

Prohibition of Certain Toxic Substances Regulations, 2012

Statutory authority

Canadian Environmental Protection Act, 1999

Sponsoring departments

Department of the Environment and Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Executive summary

Issue: Risk assessments on four substances — Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST), short-chain chlorinated alkanes, polychlorinated naphthalenes (PCNs) and tributyltins (TBTs) for non-pesticidal uses — were conducted under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). These assessments concluded that all of these substances may be harmful to the environment. Short-chain chlorinated alkanes were also found to constitute a danger in Canada to human life or health. Risk management measures are necessary to prevent harm to the environment and human health associated with these substances. In addition, all of these substances were found to meet the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations*.

Description: The proposed *Prohibition of Certain Toxic Substances Regulations, 2012* (hereafter the proposed Regulations) would prohibit the manufacture, use, sale, offer for sale or import of BNST, short-chain chlorinated alkanes, PCNs and TBTs in Canada, and of products containing them. These substances would be added to the substances already controlled under the *Prohibition of Certain Toxic Substances Regulations, 2005* and their subsequent amendments (collectively referred to as the current Regulations).

Under the proposed Regulations, a two-year temporary permission would be provided for specified BNST uses to allow industry to conduct additional research to determine new formulations and to obtain international product level performance certification for redesigned products containing substitutes to BNST. As well, the prohibition would not apply to a specified product containing TBTs below a concentration limit.

The proposed Regulations would also address a number of issues related to the clarity and consistency of the regulatory requirements which were identified by stakeholders and by the Standing Joint Committee for the Scrutiny of Regulations. The proposed Regulations also include additional provisions on reporting as well as administrative changes.

Also included in the proposed Regulations is a modification to the existing restrictions on hexachlorobenzene (HCB).

The proposed Regulations would repeal and replace the current Regulations.

Cost-benefit statement: A cost-benefit analysis was conducted to evaluate the impact of the proposed Regulations. In general, most of the impacts would occur as a result of controlling BNST; the other substances are not manufactured and are no longer in use in Canada. These impacts are summarized below.

Most of the costs would be incurred by Canadian manufacturers of lubricant oils as they would

have to pay a higher price to acquire BNST-free chemical additive products to produce their lubricant oils. The present-value of the total incremental cost to industry is estimated to be about \$18 million over the 25-year period of analysis. However, on a per facility basis, this cost represents only 0.01% of production cost. It is assumed that these costs would be passed on to consumers.

The federal government is expected to incur costs to administer and enforce the proposed Regulations when they come into force. The present value of the incremental cost to Government is estimated to be about \$0.41 million over 15 years.

It was not possible to fully, quantitatively estimate the benefits associated with the proposed Regulations, but positive benefits are expected in terms of the protection to the environment and its aquatic ecosystems. In addition, the proposed Regulations would prevent potential harm to human health as a result of exposure to short-chain chlorinated alkanes. Overall, the net impact of the proposed Regulations is expected to be positive.

Business and consumer impacts: With respect to controlling BNST, the proposed Regulations are not expected to have significant impacts on businesses in Canada. Due to the use of substitute chemical additive products, there would be a small increase in price of manufactured automotive lubricants. However, this price increase is not expected to put Canadian manufacturers at a competitive disadvantage. Consumers may incur an estimated increase in price of 0.5¢/L to acquire these new automotive lubricants.

Short-chain chlorinated alkanes and PCNs are not manufactured and are no longer in use in Canada. Tributyltins for non-pesticidal uses are not manufactured and are not in use as pure substances in Canada. As such, no impacts are expected on any businesses that would involve these substances.

Domestic and international coordination and cooperation: Recent amendments to the Protocol on Persistent Organic Pollutants (POPs) under the United Nations Economic Commission for Europe (UNECE) Convention on Long-range Transboundary Air Pollution (LRTAP) have included the addition of PCNs and short-chain chlorinated alkanes. Parties to the Protocol are required to control the import, production and use of these substances. The implementation of the proposed Regulations would allow Canada to consider ratifying the amendments to LRTAP.

Issue

The following chemical substances were assessed under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) to determine whether they meet any of the criteria set out under section 64 of CEPA 1999:

- Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST);
- Short-chain chlorinated alkanes, previously identified as short-chain chlorinated paraffins;
- Polychlorinated naphthalenes (PCNs) [chlorinated naphthalenes containing more than one chlorine atom]; and
- Tributyltins (TBTs) for non-pesticidal uses. ([see footnote 1](#))

The scientific evaluations for each of these substances found that

- The substance BNST may be harmful to aquatic organisms at low concentrations and it may biomagnify in food chains;
- Short-chain chlorinated alkanes may be harmful to certain aquatic species (for example, *Daphnia magna*) at low concentrations and are potentially harmful to humans via environmental exposure;
- PCNs may be harmful to aquatic organisms at relatively low concentrations, as well as mammals (particularly cattle) after short-term exposure at relatively low doses; and
- TBTs for non-pesticidal uses may harm various aquatic species, such as fish and molluscs and have the potential to induce sex reversal in some marine fish at low concentrations.

In addition, all of these substances were found to meet the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations*.

The final risk assessment reports on these substances concluded that 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. Therefore, they meet the criterion set out under paragraph 64(a) of CEPA 1999. In addition, short-chain chlorinated alkanes are also entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. Therefore, short-chain chlorinated alkanes further meet the criterion set out under paragraph 64(c) of CEPA 1999. Risk management measures need to be put in place to prevent harmful effects on the environment and, in the case of short-chain chlorinated alkanes, harmful effects on human health associated with these substances.

In addition, Environment Canada has identified improvements that could be made to clarify existing restrictions for hexachlorobenzene (HCB). A number of issues related to the clarity and consistency of the regulatory requirements were identified by stakeholders and by the Standing Joint Committee for the Scrutiny of Regulations and need to be addressed.

Objectives

The proposed *Prohibition of Certain Toxic Substances Regulations, 2012* (the proposed Regulations), developed under subsection 93(1) of CEPA 1999, have the following objectives:

- preventing potential risks of harm to the Canadian environment and human health, if applicable, by prohibiting the manufacture, use, sale, offer for sale or import of BNST, short-chain chlorinated alkanes, PCNs, and TBTs for non-pesticidal uses as well as products containing these substances;
- modifying the existing restrictions on HCB; and
- consolidating the *Prohibition of Certain Toxic Substances Regulations, 2005* (the 2005 Regulations) and the subsequent amendments, streamlining the regulatory text, and improving its clarity and consistency.

Description

1. Existing Regulations

The 2005 Regulations prohibit the manufacture, use, sale, offer for sale or import of the toxic substances — or products containing them — listed in Schedules 1 and 2. Schedule 1 lists toxic substances that are subject to total prohibition with the exception of incidental presence. Schedule 2 lists toxic substances that are subject to prohibitions at certain concentrations or for certain uses.

2. Proposed Regulations

The proposed Regulations are developed to manage the risks to the environment and, where applicable, to human health posed by these substances. In addition, in light of the issues identified with respect to the 2005 Regulations, the proposed Regulations would consolidate and provide more clarity and consistency to the existing regulatory requirements. The proposed Regulations are described below.

2.1 Addition of substances to Part 1 of Schedule 1

The proposed Regulations would add short-chain chlorinated alkanes and PCNs to Part 1 of Schedule 1 as well as move HCB from Part 2 to Part 1 of Schedule 1, thereby prohibiting all manufacture, use, sale, offer for sale or import of short-chain chlorinated alkanes, PCNs and HCB as well as products containing these substances, unless incidentally present. There is currently no manufacture or use of short-chain chlorinated alkanes, ([see footnote 2](#)) HCB ([see footnote 3](#)) and PCN ([see footnote 4](#)) in Canada. This prohibition would prevent a re-introduction of these substances into the Canadian market thereby protecting the Canadian environment.

- The substance HCB was first included in the *Prohibition of Certain Toxic Substances Regulations, 2003*. The current restrictions on HCB are focused on limiting the known sources of the substance, including where HCB is incidentally present in chlorinated solvents and in the manufacturing of ferric and ferrous chloride. The proposed Regulations would list HCB in Part 1 of Schedule 1, thereby prohibiting all uses of the substance.
- Short-chain chlorinated alkanes, PCNs and HCB are listed on the Protocol on Persistent Organic Pollutants (POPs) under the United Nations Economic Commission for Europe (UNECE) Convention on Long-range Transboundary Air Pollution (LRTAP). ([see footnote 5](#)). In addition, HCB is listed on the Stockholm Convention on POPs.

- Short-chain chlorinated alkanes may be incidentally present in medium-chain chlorinated alkanes in small amounts. In such instance, the prohibition on short-chain chlorinated alkanes would not apply.

2.2 Introduction of time-limited permitted uses and addition of BNST to Part 2 of Schedule 2

Under the 2005 Regulations, time-limited permitted uses of toxic substances are not allowed. The proposed Regulations would introduce temporary permitted uses, which would allow an element of flexibility in the risk management of substances. The uses listed in column 2 of Part 2 of Schedule 2 would be allowed until the expiry date listed in column 3 of Part 2 of Schedule 2. After the expiry date, the full prohibition would apply, unless a permit is issued under section 6.

The proposed Regulations would add BNST to column 1 of Part 2 of Schedule 2. This would prohibit the manufacture, use, sale, offer for sale or import of the substance or products containing it, except for listed temporary permitted uses or where a permit has been issued. All uses would be prohibited after the expiration of the specified time period.

The proposed Regulations would provide two temporary permitted uses of BNST: use as an additive in vehicle engine oil and use as an additive in commercial and industrial lubricants.

During the consultation process, industry informed Environment Canada that they have identified potential substitutes for the primary uses of BNST mentioned above. However, industry indicated that they need time to conduct additional research to determine new formulations and to obtain international certifications of engine oil reformulated with alternatives to BNST. Industry indicated that those processes may require two or more years. To this end, the proposed Regulations would allow these temporary permitted uses for two years as indicated in column 3 of Part 2 of Schedule 2.

After the time period for the temporary permitted use specified in column 3 of Part 2 expires, regulatees would be able to request a permit as specified in section 6 of the proposed Regulations.

2.3 Prohibition of substances and products listed in Part 3 of Schedule 2 and addition of TBTs

2.3.1 Change to provisions pertaining to Part 3 of Schedule 2

For substances listed in column 1 of Part 3 of Schedule 2, the prohibition would apply to the substance listed, as well as products containing the substance, except for those products listed in column 2. With respect to those products listed in column 2, the prohibition applies above the specified concentration limit listed in column 3 for the toxic substance, whether incidentally present or not.

