, offer for sale or import, or **regulations** to control releases to the lowest level of release that can be reliably measured.

Moreover, because certain data gaps to inform risk management decision-making remain, the following information should be provided (ideally on or before March 12, 2024), to the contact details identified in section 8 of this document, to inform risk management decision-making (more details on these topics can be found in section 3.5):

- Facility information, including annual quantities of substituted phenols manufactured, used, location, for specified sectors – or other industrial uses
- Use and presence in marine paints and coatings products
- Characterization, fate, and treatment of industry wastewater
- Industry best practices, techniques and technologies for minimizing losses/releases
- Provincial and municipal effluent contaminant limits
- Socio-economic impacts of proposed risk management options
- Substitutes or alternatives to the substituted phenols, including identification of uses for which no alternatives exist

Note: The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources. Risk management options may also evolve through consideration of assessments and risk management options or actions published

for other Chemicals Management Plan substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Although a risk to human health or the environment has not been identified at current levels of exposure for CAS RNs 96-69-5 and 98-54-4, there may be a concern for the environment if exposures were to increase. As a result, these substances may be considered in future initiatives to track their commercial status or identify new uses.

Other antioxidants have been identified as potential alternatives to the 4 substances which have been proposed to be harmful to the environment. Further information on alternatives can be found in section 6.1 of this document.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Government of Canada, 1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic to the environment and/or human health as set out in section 64 of CEPA[1,2], and if so, to manage the associated risks.

A group of 15 substances, listed in Annex A and referred to throughout this document as the Substituted Phenols Group, were included in the third phase of the Chemicals Management Plan (CMP) (Canada 2016).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint assessment of 15 substituted phenols in Canada. A notice summarizing the scientific considerations of the draft assessment for these substances was published in the *Canada Gazette*, Part I, on January 12, 2024 (Canada 2024). For further information, refer to the draft assessment for substituted phenols.

2.1 Draft assessment conclusion

On the basis of the information available, the draft assessment proposes that four substituted phenols (CAS RNs[3] 118-82-1, 128-37-0, 36443-68-2, and 61788-44-1) in the group are toxic under section 64(a) of CEPA because they are entering or may 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 (Canada, 2024). The draft assessment also

[1] Section 64 of CEPA: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is 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.*

[2] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude taking actions under other sections of CEPA or other Acts.

[3] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

proposes that the other 11 substances are not harmful to the environment at levels of exposure considered in the assessment.

The draft assessment proposes that the 15 substances in the substituted phenols group are not harmful to human health at levels of exposure considered in the assessment.

The draft assessment proposes that CAS RNs 128-37-0 and 36443-68-2 meet the criteria for persistence but not bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

The draft assessment also proposes that CAS RNs 118-82-1 and 61788-44-1 meet the criteria for persistence and bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

Although a risk to human health or the environment has not been identified at current levels of exposure for CAS RNs 96-69-5 and 98-54-4, there may be a concern for the environment if exposure to these substances were to increase. As a result, these substances may be considered in future initiatives to track their commercial status or to identify new uses or exposures.

A table summarising the draft assessment's proposed conclusions for all 15 substances in the Substituted Phenols Group can be found in Annex A.

The exposure sources of concern, identified in the draft assessment, are based on the potential for releases from industrial formulation activities, in particular from facilities located on small receiving water bodies which offer minimal dilution. A number of industrial formulation activities known to use one or more of the 15 substituted phenols were examined in the assessment, including formulation of fuel, formulation of fuel and lubricant additives, formulation of lubricants, formulation of paints and coatings, formulation of plastic and rubber additives, formulation of plastics and formulation of rubber. Estimated releases based on a small number of sites were shown to be a concern, primarily associated with formulation of plastics and formulation of plastic and rubber additives located on small receiving water bodies. As such, this document will focus on these industrial formulation activities (refer to section 5).

2.2 Proposed recommendation under CEPA

On the basis of the findings of the draft assessment conducted pursuant to CEPA, the Ministers propose to recommend that CAS RNs 118-82-1 and 61788-44-1 be added to Part 1 of Schedule 1 of CEPA and CAS RNs 128-37-0 and 36443-68-2, be added to Part 2 of Schedule 1 of CEPA[4]. Addition of a substance to Schedule

[4] After an assessment of a given substance under Part 5 of CEPA, other than section 83, the Ministers shall propose one of the following measures: take no further action with respect to the substance, add the substance to the List referred to in section 75.1 of the Act (unless the substance is already on that List), recommend the addition of the substance to Part 1 of the list of toxic substances of Schedule 1 to CEPA (for

1 to CEPA enables the Government to propose certain risk management measures under CEPA to manage potential ecological and human health risks associated with the substance.