2.3.2 Addition of TBTs

The proposed Regulations would add TBTs to Part 3 of Schedule 2, thereby prohibiting the manufacture, use, sale, offer for sale, or import of these substances or products containing them. However, this prohibition would not apply to the following:

- (a) tetrabutyltin containing a concentration of less than or equal to 30% by weight of TBTs; and
- (b) mono- and dibutyltins [in applications such as polyvinyl chloride (PVC) processing, glass coating or as catalysts], because TBTs are incidentally present in these products.

Although the overall objective is to manage any potential releases of TBTs to the environment, the applications noted above, in which TBTs are present, are not proposed to be prohibited as any associated releases are being addressed by other risk management measures, or have limited environmental impact. It is noted that tetrabutyltin is used in the manufacturing of the mono- and dibutyltins. During this process, the TBTs contained in the tetrabutyltin, along with the tetrabutyltin, are converted into the mono- and dibutyltins, with a large part of the TBTs eliminated. TBTs are present in tetrabutyltin as a by-product.

It should also be noted that the proposed Regulations would not apply to TBTs for pesticidal uses within the meaning of section 2 of the *Pest Control Products Act*, so as to avoid duplication of regulatory requirements.

2.4 Changes to the reporting requirements

2.4.1 Manufacture or import of toxic substances

Under the proposed Regulations, if specific reporting thresholds are met, importers and manufacturers of

toxic substances and of products containing toxic substances listed in Part 4 of Schedule 2 would be required to report to the Minister. The proposed Regulations would clarify that the reporting requirement would be triggered when a substance is imported or manufactured or when a product containing the substance is imported (whether incidentally present or not).

Therefore, if a substance is imported or manufactured and then used in the manufacture of a product in Canada, only the initial import or manufacture of the substance needs to be reported.

Submission of the reports would be required by March 31 of the year following the calendar year during which the toxic substance was manufactured or imported or the product containing the toxic substance was imported.

2.4.2 Listing of substances subject to reporting in Part 4 of Schedule 2

The proposed Regulations would add BNST and short-chain chlorinated alkanes to Part 4 of Schedule 2. As a result, manufacturers or importers of BNST, short-chain chlorinated alkanes or a product containing these substances would have to submit reports on these activities above the reporting thresholds specified. For BNST, the threshold is set at 1 kg annually. For short-chain chlorinated alkanes, the threshold is set at 1 kg annually and a concentration level greater than 0.5% by weight. The information obtained on short-chain chlorinated alkanes will aid in the determination of potential future controls on medium-chain chlorinated alkanes.

As HCB would be added to Part 1 of Schedule 1, reporting requirements for HCB would no longer apply and are therefore proposed to be removed.

2.4.3 Use of toxic substances in a laboratory for analysis, for scientific research or as a laboratory analytical standard

The reporting requirements for laboratories using the listed substances for analysis, scientific research, or as a laboratory analytic standard are set out in Schedule 3. The proposed Regulations would modify the requirements by outlining the specific information regarding the products containing the substances to be reported separately from that of the toxic substance, where applicable. These modifications would limit duplication of reporting and improve the quality of the data received regarding laboratory use of the toxic substances.

Applicable to all information provided pertaining to a product, the proposed Regulations would require that both the concentration of the toxic substance in that product, and the unit of measurement be provided for the information to be considered complete.

2.5 Administrative changes

Since the publication of the 2005 Regulations, the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzenes)* were published in the *Canada Gazette*, Part II, on November 29, 2006. In addition, the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances)* were published in the *Canada Gazette*, Part II, on October 13, 2010. The proposed Regulations would include these amendments to streamline the regulatory requirements. In general, the prohibition requirements of the substances currently listed in the 2005 Regulations as well as their subsequent amendments (collectively referred to as the current Regulations) would be maintained in the proposed Regulations.

Miscellaneous changes are proposed throughout the regulatory text to provide greater clarity on the requirements of the 2005 Regulations. For example, the term "annual weighted" would be added in front of "average concentration" to clarify that the average to be reported is not an arithmetic average but a weighted average. In addition, the term "total annual" would be added to paragraphs 9(a) and 9(c) of the proposed Regulations so that it is clear that it is the total quantity of all imports and manufacturing during a calendar year that is required to be reported.

Additional administrative changes are proposed in response to recommendations from the Standing Joint Committee for the Scrutiny of Regulations.

2.6 Proposed changes in response to recommendations from the Standing Joint Committee for the Scrutiny of Regulations

In response to the recommendations of the Committee, the word "mixture" would be removed from the regulatory text. It is important to note that while the word "mixture" would no longer be used, mixtures are captured in the proposed Regulations by reference to substances and products containing substances.

In addition, the Committee identified two areas where the French version of the 2005 Regulations differed from the English version. These discrepancies would be rectified by the proposed Regulations.

2.7 Coming into force

The proposed Regulations would repeal and replace the current Regulations and would come into force three months after the day on which they are registered.

3. Background and context

The Chemicals Management Plan (CMP) is an important policy in Canada for the control of substances. The CMP is a commitment to conduct, within a timeline, scientific assessments of substances of priority. Further, where applicable, CEPA 1999 requires the taking of control and preventive measures for substances that are determined to meet the criteria under section 64 of CEPA 1999. The development of the proposed Regulations is an integral part of these commitments.

3.1 Background and context for BNST

The substance BNST was included in the Challenge initiative under the CMP as one of approximately 200 substances identified as high priorities for action. The final screening assessment report for BNST ([see footnote 6](#)) concluded that BNST meets the criterion set out under paragraph 64(a) of CEPA 1999 and the criteria for persistence and bioaccumulation potential. A notice summarizing the scientific considerations of the final screening assessment report for BNST was published in the *Canada Gazette*, Part I, on August 1, 2009. In addition, BNST also met the criteria for virtual elimination as set out under subsection 77(4) of CEPA 1999. BNST was added to the List of Toxic Substances in Schedule 1 of CEPA 1999 on March 2, 2011, enabling its prohibition under the proposed Regulations.

3.1.1 Current uses

The substance BNST is an organic substance and is part of the diarylamine class of antioxidants. In many types of lubricant formulations, diarylamine antioxidants are used at rates of 0.2% to 1.0% by weight. ([see footnote 7](#)) BNST is used mainly as an antioxidant additive in vehicle engine oil, but is also used in commercial and industrial lubricants. Over 90% of the 482 tonnes of BNST consumed in Canada annually is used in vehicle engine oil formulations. Sales of BNST are estimated to represent 15% to 18% of the overall market for diarylamine antioxidants. Available information suggests that there may also be a minor use of BNST as an additive in rubber applications for industrial equipment and machinery. ([see footnote 8](#))

3.1.2 Release profile

Approximately 98.3% of the BNST contained in engine oils and lubricants in Canada is either chemically transformed, combusted during use of the engine, or reprocessed into industrial fuels or base oils following collection of waste engine oil. The remaining 1.7% of BNST used in Canada is released to the environment from leaks, spills, and improper disposal of lubricants, and from industrial wastewater discharge. The estimated environmental releases of BNST are as follows:

Release Mechanism	Percentage of the Quantity of BNST Used in Canada
Cleaning containers used to transport lubricant additives — to sewer	0.2%
Spills, leaks, and improper disposal of lubricants — to soil, sewer or storm water system	1.3%

Improper disposal of lubricants — to landfill	0.2%
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Source: Final Screening Assessment for the Challenge — BNST (August 2009). The report can be viewed at www.ec.gc.ca/ese-ees/default.asp?lang=En&xml=77578C0A-53F0-BE0F-1730-6CFB5E5C90B2.

Current release information is based on modelled data. However, as part of the CMP monitoring, it is planned that the presence of BNST will be monitored in municipal wastewater, sediment and biota.

3.1.3 Existing Canadian risk management activities

Federal activities

Currently, BNST is not directly subject to any existing federal risk management measures. However, as BNST is an additive contained in certain vehicle engine oils (such as crankcase oils) and other lubricants, it is indirectly controlled by existing measures for the disposal of these products. These measures, however, do not control the diffuse releases (leaks and spills) of BNST during the use of vehicle engine oil and other lubricants.

Provincial and territorial activities

There are currently no specific control measures regarding the release of BNST; however, many provinces and territories have put in place risk management measures for used engine oils. These include

- Prohibitions for land, landfill and sewer disposal of used oils;
- Permits or approval systems to control burning of used oils;
- Prohibitions or guidelines for re-use of used oils in dust suppression;
- Controls for used oil reprocessing and re-refinery operations; and
- Programs to collect and manage used oil.

Ontario has also set specific allowable “oil and grease” concentration limits for wastewater discharge for certain refineries and chemical manufacturing facilities and these measures contribute to limiting industrial releases of BNST.

Municipal activities

Municipal sewer use bylaws describe existing limits on the concentration of “oil and grease” in wastewater discharged to municipal wastewater systems. These bylaws would effectively control releases of BNST from manufacturing, lubricant blending and industrial use at facilities. However, these control measures address only industrial releases and do not control the diffuse releases of BNST.

3.1.4 Existing risk management activities in other jurisdictions

United States

The substance BNST is part of the United States Environmental Protection Agency (U.S. EPA) High Production Volume (HPV) Challenge Program which requires companies to provide and make public basic hazard information on the chemical. There are currently no control measures in place for BNST in the United States.

Europe

Under the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals substances (REACH) Program, BNST was pre-registered in 2008. As a result, by December 10, 2010, manufacturers and importers were required to submit a technical dossier to the European Chemicals Agency containing available information on chemical properties, persistence, bioaccumulation and toxicity. The European Union may undertake action on substances considered of concern after evaluation of the technical dossier.

3.1.5 Profile of industrial sectors

The petroleum and chemical manufacturing sectors are the primary industrial sectors involved with BNST. Manufacturers of BNST and manufacturers of lubricant oils in Canada would be subject to the proposed Regulations. BNST represents a very small portion of Canadian organic chemical manufacturing.

3.2 Background and context for short-chain chlorinated alkanes

Chlorinated alkanes are chlorinated hydrocarbons (n-alkanes) that can have carbon chain lengths ranging from 10 to 38. They are grouped by chain length: short-chain chlorinated alkanes (10–13 carbon atoms), medium-chain chlorinated alkanes (14–17 carbon atoms) and long-chain chlorinated alkanes (18 or more carbon atoms). Assessed ([see footnote 9](#)) under section 68 of CEPA 1999, short-chain chlorinated alkanes meet the criteria set out under paragraphs 64(a) and 64(c) of CEPA 1999. As a result, short-chain chlorinated alkanes are proposed for addition to the List of Toxic Substances in Schedule 1 of CEPA 1999, enabling prohibition under the proposed Regulations. Furthermore, these substances meet the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations*.