Until regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic or toxic to reproduction are available, CAS RNs 128-37-0 and 36443-68-2 are proposed to be recommended for addition to Part 2 of Schedule 1. Following the availability of the aforementioned criteria, the substances may be moved to Part 1 of Schedule 1, if applicable.

CEPA sets out a 2-track approach for managing risks.

Under sub-section 77(3), the Ministers are required to propose recommending the addition of a substance that poses the highest risk, as defined in paragraph (a), (b) or (c), to Part 1[5] of Schedule 1 of the Act and, in developing a proposed regulation or instrument respecting preventive or control actions, to give priority to the total, partial or conditional prohibition of activities in relation to the substance or to the release of the substance into the environment.

For other substances recommended for addition to Part 2 of Schedule 1 of the Act, the Ministers shall give priority to pollution prevention, and this could include regulatory or non-regulatory measures such as prohibition if warranted.

CAS RNs 118-82-1 and 61788-44-1 are proposed to meet the criteria for substances that may have long-term harmful effects on the environment.

CAS RNs 128-37-0 and 36443-68-2 are proposed not to meet the criteria per sub-section 77(3) for addition to Part 1 of Schedule 1 of the Act.

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft assessment for the Substituted Phenols Group and this risk management scope document.

If the Ministers finalize the recommendation to add CAS RNs 118-82-1 and 61788-44-1 to Part 1 of Schedule 1 and CAS RNs 128-37-0 and 36443-68-2 to Part 2 of Schedule 1, risk management instruments must be proposed within 24 months from the date on which the Ministers recommended that the substances be added to Schedule 1 of CEPA, and finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

substances that pose the highest risk) or recommend the addition of the substance to Part 2 of the list of toxic substances in Schedule 1 to CEPA (for other CEPA-toxic substances).

3. Proposed risk management

3.1 Proposed environmental objectives

Proposed environmental objectives are quantitative or qualitative goals to address environmental concerns.

The proposed environmental objectives address the risks outlined in section 5 of this document. The proposed environmental objectives are:

1. **CAS RNs 128-37-0 and 36443-68-2, which meet the persistence but not the bioaccumulation criteria:**
   The proposed environmental objective for CAS RNs 128-37-0 and 36443-68-2 is to prevent or minimize adverse effects on the aquatic environment. The predicted no-effect concentrations (PNECs) derived for these substances may be used as a goal to achieve this objective.

2. **CAS RNs 118-82-1 and 61788-44-1, which meet the persistence and bioaccumulation criteria:**
   The proposed environmental objective for CAS RNs 118-82-1 and 61788-44-1 is to prevent or minimize adverse effects on the aquatic environment. Either a level of quantification (LoQ) or a PNEC may be used as a measurable objective, whichever is lower[5]. Furthermore, given that CAS RNs 118-82-1 and 61788-44-1 may have a long-term harmful effect on the environment, and that they are persistent, bioaccumulative, and inherently toxic, the ultimate environmental objective for these substances will be elimination via prohibition, in order to prevent or minimize adverse effects on the environment, in accordance with subsection 90(1.1) of CEPA.

3.2 Proposed risk management objectives

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools. The proposed risk management objectives are:

1. **CAS RNs 128-37-0 and 36443-68-2, which meet the persistence but not the bioaccumulation criteria:**
   The proposed risk management objective for CAS RNs 128-37-0 and 36443-68-2 is **to limit concentrations of the substances released from industrial formulation facilities** to water, to levels that are protective of the aquatic environment, taking into account technical and economic feasibility and consideration of socio-economic factors.

[5] An LOQ has not been determined at this time.

2. **CAS RNs 118-82-1 and 61788-44-1, which meet the persistence and bioaccumulation criteria:**

   The proposed risk management objective for CAS RNs 118-82-1 and 61788-44-1 is **to prevent or minimize releases of the substances** to the aquatic environment to the greatest extent practicable, taking into account technical and economic feasibility and consideration of socio-economic factors.

These objectives will be refined on the basis of stakeholder consultation and new information, the proposed risk management actions, the outcome of the assessment, and socio-economic and technical considerations (refer to section 6). Revised environmental and risk management objectives will be presented in the Risk Management Approach document that will be published concurrently with the assessment for substituted phenols.