3.2.1 Current uses

Short-chain chlorinated alkanes were primarily used in Canada as extreme pressure additives in metalworking fluids. In 2010, total quantity of short-chain chlorinated alkanes imported into Canada was estimated to be 33 tonnes. However, companies involved have reported to have phased out the use of the substances at the end of that year. ([see footnote 10](#)) While products containing short-chain chlorinated alkanes, including paints, adhesives, sealants, rubber and plastics, may be imported into Canada, the volume of such imports is believed to be small.

3.2.2 Release profile

Estimates indicate that in 2009 ([see footnote 11](#)) approximately 15 tonnes of short-chain chlorinated alkanes were released in Canada in a dispersed manner, likely from manufacturing, use and disposal of products containing these substances. The possible sources of releases to water from manufacturing include spills, facility wash-down and drum rinsing/disposal. Estimates suggest that metalworking activities accounted for the majority of short-chain chlorinated alkanes released to the environment, mainly through the disposal of used metalworking fluids. Although these substances have been recently phased out, there is a potential for re-introduction and a risk of future releases of short-chain chlorinated alkanes to the environment. ([see footnote 12](#))

3.2.3 Existing Canadian risk management activities

Short-chain chlorinated alkanes are currently not subject to risk management measures in any jurisdiction in Canada.

3.2.4 Existing risk management activities in other jurisdictions

United States

In December 2009, the U.S. EPA published its *Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins Action Plan*, stating that "EPA intends to initiate action to address the manufacturing, processing, distribution in commerce and use of SCCPs." Details on these actions are not yet available.

European Union

The European Union adopted restrictions on the formulation and use of short-chain chlorinated alkanes in metalworking fluids and leather finishing products under the European Union Existing Substances Regulations (EEC 793/93). The Regulations prohibit placing short-chain chlorinated alkanes on the European Union market beginning January 6, 2004, in concentrations greater than 1% for use in metalworking fluids or fat liquoring of leather.

International organization

In December 2009, Parties to the United Nations Economic Commission for Europe (UNECE) Convention on Long-range Transboundary Air Pollution (LRTAP) amended the Protocol on Persistent Organic Pollutants (POPs) to add seven new substances, including short-chain chlorinated paraffins. The amendment adding short-chain chlorinated paraffins, defined specifically in Annex 1 as chlorinated alkanes with carbon-chain length of 10 to 13 atoms (i.e. short-chain chlorinated alkanes), require all Parties to the Protocol, including Canada, to eliminate their production and use, except for listed permitted uses. The implementation of the proposed Regulations would allow Canada to consider ratifying the amendments to the LRTAP.

3.3 Background and context for PCNs

Polychlorinated naphthalenes (chlorinated naphthalenes containing two to eight chlorine atoms ([see footnote 13](#)) — PCNs) have been used in applications such as cable insulation, capacitors, gauge and heat exchange fluids, instrument seals, solvents and other uses. Although PCNs are not currently manufactured or used in Canada, there is potential for their re-introduction in the future into the Canadian environment if not managed.

The final screening assessment report for PCNs concluded that they meet the criterion set out under paragraph 64(a) of CEPA 1999 as having an immediate or long-term harmful effect on the environment or its biological diversity. PCNs are proposed for addition to the List of Toxic Substances in Schedule 1 of CEPA 1999, enabling their proposed prohibition under regulations. In addition, PCNs meet the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations*.

3.3.1 Release profile

Chlorinated naphthalenes are not currently in commercial use in Canada, the United States and many other member countries of the Organisation for Economic Co-operation and Development (OECD). Polychlorinated naphthalenes (PCNs), which are a subset of chlorinated naphthalenes, are the subject of controls worldwide.

PCNs can be unintentionally generated and released into the environment from several industrial processes involving heat and/or chlorine. These processes include waste incineration, cement and magnesium production, and refining of metals such as aluminum. PCNs are also incidentally present in commercial polychlorinated biphenyl (PCB) formulations. Other sources responsible for releases of PCNs to the environment may include disposal of products containing PCNs in landfill sites and old industrial sites where PCNs were used.

Most unintentional releases of PCNs are to air. Within Canada, PCNs have been detected in arctic and urban air, water from Lake Ontario, fish and birds from the Great Lakes and environs, Pacific coast killer whales, seals and whales from the Canadian Arctic and Vancouver Island marmots. ([see footnote 14](#))

3.3.2 Existing Canadian risk management activities

Currently there are no risk management measures in Canada aimed specifically at addressing PCNs but there are various guidelines and standards targeting other chemicals [Polychlorinated Dibenzo-p-dioxins and Polychlorinated Dibenzofurans (PCDD/Fs), and PCB] that may also impact unintentional releases of PCNs.

Measures to control emissions of PCDD/Fs are thought to also control the release of PCNs in some sectors, because PCNs are often associated with the formation of PCDD/Fs and exhibit similar formation pathways.

With respect to the waste incineration sector, there is a Canada-wide standard, implemented by the Canadian Council of Ministers of the Environment, for incineration facilities that process municipal, medical and hazardous wastes that sets stringent emission limits for PCDD/Fs. A detailed review of 2000 and 2005 annual dioxins and furans air emissions from incineration showed that releases to air were reduced from 29.4 to 3.7 grams International Toxic Equivalence per year (a reduction of 87%). ([see footnote 15](#))

Polychlorinated naphthalenes may also be incidentally present in PCB formulations. PCBs are currently controlled under the 2005 Regulations and the proposed Regulations would continue to control the substance. Additionally, the *PCB Regulations, 2008*, made under CEPA 1999, set specific dates for the destruction of PCBs in service and in storage, and therefore work toward the gradual elimination of PCBs and other substances incidentally present in them, including PCNs.

3.3.1 Existing risk management actions in other jurisdictions

United States

No actions have been undertaken in the United States as the production of PCNs ceased in the 1980s.

Japan, Switzerland and the European Union

The import and manufacture of PCNs have been banned in Japan since 1979. All halogenated naphthalenes are legally banned in Switzerland. Within the European Union, the Netherlands reported that PCNs were listed as a National Priority Substance for possible future regulatory control.

International organizations

In December 2009, Parties to the Convention on LRTAP amended the Protocol on POPs to add seven new substances, including PCNs. The amendments adding PCNs require all Parties to the Protocol, once the amendments are ratified, to eliminate their production and use. In addition, in 2010, PCNs were proposed for addition to the Stockholm Convention on POPs.

3.4 Background and context for TBTs

Tributyltins are a class of chemical substances in the family of organotins having three butyl groups attached to the tin atom. The final follow-up ecological assessment report for non-pesticidal organotin compounds ([see footnote 16](#)) concluded that TBTs for non-pesticidal uses meet the criterion set out under paragraph 64(a) of CEPA 1999. Based on these conclusions, TBTs have the potential to cause harm to the environment or its biological diversity in Canada. Tributyltins were proposed for addition to the List of Toxic Substances in Schedule 1 of CEPA 1999 on October 3, 2009. In addition, they were found to meet the criteria for persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations*.

3.4.1 Current uses

Tributyltins in their pure form are currently not in commercial use in Canada, but they may be found in products that are mainly used in the PVC processing industry, and as pesticides. Minor uses of products containing TBTs include glass coatings and catalysts.

Tributyltins for non-pesticidal uses may be present in tetrabutyltin (up to 30%) and in mono- and dibutyltin compounds (less than 1%). As indicated earlier, during the manufacturing of the mono- and dibutyltins, the TBTs contained in the tetrabutyltin, along with the tetrabutyltin, are converted into the mono- and dibutyltins.

With respect to pesticidal uses of TBTs, six pest control products containing TBTs are currently registered as pesticides (material preservatives) under the authority of the *Pest Control Products Act (PCPA)* by Health Canada. Under this Act, no person shall manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under this Act, except as otherwise authorized.

3.4.2 Release profile

Tributyltin compounds have entered the environment mostly from their pesticidal uses. However, measures are in place to address most of these releases. Tributyltin compounds for non-pesticidal uses may enter the environment because of their presence in other butyltin products (mono- and di-, and tetrabutyltin) and from the environmental breakdown of tetrabutyltin.

In the past, the largest environmental releases of organotins from non-pesticidal uses occurred as a result of loss of liquid residues from shipping containers, with smaller release occurring from storage tanks and transfer lines associated with the manufacturing and use of mono- and dibutyltins. This created the potential for significant concentrations of organotins in local receiving waters and sediments. However, in recent years, facilities using mono- and dibutyltins have adopted product stewardship practices that have led to a decrease in the potential release of organotins. These releases are now being managed by risk management measures in place and other measures are being developed.

3.4.3 Existing Canadian risk management activities

Tributyltins are intermediate chemicals that are generated and consumed during the manufacture of mono-, di- and tetrabutyltin, and cannot be entirely eliminated during the process. However, the following initiatives are in place or are being developed to manage any potential release of substances where TBTs may be present:

- The *Environmental Performance Agreement Respecting the Use of Tin Stabilizers in the Vinyl Industry* ([see footnote 17](#)) has been in place since March 10, 2008, to manage the release of tin stabilizers (mono- and dibutyltins) into the environment, including any TBTs that may be present in the stabilizers.
- A Code of Practice is currently being developed under section 54 of CEPA 1999 to manage releases of tetrabutyltin to the aquatic environment, including any potential release of TBTs that may be present in tetrabutyltin. This would apply to all facilities involved with tetrabutyltin in Canada.
- Ministerial Condition No. 13618 ([see footnote 18](#)) issued by the Minister of the Environment under

section 84 of CEPA 1999 is currently in place for tetrabutyltin. The Condition imposes restrictions on the use and disposal of this substance to limit its release to the environment, and currently applies to one facility. Environment Canada would consider rescinding the Ministerial Condition once the Code of Practice is in place. The Code would incorporate most of the elements included in the Condition.

- With respect to pesticidal uses of TBTs, the use of TBTs in anti-fouling paints ([see footnote 19](#)) on ship hulls has been prohibited in Canada since 2002 following the special review by Health Canada's Pest Management Regulatory Agency. In addition, a regulatory consultation document was published on July 15, 2010; it proposed a phase-out of the remaining pesticidal uses of TBT compounds as a material preservative under the PCPA. A final regulatory decision is pending consideration of comments received during the consultation process.