3.3 Proposed risk management options under consideration

To achieve the proposed risk management objectives and to work towards achieving the proposed environmental objectives, the risk management options under consideration are the following:

- For CAS RNs 128-37-0 and 36443-68-2, **regulatory and non-regulatory initiatives** are being considered. These could include **regulations, pollution prevention planning notices, codes of practice, environmental release guidelines or performance agreements**, which could set out release limits, best practices or other requirements that will limit releases of these substances from industrial formulation facilities to the aquatic environment.
- For CAS RNs 118-82-1 and 61788-44-1, regulatory or other mandatory initiatives are being considered such as:
  - **Regulations to prohibit** the manufacture, use, sale, offer for sale or import of the substances or products containing the substances;
  - **Regulations which set out release limits and/or other requirements** to achieve the lowest level of release that can be reliably measured.

Note that these proposed risk management options are preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will also be considered in the instrument selection and development process[6]. The risk management options may also evolve through consideration of assessments and risk management

[6] The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulation (TBS, 2018), the Policy on Regulatory Development (TBS 2018), the Red Tape Reduction Action Plan (TBS, 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015).

options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.4 Performance measurement evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[7]. ECCC and HC have developed a Performance Measurement Evaluation Strategy that sets out the approach to evaluate the effectiveness of actions taken on substances found toxic under CEPA. The aim is to determine whether environmental objectives have been met and whether there is a need to revisit the risk management approach for that substance. Selection of a substance for performance measurement evaluation is conducted through readiness, prioritization and workplanning as outlined in the Performance Measurement Evaluation Strategy. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time.

The Government of Canada may plan to measure the effectiveness of the risk management actions and the progress towards meeting the risk management and environmental objectives for CAS RNs 118-82-1, 128-37-0, 36443-68-2, and 61788-44-1.

To do so, the Government of Canada may collect and analyze data, such as monitoring data obtained from the CMP monitoring and surveillance program on the environmental presence of one or more of CAS RNs 118-82-1, 128-37-0, 36443-68-2, and 61788-44-1 in surface water, sediment, wastewater treatment system effluents and biosolids.

When undertaken, the results of performance measurement and evaluation are used to inform whether further risk management action is warranted and are made available to Canadians along with recommendations for further action, if applicable.

[7] Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (that is, evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (that is, evaluate whether human health and/or environmental objectives have been met).

For more information on performance measurement evaluation (including Health Canada and Environment and Climate Change Canada's Performance Measurement Evaluation Strategy) please visit Performance measurement for toxic substances - Canada.ca.

3.5 Risk management information gaps

Interested stakeholders can provide further information to inform risk management decision-making regarding CAS RNs 118-82-1, 128-37-0, 36443-68-2, and 61788-44-1, including:

Substitutes or alternatives

- Substitute or alternative substances to the substituted phenols proposed to be harmful to the environment;
- Uses of the proposed toxic substituted phenols for which no alternatives currently exist, including information on the functional use of the substance(s), products containing the substance(s), the concentration (w/w%) of the substance(s) in final products, processes involving the substance(s), and annual use quantity;

Facility Information & Use

- The location of each industrial formulation facility, and their annual quantity of each substituted phenol or their annual quantity and concentration (w/w%) of each substituted phenols-containing products, used in industrial formulation activities, including but not limited to formulation of lubricants, fuel and lubricant additives, paints and coatings, plastics, rubber, and plastic and rubber additives;
- Annual quantity and concentration (w/w%) of substituted phenols-containing products sold to downstream users, along with their sector(s) of activity;
- Information with respect to marine paints and coatings products that may be applied to ships, including the annual quantity and concentration (w/w%) of each substituted phenols-containing product used and the types of ships treated with substituted phenols-containing products, in particular those containing CAS RN 61788-44-1;
- Industrial uses of these substituted phenols, other than the formulation activities listed above;
- Any other uses (for example, commercial, institutional, consumer, etc.) of CAS RNs 118-82-1 and 61788-44-1;

Characterization in Wastewater

- Characterization of these substituted phenol substances in final wastewater effluents released from industrial formulation and manufacturing facilities;

Additional Information

- Provincial and municipal effluent contaminant limits (for example, oil and grease, phenols, etc.) and/or other requirements respecting effluents that facilities using these substances must comply with;
- Fate and behaviour of antioxidants/substituted phenols during plastics recovery or recycling;
- Potential socio-economic impacts of proposed risk management.

Stakeholders that have information to help address these gaps should provide it on or before March 12, 2024 to the address identified in section 8.

4. Background

4.1 General information on certain substituted phenols

Pursuant to section 68 or 74 of CEPA, the Ministers have conducted an assessment of 15 substances referred to collectively under the CMP as the Substituted Phenols Group. As outlined in section 2.1 of this document, the draft assessment proposes that CAS RNs 118-82-1, 128-37-0, 36443-68-2, and 61788-44-1 are toxic under section 64(a) of CEPA.

Of the four substances proposed toxic, one (CAS RN 128-37-0) occurs naturally in the environment (Gharbi et al. 2017; Aourahoun et al. 2014; Babu and Wu 2008; Usman et al. 2016). The remaining three substances do not occur naturally in the environment. Three substances (CAS RNs 118-82-1, 128-37-0 and 36443-68-2) are discrete substances. CAS RN 61788-44-1 is a substance of unknown or variable composition, complex reaction products or biological materials, consisting of components of monostyrenated phenol (non-hindered phenol), distyrenated phenol (partially hindered phenol), and tristyrenated phenol (fully-hindered phenol).

Substances in this group were included in surveys issued pursuant to section 71 of CEPA (EC 2009, 2013; ECCC 2017). Of the 4 proposed toxic substances, all were reported to have import in Canada above the 100 kg reporting threshold; additionally, 2 substances were also reported to be manufactured in Canada above the 100 kg reporting threshold. As reported manufacture quantities were low (<1,000 kg per year), the manufacture of substituted phenols is not considered to be a major activity in Canada. Table 1 presents a summary of information reported for manufacture and import quantities in Canada for the four proposed toxic substances (EC 2009, 2013; ECCC 2017).

Table 1. Canadian manufacturing and imports for 4 substances in the Substituted Phenols Group proposed to be harmful to the environment

CAS RN	Total manufacture (kg)[a]	Total imports (kg)[a]	Reporting year
118-82-1	Not reported [b]	10 000 – 100 000	2008
128-37-0	100 – 1 000	100 000 – 1 000 000	2011
36443-68-2	Not reported [b]	10 000 – 100 000	2008, 2016
61788-44-1	100 – 1 000	1 000 – 10 000	2011

[a] Values reflect quantities reported in response to the surveys conducted under section 71 of CEPA (Environment Canada 2009; 2013, ECCC 2017). See surveys for specific inclusions and exclusions.
[b] There is no report of manufacturing above the 100 kg reporting threshold for the reporting year.

4.2 Current uses and identified sectors

Substances in the Substituted Phenols Group are used primarily as antioxidants as a processing aid in industrial formulation and to help extend service life and product use in a wide variety of industrial and consumer applications. Based on reported use quantities, these substances are used in Canada mainly as lubricant and fuel additives, plastic and rubber additives, lubricants, fuels, plastic products, rubber products, and paints and coatings. Lower-volume uses include personal care products, as a component in the manufacture of food packaging materials, adhesives and sealants, and fabric and textiles (EC 2009, 2013; ECCC 2017; information received under the *Fuels Information Regulations, No. 1*). These substances may also be found in automotive care products, fillers, colouring and odour agents, surface treatment products, electronics, cosmetics, air fresheners, glow sticks, hunting accessories, stamp pads, wood epoxy glue and other do-it-yourself products (ECCC, HC 2020). Substances such as phenolic antioxidants or polyphenols may also be naturally occurring in plant-based materials (foods, lignins) or released through processing of such materials (Ho et al. 1992; KA Jung et al. 2015).

No monitoring data in environmental media were identified for substances in the Substituted Phenols Group in Canada; however, measured concentrations in influent, effluent, and biosolid samples from selected Canadian wastewater treatment systems have been reported for eight substances in the group. These substances were detected in samples collected from both influent and effluent streams at primary, secondary and lagoon wastewater treatment systems (Lu et al. 2019).

5. Exposure sources and identified risks

Point source releases of these substances are expected to occur during their use in various industrial applications. Surface water is expected to be the main receiving compartment following release through wastewater treatment systems. After entering surface water, these substances may partition to sediment to some extent, depending on their water solubility and partition coefficients. These substances may also enter soil from wastewater treatment system biosolids, which are commonly used for soil enrichment.

All four of the proposed toxic substances are expected to be persistent and have a long residence time in the environment. CAS RNs 118-82-1 and 61788-44-1 are expected to be bioaccumulative.