3.4.4 Existing risk management activities in other jurisdictions

European Union

The European Union has adopted a decision on May 28, 2009, that would prohibit the use of triorganotin compounds (which include tributyltins) and of dibutyltins in articles as a material preservative, where the concentration in the article, or part thereof, is greater than the equivalent of 0.1% by weight of tin. The prohibition for triorganotins has been in effect as of July 1, 2010, and the one for dibutyltins will be in effect on January 1, 2012.

International organization

The International Maritime Organization's International Convention on the Control of Harmful Anti-fouling Systems on Ships was adopted in October 2001 and came into force in September 2008. The Convention stipulates that, effective January 1, 2003, ships shall not apply or re-apply organotin compounds (including TBTs) that act as biocides in anti-fouling systems. The Convention also stipulates that, effective January 1, 2008, ships shall either not bear such compounds on their hulls or external parts or surfaces, or shall bear a coating that forms a barrier to such compounds leaching from underlying non-compliant anti-fouling systems. To implement the terms of the Convention, Parties are required to put in place measures to prohibit and/or restrict the use of harmful anti-fouling systems on ships. Canada is a Party to this Convention, and in order to meet its obligations under the Convention, Health Canada prohibited the use of TBTs in anti-fouling paints in 2002.

Regulatory and non-regulatory options considered

Several regulatory and non-regulatory options have been considered, and the rationales for rejecting or accepting them are provided below.

1. BNST

Status quo

The substance BNST has been found to meet the criteria for persistence, bioaccumulation potential and toxicity to non-human organisms. Taking no action would result in the continued release of BNST into the Canadian environment, which would further exacerbate the risks identified above. Therefore, maintaining the status quo is rejected.

Market-based instruments

Market-based instruments which were taken into consideration are environmental fees or charges. Environmental charges can be applied to persons manufacturing, importing, selling or using the substance or products containing the substance. For example, a charge on products containing BNST would provide the incentive for industry to modify its process or to use a substitute for BNST. However, a charge would not provide the certainty that the substance would be phased out entirely. Therefore, these instruments do not appear to be appropriate to achieve the lowest level of release of BNST to the environment. Consequently, they have not been considered any further.

Voluntary measures

Voluntary measures such as environmental release guidelines and pollution prevention plans were also considered for the management of BNST. Given the risks associated with BNST, there is no guarantee that, being voluntary, these measures would achieve the lowest level of release of BNST to the environment.

Hence, voluntary measures were not considered appropriate.

Regulations

Prohibiting the manufacture, use, sale, offer for sale or import of BNST or of products containing BNST provides the certainty that the release of BNST to the environment would be reduced to the lowest level. In addition, the Regulations would provide flexibility to affected parties to continue to use the substance, on a temporary basis, in order to allow adequate substitutes to be selected and placed on the market. The Regulations were considered the best option.

2. Short-chain chlorinated alkanes, PCNs, TBTs and administrative changes

Short-chain chlorinated alkanes, PCNs, and TBTs for non-pesticidal uses were assessed as meeting one or more of the criteria set out under section 64 of CEPA 1999 with potential risks to the environment or human health. It was recommended to add short-chain chlorinated alkanes, PCNs and TBTs to the list of toxic substances under CEPA 1999 (Schedule 1). These additions would allow the development of proposed instruments respecting preventative or control actions in relation to these substances. A regulation is the preferred instrument to prevent the potential for re-introduction in the Canadian marketplace of these three substances. In addition, the issues identified by the Standing Joint Committee for the Scrutiny of Regulations and other stakeholders can only be addressed through the proposed Regulations.

With respect to TBTs, the potential releases from the activities for which the proposed Regulations would not apply are being addressed by other risk management measures.

Furthermore, short-chain chlorinated alkanes and PCNs have been added to the POPs Protocol under the UNECE Convention on Long-range Transboundary Air Pollution (LRTAP), requiring all Parties to the Protocol, including Canada, to eliminate their production and use. The implementation of the proposed Regulations would allow Canada to consider ratifying the amendments to the LRTAP.

Benefits and costs

Analytical framework

The approach to the cost-benefit analysis identifies, quantifies and monetizes, to the extent possible, the incremental costs and benefits associated with the proposed Regulations. The cost-benefit framework consists of the following elements:

Incremental impact: Incremental impacts are analyzed in terms of release reductions and costs and benefits to interested parties and the economy as a whole. The incremental impacts were determined by comparing two scenarios: one without the proposed Regulations and the other with the proposed Regulations. The two scenarios are presented below.

Timeframe for analysis: The time horizon used for evaluating the impacts is 25 years. The first year of the analysis is 2012.

Approach to cost and benefit estimates: To the extent possible, all costs and benefits have been estimated in monetary terms and are expressed in 2010 Canadian dollars. Where this was not possible due either to a lack of appropriate data or to difficulties in valuing certain components or data inputs, the costs and benefits have been evaluated in qualitative terms.

Discount rate: A real discount rate of 3% was used for this analysis. A sensitivity analysis varying the discount rate between 3% and 7% to test the volatility of the estimates to the discount rate was also conducted.

Cost and benefit estimates for BNST are based on a 2011 study conducted for Environment Canada by HDR Corporation. [\(see footnote 20\)](#)

1. Impacts of prohibiting BNST

Business-as-usual scenario

The substance BNST is a relatively inexpensive additive; the substance has very desirable antioxidant characteristics resulting in improved performance of lubricant products. For these reasons, industry would have no incentive to switch to an alternative substance in the absence of federal regulations. It was

therefore assumed, under the business-as-usual (BAU) scenario, that the current pattern of manufacture, import and use of BNST by the industry would continue and the total quantity used yearly would be determined by the demand for final products for which the use of the substance is intended. In the absence of regulatory measures, the production of BNST in Canada is expected to increase on average at a level equivalent to the growth rate of the chemical sector, which is 0.9%. The total release of BNST from use, from 2012 to 2036, is estimated to be approximately 200 tonnes.

Regulatory scenario

Under the regulatory scenario, the manufacture, use, sale, offer for sale or imports of BNST or of products containing BNST would be discontinued. The proposed Regulations are expected to come into force in 2012. For the years 2012 and 2013, BNST releases would continue as a result of the two-year temporary permitted uses of BNST as an additive in engine oil and commercial/industrial lubricants. These temporary permitted uses allow companies a reasonable amount of time to reformulate products with alternative additives and to obtain international certifications of engine oil containing substitutes to BNST. However, after the temporary permitted uses expire, companies that manufacture, use, sale, offer for sale or import BNST or products containing it would be required to obtain permits, under the proposed Regulations, if they want to continue their activities with BNST. Where necessary, a permit may be issued for one year and renewed twice for a total period of three years. It is not possible to know with certainty the number of regulatees that may require a permit to continue their activities. To be conservative, it is assumed that all regulatees would apply for permits and their renewals for a total period of three years and would incur the associated costs. As a result, releases of the substance may continue during this period.

Benefits to Canadians

At the end of the permitting period, releases of BNST into the environment from the uses identified would be almost entirely eliminated. It is estimated that, from 2017 to 2036, releases of approximately 200 tonnes of BNST into the environment would be avoided.

Environmental benefits are expected as a result of the prohibition. The reduction of BNST is likely to improve water quality, thus indirectly stimulating aquatic biodiversity and improving the health of an entire ecosystem. However, it is challenging to accurately estimate the quality of these water bodies and subsequent improvements and their valuation as a result of the proposed Regulations, since no monitoring data on receiving water bodies is yet available. While specific site data is not available, a study, by Johnston et al. (2005), ([see footnote 21](#)) estimates the willingness to pay for a marginal improvement in water quality for aquatic species. Conducting a meta-analysis of over 30 U.S. studies on the willingness to pay (WTP) for aquatic resources improvements that affect fish and other aquatic species, the study finds that for a small improvement in water quality that affects fish (an improvement of 0.5 on the 10-point Water Quality Ladder ([see footnote 22](#)) index from 7.0 to 7.5), households would be willing to pay between \$3.07 to \$6.89 annually in 2002 U.S. dollars (\$5.54 to \$12.44 in 2010 Canadian dollars). Given the similarities between the environmental quality in both Canada and the United States and the integrative nature of our economies, it is assumed that citizens in both countries would have similar willingness to pay for environmental improvement of this nature. In light of the lack of data on the number, location and quality of receiving environment, a total estimate of benefit could not be provided using the above WTP estimates. However, it is expected that the proposed Regulations would result in some improvement in environmental quality.

Cost to industry

Manufacturers of BNST and of engine oil and commercial and industrial lubricants using chemical additive products that contain BNST in Canada would incur costs to meet the requirements of the proposed Regulations. These costs include substance and products substitution as well as reporting. The present value of the total cost to industry is estimated to be about \$18 million. These costs are analysed below.

Permitting, reporting and initial preparation costs

Although there are no regulatory fees for applying for permits, the preparation of a permit application would require labour to collect data and assemble the required supporting information, and to draft the actual application.

In addition, during the first two years of the proposed Regulations coming into force, the establishments involved with the manufacture or import of BNST or products containing it would need to provide to the Minister of the Environment a report outlining details of the manufacture, distribution and use of BNST.

In order to meet the requirements of the proposed Regulations, regulatees would incur initial transition costs such as assessing the applicability of the Regulations to the particular establishment and evaluating the needs for other transformations, including training needs.

The associated costs to undertake these activities are estimated to be minimal and the present value of these costs over the 25-year period is estimated to be about \$120,000.

Cost of reformulated chemical additive products

Substituting BNST in engine oils and industrial and commercial lubricant formulations with alternative antioxidants is possible; other diarylamine antioxidants as well as phenolic- or zinc-based antioxidants exist. Substitution costs are expected to be incurred as a result of the substitution ratio between BNST and the substitute substance in specific products. According to stakeholders, the prices of substitutes would be similar to that of BNST, but a greater quantity of the substitute may be required to achieve the same performance. Environment Canada estimates the price of BNST to be about \$5/kg. This price is used as a proxy to calculate the incremental cost associated with using a substitute.

It is assumed that the substitution of BNST in chemical additive products would begin before the end of 2016. This is based on the assumption that manufacturers would use existing inventories of BNST or products containing BNST before starting to use a BNST substitute.

While reformulation costs would be incurred by manufacturers of chemical additive products outside of Canada, it is conservatively assumed that these costs would be passed on to the lubricant manufacturers in Canada. According to stakeholders, each product would require two or more years to be reformulated and certified.

Overall, it is estimated that the present value of the costs to industry to use reformulated chemical additive products would be \$17.67 million. It is expected that this cost would be passed on to Canadian lubricant manufacturers that use these chemical additive products.