Releases of one or more of the toxic substituted phenols from industrial formulation sites that are predicted to occur at levels of concern were sites associated with small receiving water bodies which offer minimal dilution. The major identified industrial sectors where the four proposed toxic substances are reported to be used can include (ECCC, HC 2020; OECD 2004a, 2004b, 2009a, 2009b):

- *Formulation of lubricant and fuel additives*: losses to wastewater through raw material handling and packaging of the final additive package.
- *Formulation of plastic and rubber additives*: losses to wastewater through raw material handling and compounding of raw additive powders of certain particle sizes.
- *Formulation of lubricants*: losses to wastewater during raw material handling and packaging of the final lubricant.
- *Formulation of plastics products*: losses to wastewater during raw material handling, compounding and conversion of raw additive powders of certain particle sizes. Losses are initially to the atmosphere as dust or fume which may settle and enter wastewater through facility washdown.
- *Formulation of rubber products*: losses to wastewater during raw material handling, compounding and conversion. These can include direct cooling water, wastewater from air treatment, wastewater from vulcanisation, as well as washing and cleaning of production tools and processes.
- *Formulation of paints and coatings*: losses to wastewater during equipment cleaning.

Additional sector uses include formulation of fuels, the formulation of personal care products, and the use of personal care products. CAS RN 61788-44-1 is also used in marine coating products that may be applied to ships.

6. Risk management considerations

6.1 Alternatives and alternate technologies

Substituted phenols are used as antioxidants to prevent oxidation during formulation and/or to extend the service life of the formulated product. Other antioxidants are available, but their interchangeability with substituted phenols is unknown, as is their suitability across formulation processes or product types. Not all alternatives may be appropriate or provide the equivalent result in quality or stability to a product. Other antioxidants can include: organophosphites, amines and thioesters (AccuStandard 2019; Zeifel et al. 2009). Among potential substitutes, alkyl aryl phosphites which are used as secondary antioxidants have been assessed and found to not be posing a risk to human health or the environment based on the quantities and exposure conditions considered at the time of the assessment, while aromatic amines are currently under assessment (ECCC, HC 2019).

Other substituted (hindered) phenols have been assessed. Suitability as alternatives should take into consideration hazard and exposure characterization in the assessment and the potential to cause harm to the environment and/or human health. Previously assessed substituted phenols include (EC 2011a, 2011b; EC, HC 2009, 2010; ECCC, HC 2016):

- 2,4,6-TTBP (CAS RN 732-26-3) and DTBSBP (CAS RN 17540-75-9) were assessed as toxic (section 64(a)).
- MBMBP (CAS RN 119-47-1) and benzenepropanoic acid ester (CAS RN 70331-94-1) were assessed as not toxic, taking into consideration the quantities and exposure conditions considered at that time.
- Methylstyrenated phenol (MSP) (CAS RN 68512-30-1) was assessed as not toxic in 2008 as no industrial activities in relation to the substance were identified at the time and therefore it was not entering the environment at levels that could have posed a risk to human health or to the environment (Canada 2008). However, given the persistent, bioaccumulative, and inherently toxic properties, the Significant New Activity provisions were applied. This substance is undergoing re-assessment following the receipt of multiple Significant New Activity Notifications and has been proposed toxic (ECCC, HC 2021).

Although a risk to human health or the environment has not been identified at current levels of exposure for CAS RNs 96-69-5 and CAS RN 98-54-4, there may be a concern for the environment if exposures to these substances were to increase. CAS RN 98-54-4 is also present in marine coatings and could be used as a potential alternative to MSP or CAS RN 61788-44-1. As a result, these substances may be considered in future initiatives to track their commercial status or identify new uses. Some of the above-mentioned substances have been identified as potential alternatives to one or more of the 4 substituted phenol substances which have been proposed to be harmful to the environment. Therefore, changes in use patterns for these substances, such as using them as an alternative for chemicals with similar uses or functions, could lead to higher levels of exposure, which could pose a risk to the environment or human health.

As MSP and CAS RN 61788-44-1 are proposed for elimination via prohibition, there could be additional concerns in the future if CAS RN 98-54-4 is used more broadly (that is as a substitute for other substituted phenols).

No information was found regarding technological alternatives to the use of substituted phenols in industrial formulation activities.

6.2 Socio-economic and technical considerations

Antioxidants, such as substituted phenols, help to prolong the life of products by preventing their degradation from exposure to oxygen. Degradation can include loss of strength, breakdown or discolouration. In preventing or slowing down these types of degradation, the antioxidants prolong the service life of the product and delay the need for replacement or repair.

As outlined in section 4, releases of substituted phenols result primarily through material losses during handling and processing, as well as from equipment and plant cleaning. Various best available techniques and best environmental practices to prevent and minimize these types of losses are likely available. However, the effectiveness of such techniques and practices to limit releases to levels protective

of the environment is not known. Available techniques and practices will range from sector to sector, and could include, for example (ChemTrac 2010; European Commission 2007):

- Use of oil/water separators to remove oil from oily wastewater prior to disposal or discharge.
- Use of activated carbon to remove soluble organics from contact cooling and heating water.
- Installation of closed-loop water cooling or heating systems to reduce water contamination through reuse and recycling.
- Pre-rinsing of equipment in contact with harmful substances and collection of the first rinsate for destruction or disposal in a secure landfill.
- Use of automated dispensing equipment for chemicals to reduce waste due to spills from manual dispensing, and to provide quality control.

For the substituted phenols (see section 3.1) where prohibition is among the options to achieve the lowest level of release possible, all uses of the substance will need to be given consideration of socio-economic impacts.

As noted in section 7, Canada has established an agenda to address plastic waste and pollution (Canada 2019; CCME 2019). In moving toward Canada's goal of zero plastic waste, the entire lifecycle of plastic will need to be considered, including the toxic substances contained in some plastics. As such, consideration of the fate of substituted phenols in plastics recovery and recycling and potential controls to prevent releases of substituted phenols through the plastics lifecycle may also be needed in light of new efforts or requirements to increase recycling of plastics and to increase the recycled content of plastics in recycled products.

Socio-economic factors will be considered in the selection process for a regulation or instrument respecting preventive or control actions, and in the development of the risk management objectives as per the guidance provided in the Treasury Board document Policy on Regulatory Development (TBS 2018).

In addition, socio-economic factors will be considered in the development of regulations, instrument(s) or tool(s), to address risk management objective(s), as identified in the Cabinet Directive on Regulation (TBS 2018) and Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

7. Overview of existing risk management

7.1 Related Canadian risk management context

No risk management actions specific to releases of the four substituted phenols proposed toxic from industrial formulation activities were identified in Canada.

CAS RN 128-37-0 is the only substituted phenol that is listed on the National Pollutant Release Inventory with a threshold category of 1A, which means a report is required from a facility if the substance is manufactured, processed or otherwise used at a concentration ≥ 1% by weight and in a quantity of 10 tonnes or more, and employees work 20,000 hours or more at a facility (Canada 2017). In 2017, one facility reported 1 kg of releases of CAS RN 128-37-0 (NPRI, 1994-2017).

Effluent discharge limits or other wastewater discharge requirements may be set for industrial facilities engaged in formulation activities at the provincial or municipal level, including parameters such as phenols, phenolics or oil and grease. These requirements may influence the release of substituted phenols to the aquatic environment.

The Government of Canada adopted the Ocean Plastics Charter in 2018, which lays the groundwork to ensure plastics are designed for reuse and recycling (Canada 2022). Also, in 2018, the Canadian Council of Ministers of the Environment agreed to work collectively toward a common goal of zero plastic waste, and approved in principle a Canada-wide strategy on zero plastic waste (CCME 2018). The strategy provides a framework for action to better prevent, reduce, reuse, recover, and clean up plastic waste.

In 2019 and 2020, federal, provincial and territorial environment ministers released two phases of the Action Plan on Zero Plastic Waste. The Phase 1 Action Plan will focus on a number of result areas including support for recycling infrastructure. Efforts to increase the recycling of plastics as well as to increase recycled content in plastic products may influence the use of antioxidants such as substituted phenols in plastic materials The Canadian Council of Ministers of the Environment has endorsed a 50% recycled content requirement in plastic products, where applicable, by 2030. Incidental releases of substituted phenols from plastics recycling processes may need to be examined as emerging plastic regulations are adopted.

7.2 Pertinent international risk management context

7.2.1 United States

At the federal level in the United States (US), all four substances are labeled as active commercial substances in the *Toxic Substances Control Act* (TSCA) Inventory (US EPA 2022). If a specified quantity threshold is met, manufacturers and importers may be required to report information on the substance to the United States Environmental Protection Agency under the TSCA's Chemical Data Reporting Rule.

The CAS RNs 118-82-1, 128-37-0, 36443-68-2 and 61788-44-1 are present in registered pesticides under the *Federal Insecticide, Fungicide, and Rodenticide Act.* CAS RNs 128-37-0, 36443-68-2 and 61788-44-1 are approved for non-food use, CAS RN 118-82-1 and 128-37-0 are approved for fragrance use, and CAS

RNs 128-37-0 and 36443-68-2 are approved for food use (US eCFR 2023a, US eCFR 2023b).