Cost of product line substitution

Costs would be incurred for substituting the production of BNST with the production of another substance. In general, most specialty chemical manufacturing companies are set up to quickly change products to meet new demands by clients. It is assumed that the equipment used to manufacture BNST can also be used to manufacture other chemicals and therefore any required capital costs would likely be minimal. In addition, manufacturers are likely to have a good knowledge of the existing market and trends and be able to quickly identify options. However, there may be a cost associated with marketing and other activities related to informing their customers about the uses of the substitutes in their particular applications. These costs are estimated to total about \$190,000 in present-value terms.

Distributional and competitiveness impacts

The proposed Regulations are not expected to have any effect on industry's competitiveness. While domestic engine oil and lubricant manufacturers would be prohibited from using chemical additive products containing BNST, the import of products that contain BNST would be prohibited as well, creating a level playing field for engine oil and lubricant manufacturers.

Canadian manufacturers of BNST might be impacted by the prohibition. However, the industry has indicated that potential BNST substitutes are available and these could be manufactured for use in the production of engine oil and lubricants.

In foreign markets, domestic manufacturers who export engine oils and commercial and industrial lubricants may be at a competitive disadvantage should they have to increase the price of their products on these markets and should competing products containing BNST supplied in these markets be less expensive. However, the average annual incremental cost to Canadian manufacturers of engine oils and industrial and commercial lubricants is estimated to be close to \$120,000, which represents 0.01% of average production costs per facility. As such, this increased cost is minimal and the resulting impact on competitiveness in foreign markets is expected to be negligible.

Consumers would be impacted to the extent that manufacturers would pass on a fraction or all of their increased costs further down the distribution chain in the form of a price increase. To be conservative, it is assumed that all of the cost increase would be passed on to consumers.

The quantity of lubricants containing BNST used annually in Canada is estimated to be about 182 million litres per year. Using this quantity and the assumption above, it is estimated that the annual average incremental cost increase of a litre of automotive lubricants as a result of the proposed Regulations amounts to about 0.5¢/L. This cost can be considered negligible.

2. Impacts of prohibiting short-chain chlorinated alkanes

Benefits

As presented in the "Description" section above, the use of short-chain chlorinated alkanes has recently been phased out by the industry. As a result, releases of short-chain chlorinated alkanes are assumed to be negligible. One of the benefits of the proposed Regulations is preventing the re-introduction of the substance, thereby eliminating the potential risks of damage to the environment and human harm.

Short-chain chlorinated alkanes have been added to the POPs Protocol under the UNECE Convention on Long-range Transboundary Air Pollution (LRTAP), requiring all Parties to the Protocol, including Canada, to eliminate their production and use. The implementation of the proposed Regulations would allow Canada to consider ratifying the amendments to the LRTAP.

Costs

There is currently no manufacturer of short-chain chlorinated alkanes in Canada. During the consultation meeting on the proposed path forward in the risk management of chlorinated alkanes held late 2009, the sole manufacturer in the United States of short-chain chlorinated alkanes has indicated a possible phase-out of production in the short term. Furthermore, the remaining users of the substance in Canada phased out their use in early 2010.

Currently, short-chain chlorinated alkanes consumed in Canada are in imported products. Impacts are thus expected on Canadian importers of products containing short-chain chlorinated alkanes. However, information gathered from short-chain chlorinated alkanes manufacturers suggest that the volume of imported products containing these substances is small, as imported products containing the substance are not expected to be coming from the United States or Europe. Given the prohibition on imports, the importers would either switch to different products or would need to import short-chain chlorinated alkane free products. The potential increased cost to the importers is expected to be relatively low, and these minimal costs are assumed to be passed onto consumers.

3. Impacts of prohibiting PCNs and TBTs

Polychlorinated naphthalenes and TBTs for non-pesticidal uses are not currently manufactured or used as pure substances in Canada. Furthermore, current activities where TBTs are present in other organotin compounds would not be prohibited. As a result, the proposed Regulations are not expected to result in any incremental costs to industries. However, the proposed Regulations would prevent a re-introduction of these substances and of products containing them in the Canadian market, thereby eliminating the risk of release of PCNs and resulting ecological harm. Furthermore, they would serve to reduce any potential transboundary emissions of PCNs and protect the environment from its risks on a global level, signalling Canada's commitment to take action on PCNs to its international partners.

4. Other impacts

The impacts of the administrative changes contained in the proposed Regulations are expected to be minimal. Limited cost savings are expected for industry as a result of the reduced reporting requirements. Reporting activities should already be in place for all affected businesses, with the changes expected to be reflected in slight modifications of their existing practices. Negligible record-keeping costs are expected to be incurred from changes in reporting requirements for laboratories performing scientific research and facilities submitting permit applications.

5. Impacts on the federal Government

The federal Government would incur costs totalling about \$410,000 over 15 years in present value. This cost would be incurred for compliance promotion and enforcement of the provisions of the proposed Regulations, as well as for administration of permits.

Compliance promotion

Compliance promotion activities are intended to encourage the regulated community to achieve

compliance. Compliance promotion costs would require a budget of \$47,000 during the first year after the coming into force of the proposed Regulations. Compliance promotion activities could include mailing out of the finalized Regulations, developing and distributing promotional materials (such as a fact sheet and Web material), advertising in trade and association magazines and attending trade association conferences. This might also include responding to and tracking inquiries in addition to contributing to the compliance promotion database.

In the second year following the coming into force of the proposed Regulations, compliance promotion costs would require an annual budget of \$62,500. Activities could include follow-up actions to year one activities, analysis of the community affected by the Regulations, sending reminder letters, and the publication of reminder fact sheets. Other activities may possibly involve responding to and tracking inquiries, and contributing to the compliance promotion database.

In the third and fourth years following the coming into force of the proposed Regulations, compliance promotion could require an additional budget of \$33,000 and \$24,100 respectively. Compliance promotion activities will possibly be kept at a maintenance level and be limited to responding to and tracking inquiries in addition to contributing to the compliance promotion database. Note that more compliance promotion may be required if, following enforcement activities, compliance with the Regulations is found to be low.

Enforcement

Government of Canada enforcement activities are intended to ensure compliance with the Regulations. In 2012, an estimated one-time cost of \$53,000 would be required for the training of enforcement officers and \$2,500 to meet information management requirements.

The annual enforcement costs during the first 15 years are estimated to be \$16,000 broken down as follows: \$6,000 for inspections, \$5,500 for investigations, \$500 for measures to deal with alleged violations (including warnings, environmental protection compliance orders and injunctions), and about \$4,000 for prosecutions. After this period, the incremental enforcement costs are estimated to be minimal.

Other costs are expected on the Government; these include the processing of permit applications as well as monitoring and surveillance of the presence of BNST in environmental media such as wastewater, sediments and biota. The present value of the incremental cost to process permit applications is estimated to be about \$13,000 in present-value terms. Cost associated with monitoring for BNST is estimated to be small but is not accounted for in the analysis.

6. Overall impacts

As presented above, the proposed Regulations would result in both costs and benefits to stakeholders. Most of the costs would be incurred as a result of controlling BNST with the proposed Regulations estimated to result in a present value of incremental cost of \$18.4 million. For short-chain chlorinated alkanes, PCNs, and TBTs for non-pesticidal uses, the proposed Regulations are estimated to impose negligible costs on regulatees since these substances are not manufactured or currently used as pure substances in Canada.

Costs to the Government associated with managing releases of these substances are estimated to be low.

While it was not possible to quantify the benefits associated with the proposed Regulations, positive benefits are expected in terms of the protection to the environment and its aquatic ecosystem, including protecting the health of Canadians against exposure to short-chain chlorinated alkanes. Furthermore, the proposed Regulations would demonstrate Canada's commitment to meet its international obligations by reducing releases of POPs.

Overall, the net impact of the proposed Regulations is expected to be positive.

The present value of the monetized incremental costs, and the qualitative costs and benefits of the proposed Regulations are summarized in the following table:

Table 3: Incremental cost-benefit statement (in millions of 2010 dollars)

Cost-benefit	2014	2022	Final Year:	Total Present	Average

statement			2036	Value	Annual
A. Quantified costs (BNST)					
<i>Industry costs</i>					
Permitting, reporting and initial preparation cost	0.03	0.00	0.00	0.12	~0.01
Cost of reformulated chemical additive products	6.00	0.49	0.49	17.67	0.71
BNST production line substitution	0.00	0.00	0.00	0.19	0.01
Total industry cost	6.0	0.5	0.5	18	0.7
<i>Government costs</i>					
Enforcement	0.07	0.00	0.00	0.24	~0.01
Compliance promotion	0.05	0.00	0.00	0.16	~0.01
Reviewing permit applications	0.00	0.00	0.00	0.01	~0.00
Total government cost	0.12	0.00	0.00	0.41	0.02
Total cost	6.1	0.5	0.5	18.4	0.75
B. Qualitative impacts					
Environment	Protecting the environment and its ecosystem against damages from BNST, short-chain chlorinated alkanes, PCNs, and non-pesticidal uses of TBTs by preventing future releases of these substances.				
Human health	Protecting the health of Canadians against future releases of short-chain chlorinated alkanes.				
7. Sensitivity analysis Industry	Reducing administrative burden with respect to reporting and improving the clarity of the regulatory text.				

Sensitivity analysis was conducted by varying the discount rate from 3% to 7% to determine the direction and magnitude of changes to the final estimates of incremental costs associated with the proposed Regulations. The results, presented in Table 4, indicate that changes in the estimates of costs were proportional to changes in the discount rate.

Table 4: Summary of impacts (millions of 2010 dollars)

Discount rate	Undiscounted	3%	7%
Costs	23.4	18.4	14.1

The implementation of the proposed Regulations would result in a quantified cost of \$18.4 million over 25 years in present value. The bulk of this cost is associated with chemical additive products reformulation and would be incurred indirectly by domestic engine oil and industrial and commercial lubricant manufacturers, who would likely pass on their costs to consumers.

Rationale

As a result of scientific assessment, the substances BNST, short-chain chlorinated alkanes, PCNs and TBTs for non-pesticidal uses were found to have or may have an immediate or long-term harmful effect on the environment or its biological diversity. In addition, short-chain chlorinated alkanes also constitute or may constitute a danger to human life or health. Developing the proposed Regulations to protect the environment and human health is therefore the most appropriate course of action. Consequently, these Regulations are being proposed and were developed based on consultation with stakeholders.

Impacts associated with the implementation of the proposed Regulations on the various substances and affected sectors were evaluated and analyzed. With regards to BNST, the proposed Regulations are estimated to result in material impacts on manufacturers of the substance and of final products that contain the substance. The present value of the incremental cost of meeting the requirements of the proposed Regulations is estimated to be \$18.4 million. It was not possible to estimate the total benefits associated with preventing future releases of BNST by prohibiting its manufacture and use. However, it is assumed that households would be willing to pay between \$5.54 and \$12.44 for a small improvement in water quality. It is expected that the proposed Regulations would result in some improvement in environmental quality.