The Manufacture of Amino/Phenolic Resins: National Emission Standards for Hazardous Air Pollutants is a facility-based standard to reduce emissions of hazardous air pollutants (HAPs) from existing and all new facilities that manufacture amino resins or phenolic resins. The US defines HAPs as toxic air pollutants known or suspected to cause cancer or other serious health effects, or adverse environmental effects. While the four proposed toxic substances are not specifically listed as this is a facility-based standard, it does note that the source category includes any facility that manufactures synthetic resin obtained by phenol or substituted phenols (US EPA 2018).

7.2.2 European Union

No risk management actions specific to releases of the four proposed toxic substances from industrial formulation activities were identified in the European Union (EU). However, two of the four substances are being further evaluated.

All four proposed toxic substituted phenols are registered under the Registration, Evaluation, Authorization, and Restrictions of Chemicals regulations of the EU due to their adverse effects on human health and the environment (ECHA 2023a).

The CAS RNs 118-82-1, 128-37-0, and 61788-44-1 are included on the Community Rolling Action Plan (CoRAP) List for evaluation (ECHA 2023b)[8]. The evaluation for CAS RNs 118-82-1 and 128-37-0 is ongoing and may lead to additional risk management measures. The evaluation for CAS RN 61788-44-1 has a conclusion under preparation and may also lead to additional risk management measures.

7.2.3 Australia

No risk management actions specific to releases of the four proposed toxic substances from industrial formulation activities were identified in Australia. In Australia, the four substituted phenols are listed on the Australian Inventory of Industrial Chemicals and can only be used commercially by registered manufacturers and importers, though registered manufacturers and importers are not required to notify the Australian Government of their activities with the substance under the Australian Industrial Chemicals Introduction Scheme (AICIS 2023).

7.3.1 Risk management alignment

There is limited risk management alignment between Canada and risk management actions undertaken in the US, the EU, and Australia, as Canada appears to be the first jurisdiction to propose preventive or control actions to

[8] The grounds for including one of the substances on the evaluation list include potential endocrine disruptor, high aggregated tonnage, suspected CMR (carcinogenic, mutagenic or toxic for reproduction), suspected PBT/vPvB (persistent, bioaccumulative, and toxic, or very persistent and very bioaccumulative), suspected sensitizer, consumer use, exposure of environment, exposure of workers, wide dispersive use, exposure of sensitive populations and suspected reprotoxic.

address releases of these four substances to the aquatic environment from industrial formulation activities. While the substances are suspected of being of concern in other jurisdictions, no restrictions or controls have yet been applied. Other identified requirements focus primarily on reporting. Inclusion of three of the four substances on the EU's CoRAP list indicates that the substances have or will undergo evaluation by a Member State which may lead to EU-wide risk management measures such as restrictions or other actions (ECHA 2023b).

8. Next steps

8.1 Public comment period

Industry and other interested stakeholders are invited to submit comments on the content of this document or other information that would help to inform decision-making (such as outlined in section 3). Please submit additional information and comments prior to March 12, 2024.

If the final assessment confirms that CAS RNs 118-82-1, 128-37-0, 36443-68-2, and 61788-44-1 are toxic, a risk management approach, outlining and seeking input on the proposed risk management instruments, would be published concurrently with the assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on the risk management scope should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Plan
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: substances@ec.gc.ca

Companies who have a business interest in substituted or hindered phenols are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding substituted phenols and may be contacted for further information.

Stakeholders and members of the public who are interested in being notified of CMP publications are invited to subscribe for the latest news on the CMP. Stakeholders and members of the public who would like to receive CMP Publication Plans on a quarterly basis by email, can contact: substances@ec.gc.ca.

8.2 Timing of actions

Electronic consultation on the draft assessment and risk management scope: January 12, 2024 to March 12, 2024. This should include the submission of public comments, additional studies and information on the substituted phenols.

Publication of responses to public comments on the draft assessment and risk management scope: concurrent to the publication of the assessment and, if required, the risk management approach.

Publication of responses to public comments on the risk management approach, if applicable and if required, the proposed instruments: At the latest, 24 months from the date on which the Ministers recommended that certain substituted phenols be added to Schedule 1 of CEPA.

Consultation on the proposed instruments, if required: 60-day public comment period starting upon publication of each proposed instrument.