For short-chain chlorinated alkanes, PCNs, and TBTs for non-pesticidal uses, the proposed Regulations are estimated to impose negligible cost on regulatees as these substances are not manufactured or currently used as pure substances in Canada. The increased costs to meet the requirements of the proposed Regulations for these substances are expected to be manageable and would not result in a big impact on consumers. On the other hand, the proposed Regulations would provide protection to the environment and its ecosystem as well as to human health. There is also the added benefit of demonstrating Canada's commitment to put measures in place to meet its international obligations by reducing releases of POPs. Costs to the government associated with managing releases of these substances are estimated to be low to negligible as well.

Consultation

1. Addition of BNST

In September 2010, Environment Canada informed the provincial and territorial governments through the Canadian Environmental Protection Act National Advisory Committee (CEPA NAC) about the proposed Regulations and provided them with an opportunity to consult. No comments were received from CEPA NAC members.

Environment Canada has also consulted with stakeholders (including industry, and environmental non-governmental organizations [ENGOs]) on the addition of BNST to the proposed Regulations through a consultation document sent to stakeholders and published on the CEPA Registry Web site on November 17, 2010, for a 30-day comment period. Furthermore, on November 18, 2010, a multi-stakeholder consultation meeting via conference call was held to discuss the proposed path forward for the risk management of BNST in Canada.

In addition to comments provided during the consultation via conference call, two submissions were also received. Those comments were considered in the development of the proposed Regulations. Overall, stakeholders do not oppose the proposed measure for BNST. A summary of the comments and responses of Environment Canada is provided below.

- Stakeholders asked if Environment Canada plans to measure BNST presence in the environment.

Environment Canada indicated that BNST would be part of the monitoring and surveillance activities that come under the CMP. This would be conducted after the analytical method for detection is developed.

- Stakeholders asked how Environment Canada will consider the social and economic aspect of the proposed Regulations.

Environment Canada indicated that the impact of the proposed Regulations would be evaluated within a cost-benefit framework, that includes socio-economic considerations and a summary of the findings would be presented in the Regulatory Impact Analysis Statement that would accompany the publication of the proposed Regulations.

- Industrial stakeholders and ENGOs representatives had questions about the length of time before BNST will be totally prohibited under the proposed Regulations.

Environment Canada clarified that the proposed Regulations would include a provision for temporary permitted uses for BNST to provide time to industry to conduct additional research for substitutes or to reformulate their products.

- An organisation representing some users of lubricants containing BNST expressed their concern about the potential impact of the proposed measures on their company members. They wondered about the availability of alternative substances.

Environment Canada responded that information received from BNST manufacturers and chemical additive product manufacturers suggested there are identified potential substitutes to BNST. Environment Canada believes that the impacts on businesses would be manageable given the existence of BNST substitutes coupled with the provision for temporary permitted uses.

- The same organization also recommended that suppliers of products containing BNST be identified and engaged in the development process of the proposed risk management measure.

Environment Canada indicated that manufacturers, importers and users were identified in 2007 as part of the mandatory survey set out under section 71 of CEPA 1999, and then engaged in multilateral discussions. The information and input provided by them were used in the risk management development process in order to address the different potential impacts related to the proposed measure.

2. Addition of short-chain chlorinated alkanes

On August 30, 2008, the Proposed Risk Management Approach for Chlorinated Paraffins was published on Environment Canada's Web site for a 60-day public comment period. Furthermore, on October 22, 2009, a multi-stakeholder consultation meeting was held in Toronto to discuss a proposed path forward for the risk management of chlorinated paraffins in Canada. In addition, stakeholders were invited to provide written comments to Environment Canada on the related consultation document that was also available online.

Thirteen written submissions regarding the risk management of all chlorinated alkanes were received from industry, ENGOs and other government departments during the consultation period. However, one comment specific to the risk management for short-chain chlorinated alkanes was made. The full text of the responses to comments can be viewed on the chlorinated paraffin Web page on Environment Canada's Pollution and Waste Web site at www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=148DE7B6-5B9A-42D8-884F-920978DC3C99.

- An industry stakeholder indicated that there was no need to include exemptions on the use of short-chain chlorinated alkanes as these substances were already phased out or were being phased out in Canada.

The Government of Canada has considered the above-noted comment and has determined that

short-chain chlorinated alkanes would not be subject to any specific exemptions under the proposed Regulations.

3. Addition of PCNs

On July 2, 2009, Environment Canada informed the governments of the provinces and territories through the CEPA NAC about proposed control measures that would prohibit the manufacture, use, sale, offer for sale or import of PCNs and products containing PCNs and provided them with an opportunity to provide feedback. No comments were received from CEPA NAC members.

At the same time, Environment Canada consulted with stakeholders on the proposed control measures to prohibit the manufacture, use, sale, offer for sale or import of PCNs and products containing PCNs through a consultation document sent to stakeholders and published on Environment Canada's Web site. No comments opposing the proposed control measures were received.

4. Addition of TBTs

On December 21, 2010, Environment Canada informed the governments of the provinces and territories through the CEPA NAC about the addition of TBTs to the proposed Regulations and provided them with an opportunity to consult. No comments were received from CEPA NAC members.

Environment Canada has also consulted with stakeholders on the addition of TBTs to the proposed Regulations through a consultation document sent to stakeholders and published on the Web on January 19, 2011, for a 30-day comment period. Industry indicated that they supported this proposal.

In August 2009, the Proposed Risk Management Approach for Non-Pesticidal Organotin Compounds ([see footnote 23](#)) was published by Environment Canada and Health Canada for a 60-day public comments period. During the consultation period, four submissions were received: two from the industry, one from an industry association and one from an ENGO. A summary of the main issues raised as well as Environment Canada's responses to them are presented below.

- Industry supported the exclusion of activities where TBTs may be present and recommended that these activities be specifically identified as exemptions in the proposed Regulations, including exemptions for storage, transportation and disposal of tin stabilizers, given that they would be covered by the existing Environmental Performance Agreement.

Environment Canada has examined these recommendations and indicated that the proposed Regulations would not prohibit the identified activities.

- An ENGO representative expressed concern regarding the permitted uses of products where TBTs are present and recommended adding the associated activities to Part 2 of Schedule 2 of the Prohibition Regulations and prescribing specific limits for TBTs that may be present in products or food as contaminants.
- An ENGO representative disagreed with the decision to rely on the Environmental Performance Agreement Respecting the Use of Tin Stabilizers in the Vinyl Industry to reduce the release of organotins (which would include the potential release of TBTs that may be present in other organotin compounds) into the environment.

In response to these two comments, Environment Canada indicated that the result of the verifications that have been conducted to date on close to half of the facilities covered by the Environmental Performance Agreement revealed that measures are currently in place, or in a few cases are being developed, to prevent the potential releases of these substances at these facilities. Furthermore, in 2005, a Ministerial Condition was published under subsection 84(5) of CEPA 1999 which currently imposes restrictions on the use and disposal of tetrabutyltin, thereby limiting the release of this substance to the environment. The facility subject to this Condition is in compliance with its requirements. In addition, the proposed Code of Practice would identify best management practices that will seek to limit any potential releases of tetrabutyltin. The facilities that would be covered by the Code are expected to apply these practices. It is noted that the Conditions and the Code also address any potential release of TBTs present in tetrabutyltin or resulting from its environmental breakdown.

As a result, Environment Canada concluded it is not necessary to prescribe specific limits to control the potential releases of TBTs from these activities because they are being addressed by the other risk management measures, or have limited environmental impact.

With respect to the comment pertaining to adding limits to prevent TBTs from being transferred to food as a contaminant, Health Canada has set a tolerable daily intake of 0.25 µg/kg bw/day for tributyltins in foods. Any risk management would be performed on a case-by-case basis if contamination of a food were found.

5. Administrative changes

On December 18, 2007, a consultation document on the proposed administrative changes was posted on Environment Canada's CEPA Registry for a 38-day comment period. In addition, a letter was sent to stakeholders informing them of the publication and consultation period. The consultation document provided an overview of the regulatory amendments that were being considered.

Environment Canada has informed provincial and territorial governments about the proposed Regulations via an email to the CEPA NAC dated December 3, 2008, in which a formal opportunity to consult was offered. Comments received from CEPA NAC have been considered in developing the proposed Regulations.

The main views that were raised by stakeholders, Environment Canada's response to them and how they have been taken into account when developing the proposed Regulations are summarized below. Complete responses to the comments received are available at www.ec.gc.ca.

Prohibition of substances and products listed in Part 1 of Schedule 2

- Industry stakeholders had concerns with the proposed rewording of paragraph 5(a) of the 2005 Regulations. They indicated the proposed wording of section 5 could be misinterpreted to mean that products other than those set out in Part 1 of Schedule 2 would be prohibited.

After consideration, Environment Canada determined that the modification was not necessary but will instead provide clarity on the requirements of paragraph 5(a) in compliance promotion materials. It should be noted that the prohibition applies to the toxic substances listed in column 1 of Part 1 of Schedule 2 and only to the products and mixtures listed in column 2 that contain the toxic substances above the specified concentration limit. The prohibition also applies when the substance is incidentally present.

Reporting requirements

- Industry stakeholders raised concerns about the availability of information with respect to the country of origin, and questioned the necessity to provide quantities exported. In addition, manufacturers were also concerned about the new requirement to provide customer specific sales data.

Environment Canada has considered these concerns and the proposed Regulations would remove these requirements.

- Some industry stakeholders have indicated to Environment Canada that multiple reporting on the same quantity of a substance is required under the current Regulations, including when a substance is first imported and later when a product containing the same substance imported is manufactured.

Environment Canada has considered these concerns and as a result, the proposed Regulations would remove duplication of reporting.

Mixtures

- A non-governmental organization had concerns about the removal of the word "mixture" as they felt that this may reduce the scope of the Regulations.

Environment Canada clarifies that the proposed Regulations applicable to substances and products containing them would also apply to mixtures of listed substances.

Weighted average

- A provincial government representative requested that a definition be added to the proposed Regulations for the term "weighted average."

While a definition was not added to the proposed Regulations, compliance promotion materials will

provide guidance on how to calculate a weighted average for those subject to the Regulations.

Implementation, enforcement and service standards

Implementation

The proposed Regulations would come into force three months following the registration date. The compliance promotion approach for the main parts of the proposed Regulations would be similar to that taken for the 2005 Regulations, which includes maintaining a database of stakeholders, maintaining a Web site on CEPA Registry for the Regulations, and responding to inquiries from stakeholders. In addition, promotional material (such as fact sheets and Web materials) is under development and may be distributed. Environment Canada would undertake outreach activities to raise potential industry stakeholder awareness of the prohibition and associated requirements.

Enforcement

As the proposed Regulations would be promulgated under CEPA 1999, enforcement officers will, when verifying compliance with the Regulations, apply the Compliance and Enforcement Policy implemented under the Act. The Policy outlines measures designed to promote compliance and consultation on the development of regulations. A copy of the Policy may be obtained from the following Web site: www.ec.gc.ca/CEPARRegistry/documents/policies/candepolicy/toc.cfm. When verifying compliance, enforcement officers will abide by the Compliance and Enforcement Policy. The Compliance and Enforcement Policy also sets out the range of possible responses to violations, including warnings, directions, environmental protection compliance orders, ticketing, ministerial orders, injunctions, prosecution, and environmental protection alternative measures (which are an alternative to a court trial after the laying of charges for a violation under the Act). In addition, the Policy explains when Environment Canada will resort to civil suits by the Crown for costs recovery.

When, following an inspection or an investigation, an enforcement officer discovers an alleged violation, the officer will choose the appropriate enforcement action based on the following factors:

- *Nature of the alleged violation*: This includes consideration of the damage, the intent of the alleged violator, whether it is a repeat violation, and whether an attempt has been made to conceal information or otherwise subvert the objectives and requirements of the Act.
- *Effectiveness in achieving the desired result with the alleged violator*: The desired result is compliance within the shortest possible time and with no further repetition of the violation. Factors to be considered include the violator's history of compliance with the Act, willingness to co-operate with enforcement officers, and evidence of corrective action already taken.
- *Consistency*: Enforcement officers will consider how similar situations have been handled in determining the measures to be taken to enforce the Act.

Service standards

The proposed Regulations include provisions for regulatees to request permits from the Minister of the Environment. The applications for permits would be reviewed by Environment Canada. The administrative procedure may take up to 60 working days. Environment Canada would make every effort to respond quickly to permit applications.

Contacts

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PROPOSED REGULATORY TEXT

Notice is hereby given, pursuant to subsection 332(1) ([see footnote a](#)) of the *Canadian Environmental Protection Act, 1999* ([see footnote b](#)), that the Governor in Council proposes, pursuant to subsection 93(1) of that Act, to make the annexed *Prohibition of Certain Toxic Substances Regulations, 2012*.

Any person may, within 75 days after the date of publication of this notice, file with the Minister of the Environment comments with respect to the proposed Regulations or, within 60 days after the date of publication of this notice, file with that Minister a notice of objection requesting that a board of review be established under section 333 of that Act and stating the reasons for the objection. All comments and notices must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be sent to the Director, Chemicals Management Division, Department of the Environment, Gatineau, Quebec K1A 0H3.

A person who provides information to the Minister may submit with the information a request for confidentiality under section 313 of that Act.

Ottawa, June 23, 2011

JURICA ČAPKUN
Assistant Clerk of the Privy Council

PROHIBITION OF CERTAIN TOXIC SUBSTANCES REGULATIONS, 2012

APPLICATION

Application

1. Subject to sections 2 and 3, these Regulations apply to toxic substances that are both specified in the List of Toxic Substances in Schedule 1 to the *Canadian Environmental Protection Act, 1999* and set out in either Schedule 1 or 2 to these Regulations.

Non-application — substance

2. These Regulations do not apply to any toxic substance

(a) that is contained in a hazardous waste, hazardous recyclable material or non-hazardous waste to which Division 8 of Part 7 of the *Canadian Environmental Protection Act, 1999* applies;

(b) that is contained in a pest control product as defined in subsection 2(1) of the *Pest Control Products Act*; or

(c) that is present as a contaminant in a chemical feedstock that is used in a process from which there are no releases of the toxic substance and on the condition that the toxic substance is destroyed or completely converted in that process to a substance that is not a toxic substance set out in either Schedule 1 or 2.

Non-application — use

3. (1) These Regulations, except for subsections (2) and (3), do not apply to any toxic substance, or to any product containing it, that is to be used in a laboratory for analysis, in scientific research or as a laboratory analytical standard.

Information to the Minister — more than 10 g

(2) Every person must submit to the Minister in any calendar year the information set out in Schedule 3 for each toxic substance or a product containing it that they intend to use for a purpose referred to in subsection (1) as soon as possible before the use of more than 10 g of the substance in that calendar year.

On-going use

(3) Any person that, on the day on which these Regulations come into force, is using a toxic substance or product referred to in subsection (1) for a use referred to in that subsection must, if the quantity of the toxic substance used, by itself or in a product, exceeded 10 g in the calendar year immediately before the coming into force of these Regulations, submit to the Minister, within 60 days after that day, the information set out in Schedule 3. The information must be submitted only once in a calendar year in respect of each substance or product.

Addition of a substance

(4) If, after the coming into force of these Regulations, a toxic substance is added to Schedule 1 or 2, any person that, on the day on which the Regulations adding the toxic substance come into force, is using the toxic substance or a product containing it for a use referred to in subsection (1) must, if the quantity of the toxic substance used, by itself or in a product, exceeded 10 g in the calendar year immediately before the coming into force of the Regulations adding the toxic substance, submit to the Minister, within 60 days after the day on which those Regulations come into force, the information set out in Schedule 3. The information must be submitted only once in a calendar year in respect of each substance or product.

PROHIBITIONS

Toxic substance — Schedule 1

4. (1) Subject to section 6, a person must not manufacture, use, sell, offer for sale or import a toxic substance set out in Schedule 1 or a product containing it unless the toxic substance is incidentally present.

Non-application

(2) Subsection (1) does not apply to a product that is a manufactured item that is formed into a specific physical shape or design during its manufacture and that has, for its final use, a function or functions dependent in whole or in part on its shape or design, if a toxic substance set out in Part 2 of Schedule 1 is present in that product.

Toxic substance — Schedule 2

5. (1) Subject to subsection (2) and section 6, a person must not manufacture, use, sell, offer for sale or import a toxic substance set out in column 1 of Part 1, 2 or 3 of Schedule 2 or a product containing it unless the toxic substance is incidentally present.

Permitted activities — Schedule 2

(2) The prohibition to manufacture, use, sell, offer for sale or import a toxic substance set out in column 1 of Part 1, 2 or 3 of Schedule 2 or a product containing it does not apply if

(a) the toxic substance set out in column 1 of Part 1 of Schedule 2 or a product containing it is designed for a use set out in column 2;

(b) the toxic substance set out in column 1 of Part 2 of Schedule 2 or a product containing it is designed for a use set out in column 2 and that activity occurs before the date set out in column 3; or

(c) a product set out in column 2 of Part 3 of Schedule 2 containing the toxic substance set out in column 1 in a concentration less than or equal to that set out in column 3 including any incidental presence of the substance.

Exception — incidental presence

(3) For greater certainty, the exception regarding the incidental presence set out in subsection (1) does not apply in the case of a product referred to in paragraph (2)(c).

PERMITS

APPLICATION

Requirement for permit

6. (1) Any person that, on the day on which these Regulations come into force, is carrying on an activity

referred to in the prohibition set out in section 4 or 5 may continue that activity if they have been issued a permit under section 7.

Addition of substance

(2) In the case of a toxic substance added either to Schedule 1 and referred to in section 4, or to Schedule 2 and referred to in section 5, any person that, on the day on which the Regulations adding the toxic substance come into force, is carrying on an activity referred to in subsection (1) may continue that activity if they have been issued a permit under section 7.

Temporary permitted uses

(3) Any person that, on the day on which the period set out in paragraph 5(2)(b) for which a temporary permitted use expires, is carrying out any activity set out in that paragraph, may continue that activity if they have been issued a permit under section 7.

Required information

(4) An application for a permit must be submitted to the Minister and contain the information set out in Schedule 4.

CONDITIONS OF ISSUANCE

Issuance

7. (1) Subject to subsection (2), the Minister must issue the permit if the following conditions are met:

(a) there is no technically or economically feasible alternative or substitute available to the applicant at the time of the application, other than a substance regulated under these Regulations, for the toxic substance;

(b) the applicant has taken the necessary measures to minimize or eliminate any harmful effect of the toxic substance on the environment and human health; and

(c) a plan has been prepared respecting the toxic substance, identifying the measures to be taken by the applicant so that the applicant's activity will be in compliance with these Regulations, and the period within which the plan is to be implemented does not exceed three years from the day on which a permit is first issued to the applicant.

Grounds for refusing permit

(2) The Minister must refuse to issue a permit if

(a) the Minister has reasonable grounds to believe that the applicant has provided false or misleading information in support of their application; or

(b) information required under subsection 6(4) has not been provided or is insufficient to enable the Minister to process the application.

Expiry and permit renewal

(3) A permit expires 12 months after the day on which it is issued unless, at least 30 days before the day on which the permit expires, the applicant submits an application for renewal in accordance with subsection 6(4). The validity of the first permit may only be extended twice, subject to the same conditions.

REVOCATION

Revocation

8. (1) The Minister must revoke a permit if the conditions set out in paragraphs 7(1)(a) to (c) are no longer met or if the Minister has reasonable grounds to believe that the permit holder has provided false or misleading information to the Minister.

Conditions for revocation

(2) The Minister must not revoke a permit unless the Minister has provided the permit holder with

(a) written reasons for the revocation; and

(b) an opportunity to be heard, by written representation, in respect of the revocation.

REPORTS

Annual report

9. Every person that manufactures or imports a toxic substance set out in column 1 of Part 4 of Schedule 2 or that imports a product containing, whether incidentally or not, that toxic substance must submit to the Minister a report that contains the information set out in Schedule 5 by March 31 of the year following the calendar year during which either the toxic substance was manufactured or the substance or the product was imported if, in that year

(a) the total annual quantity of the toxic substance manufactured or imported was equal to or greater than that set out in column 2, if any;

(b) the product contained the toxic substance in an annual weighted average concentration equal to or greater than that set out in column 3, if any; or

(c) the total annual quantity of the toxic substance manufactured or imported and its annual weighted average concentration in the product were equal to or greater than those set out in column 4, if any.

ACCREDITED LABORATORY

Accredited laboratory

10. Any concentration or quantity required to be determined under these Regulations must be determined, in accordance with generally accepted standards of scientific practice, by a laboratory that is accredited under the International Organization for Standardization standard ISO/IEC 17025:2005, entitled *General requirements for the competence of testing and calibration laboratories*, as amended from time to time, or by a laboratory that meets an equivalent standard.