Publication of the final instruments, if required: At the latest, 18 months from the publication of the preceding proposed instrument.

These are planned timelines, and are subject to change.

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ANNEX A. substituted phenols – identifiers and assessment summary

CAS RN[9]	DSL Name (English)	Common Name/Acronym/ Trade Names	Assessment Conclusion	Persistence and Bioaccumulation[10]	Proposed for Part 1 of Schedule 1
85-60-9	Phenol, 4,4'-butylidenebis[2-(1,1-dimethylethyl)-5-methyl-		Proposed to not meet the criteria of CEPA s. 64		
96-69-5	Phenol, 4,4'-thiobis[2-(1,1-dimethylethyl)-5-methyl-	AO44S25 Antioxidant 300 Lowinox TBM-6 Santonox R Santowhite Crystals Sumilizer WX-R Sumilizer WX-RC	Proposed to not meet the criteria of CEPA s. 64 Identified as having a high hazard of environmental concern		
96-76-4	Phenol, 2,4-bis(1,1-dimethylethyl)-	2,4-DTBP	Proposed to not meet the criteria of CEPA s. 64		
98-54-4	Phenol, 4-(1,1-dimethylethyl)-	KPA-1800 KPT-F1360 KPT-S1503 p-tert.-Butylphenol SONGNOX PTBP	Proposed to not meet the criteria of CEPA s. 64 Identified as having a high hazard of environmental concern		
118-82-1	Phenol, 4,4'-methylenebis[2,6-bis(1,1-dimethylethyl)-	TMBD, AO-702, ANTIOXIDANT E702, IONOL 220	Toxic - Proposed to meet the criteria of CEPA s. 64(a)	Meets Persistence and Bioaccumulation criteria	Meets the criteria for Part 1 of Schedule 1
128-37-0	Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	BHT 4-HYDROXY-3,5-DI-TERT-BUTYLTOLUENE 4-methyl-2,6-di-tert-butylphenol antioxidant premix (BHT) of technical grade Agidol 1 BHT of technical grade antioxidant premix, of A and B types	Toxic - Proposed to meet the criteria of CEPA s. 64(a)	Meets Persistence criteria; Does not meet Bioaccumulation criteria	

[9] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

[10] Persistence and bioaccumulation information are presented for substances assessed as toxic.

CAS RN[9]	DSL Name (English)	Common Name/Acronym/ Trade Names	Assessment Conclusion	Persistence and Bioaccumulation[10]	Proposed for Part 1 of Schedule 1
		BUTYLATED HYDROXY TOLUENE P-CRESOL, 2,6-DI-TERT-BUTYL-			
128-39-2	Phenol, 2,6-bis(1,1-dimethylethyl)-	2,6-DTBP Ethanox 701 Ethyl 701 Ethyl AN 701 Irganox L 140 Isonox 103 TK 12891	Proposed to not meet the criteria of CEPA s. 64		
1843-03-4	Phenol, 4,4',4''-(1-methyl-1-propanyl-3-ylidene)tris[2-(1,1-dimethylethyl)-5-methyl -	AO-CA	Proposed to not meet the criteria of CEPA s. 64		
2082-79-3	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, octadecyl ester	Irganox 1076, Hostanox 016 FF Hostanox 016 P	Proposed to not meet the criteria of CEPA s. 64		
4221-80-1	Benzoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, 2,4-bis(1,1-dimethylethyl)phenyl ester	UV-120	Proposed to not meet the criteria of CEPA s. 64		
6386-38-5	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, methyl ester		Proposed to not meet the criteria of CEPA s. 64		
35958-30-6	Phenol, 2,2'-ethylidenebis[4,6-bis(1,1-dimethylethyl)-	AO22E46	Proposed to not meet the criteria of CEPA s. 64		
36443-68-2	Benzenepropanoic acid, 3-(1,1-dimethylethyl)-4-hydroxy-5-methyl-, 1,2-ethanediylbis(oxy-2,1-ethanediyl) ester	AO-245	Toxic - Proposed to meet the criteria of CEPA s. 64(a)	Meets Persistence criteria; Does not meet Bioaccumulation criteria	
41484-35-9	Benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, thiodi-2,1-ethanediyl ester		Proposed to not meet the criteria of CEPA s. 64		
61788-44-1	Phenol, styrenated	HIRENOL PL 500 Novares LS Novares YS	Toxic - Proposed to meet the criteria of CEPA s. 64(a)	Meets Persistence criteria and Bioaccumulation criteria	Meets the criteria for Part 1 of Schedule 1