PRESENTATION OF INFORMATION

Certification

11. (1) Any information or an application for a permit required to be submitted to the Minister under these Regulations must bear the signature of the interested person or their authorized representative and be accompanied by a certification dated and signed by the interested person or the person authorized to act on their behalf, stating that the information is accurate and complete.

Writing or electronic format

(2) The information, application for a permit and certification may be submitted either in writing or in an electronic format that is compatible with the one that is used by the Minister.

RECORD KEEPING

Records

12. (1) Every person that submits information to the Minister under these Regulations must keep a record containing a copy of that information, a copy of the certification and any documents supporting the information, including test data, if applicable, for a period of at least five years beginning on the date of the submission of the information.

Location

(2) The records must be kept at the person's principal place of business in Canada or, on notification to the Minister, at any other place in Canada where the records can be inspected.

TRANSITIONAL

Activity referred to in the *Prohibition of Certain Toxic Substances Regulations, 2005*

13. A permit must not be obtained under these Regulations for an activity prohibited under the *Prohibition of Certain Toxic Substances Regulations, 2005*.

REPEAL

Repeal

14. The *Prohibition of Certain Toxic Substances Regulations, 2005* ([see footnote 24](#)) are repealed.

COMING INTO FORCE

After registration — 3 months

15. These Regulations come into force three months after the day on which they are registered.

SCHEDULE 1

(Sections 1 to 4 and 6 and Schedule 3)

PART 1

PROHIBITED TOXIC SUBSTANCES

Item Toxic Substance

1. Dodecachloropentacyclo [5.3.0.0^{2,6}.0^{3,9}.0^{4,8}] decane (Mirex)
2. Polybrominated Biphenyls that have the molecular formula $C_{12}H_{(10-n)}Br_n$ in which "n" is greater than 2
3. Polychlorinated Terphenyls that have the molecular formula $C_{18}H_{(14-n)}Cl_n$ in which "n" is greater than 2
4. Bis(chloromethyl) ether that has the molecular formula $C_2H_4Cl_2O$
5. Chloromethyl methyl ether that has the molecular formula C_2H_5ClO
6. (4-Chlorophenyl) cyclopropylmethanone, O-[(4-nitrophenyl)methyl] oxime that has the molecular formula $C_{17}H_{15}ClN_2O_3$
7. *N*-Nitrosodimethylamine, which has the molecular formula $C_2H_6N_2O$
8. Hexachlorobutadiene, which has the molecular formula C_4Cl_6
9. Dichlorodiphenyltrichloroethane (DDT), which has the molecular formula $C_{14}H_9Cl_5$
10. Hexachlorobenzene

11. Polychlorinated naphthalenes, which have the molecular formula $C_{10}H_{8-n}Cl_n$ in which "n" is greater than 1
12. Chlorinated alkanes that have the molecular formula $C_nH_xCl_{(2n+2-x)}$ in which $10 \leq n \leq 13$

PART 2

PROHIBITED TOXIC SUBSTANCES UNLESS PRESENT IN MANUFACTURED ITEMS

Item Toxic Substance

1. Hexane, 1,6-diisocyanato-, homopolymer, reaction products with alpha-fluoro-omega-2-hydroxyethyl-poly(difluoromethylene), C16-20-branched alcohols and 1-octadecanol
2. 2-Propenoic acid, 2-methyl-, hexadecyl ester, polymers with 2-hydroxyethyl methacrylate, gamma-omega-perfluoro-C10-16-alkyl acrylate and stearyl methacrylate
3. 2-Propenoic acid, 2-methyl-, 2-methylpropyl ester, polymer with butyl 2-propenoate and 2,5 furandione, gamma-omega-perfluoro-C8-14-alkyl esters, tert-Bu benzenecarboperoxoate-initiated
4. 2-Propen-1-ol, reaction products with pentafluoroiodoethane tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine

SCHEDULE 2

(Sections 1 to 3, 5, 6 and 9 and Schedules 3 and 5)

PERMITTED USES, CONCENTRATION LIMITS AND REPORTING THRESHOLDS

PART 1

PERMITTED USES

Column 1	Column 2
Item Toxic Substance	Permitted Uses
1. Benzidine and benzidine dihydrochloride that have the molecular formulas $C_{12}H_{12}N_2$ and $C_{12}H_{12}N_2 \cdot 2HCl$, respectively	(a) Staining for microscopic examination, such as immunoperoxidase staining, histochemical staining or cytochemical staining (b) Reagent for detecting blood in biological fluids (c) Niacin test to detect some micro-organisms (d) Reagent for detecting chloralhydrate in biological fluids

- | | | |
|----|--|--|
| 2. | 2-Methoxyethanol, which has the molecular formula $C_3H_8O_2$ | (a) Adhesives and coatings for aircraft refinishing

(b) Semiconductor manufacturing process |
| 3. | Pentachlorobenzene, which has the molecular formula C_6HCl_5 | Any use with any chlorobiphenyls described in item 1 of the List of Toxic Substances in Schedule 1 to the <i>Canadian Environmental Protection Act, 1999</i> |
| 4. | Tetrachlorobenzenes, which have the molecular formula $C_6H_2Cl_4$ | Any use with any chlorobiphenyls described in item 1 of the List of Toxic Substances in Schedule 1 to the <i>Canadian Environmental Protection Act, 1999</i> |

PART 2

TEMPORARY PERMITTED USES

Column 1	Column 2	Column 3
Item Toxic Substance	Permitted Uses	Expiry Date
1. Benzenamine, <i>N</i> -phenyl-, reaction products with styrene and 2,4,4-trimethylpentene	(a) Additive in vehicle engine oil (b) Additive in commercial or industrial lubricant	(a) 2 years after the coming into force of these Regulations (b) 2 years after the coming into force of these Regulations

PART 3

PERMITTED CONCENTRATION LIMITS

Column 1	Column 2	Column 3
Item Toxic Substance	Product Containing the Toxic Substance	Concentration Limit of the Toxic Substance
1. 2-Methoxyethanol, which has the molecular formula $C_3H_8O_2$	Diethylene glycol methyl ether, which has the molecular formula $C_5H_{12}O_3$	0.5% (w/w)
2. Tributyltins, which contain the grouping $(C_4H_9)_3Sn$	Tetrabutyltin, which has the molecular formula $(C_4H_9)_4Sn$	30% (w/w)

PART 4

REPORTING THRESHOLDS

Column 1	Column 2	Column 3	Column 4
Item Toxic Substance	Annual Quantity	Annual Weighted Average Concentration	Annual Quantity and Annual Weighted Average Concentration
1. Benzidine and benzidine dihydrochloridethat have the molecular formulas $C_{12}H_{12}N_2$ and $C_{12}H_{12}N_2 \cdot 2HCl$, respectively	1 kg		
2. Benzenamine, <i>N</i> -phenyl-, reaction products with styrene and 2,4,4-trimethylpentene	1 kg		
3. Chlorinated alkanes that have the molecular formula $C_nH_xCl_{(2n+2-x)}$ in which $10 \leq n \leq 13$			1 kg and 0.5% (w/w)

SCHEDULE 3
(Subsections 3(2) to (4))

INFORMATION RELATED TO THE USE OF CERTAIN TOXIC SUBSTANCES IN A LABORATORY FOR ANALYSIS,
IN SCIENTIFIC RESEARCH OR AS A LABORATORY ANALYTICAL STANDARD

1. Information respecting the laboratory where a toxic substance or a product containing it is used or is to be used:

(a) the name, civic and postal addresses, telephone number and, if any, email address and fax number of the laboratory; and

(b) the name, title, civic and postal addresses, telephone number and, if any, email address and fax number of the person authorized to act on the laboratory's behalf, if any.

2. Information respecting each toxic substance set out in Schedule 1 or 2, and each product containing it that is used or is to be used:

(a) the name of the toxic substance and the name of the product, if applicable;

(b) the anticipated period of its use;

(c) the estimated quantity of the toxic substance to be used in a calendar year and its unit of measurement;

(d) the identification of each proposed use and each actual use, as the case may be; and

(e) in the case of a product,

(i) the estimated quantity of the product to be used in a calendar year and its unit of measurement, and

(ii) the estimated concentration of the toxic substance in that product and its unit of measurement.

SCHEDULE 4
(Subsection 6(4))

INFORMATION REQUIRED IN AN APPLICATION FOR A PERMIT

1. Information respecting the applicant:

(a) their name, civic and postal addresses, telephone number and, if any, email address and fax number; and

(b) the name, title, civic and postal addresses, telephone number and, if any, email address and fax number of the person authorized to act on the applicant's behalf, if any.

2. In the case of a toxic substance referred to in either section 4 or 5 of these Regulations or a product containing it, the following information:

(a) the name of the toxic substance and the name of the product, if applicable;

(b) the estimated quantity of the toxic substance to be manufactured, used, sold, offered for sale or imported in a calendar year and its unit of measurement;

(c) in the case of a product,

(i) the estimated quantity of the product to be manufactured, used, sold, offered for sale or imported in a calendar year and its unit of measurement, and

(ii) the estimated concentration of the toxic substance in that product and its unit of measurement;

(d) the identification of each proposed use, if known; and

(e) if the applicant is a manufacturer, seller or importer, the name, civic and postal addresses, telephone number and, if any, email address and fax number of each person in Canada to whom the applicant intends to sell a toxic substance or a product containing it and the name of each toxic substance or product.

3. Information that demonstrates that there is no technically or economically feasible alternative or substitute available to the applicant at the time of the application, other than a substance regulated under these Regulations, for the toxic substance.

4. Information that explains what measures have been taken to minimize or eliminate any harmful effect of the toxic substance on the environment and human health.

5. A description of the plan prepared respecting the toxic substance identifying the measures to be taken by the applicant so that the applicant's activity will be in compliance with these Regulations as well as the period within which the plan is to be implemented.

SCHEDULE 5 (Section 9)

INFORMATION RELATING TO THE MANUFACTURE OR IMPORT OF TOXIC SUBSTANCES

1. Information respecting the manufacturer or importer:

(a) their name, civic and postal addresses, telephone number of their principal place of business and, if any, email address and fax number; and

(b) the name, title, civic and postal addresses, telephone number and, if any, email address and fax number of the person authorized to act on behalf of the manufacturer or importer, if any.

2. Information respecting each toxic substance set out in column 1 of Part 4 of Schedule 2 that is imported and manufactured and each product containing it imported during a calendar year:

(a) the name of the toxic substance and the name of the product, if applicable;

(b) the calendar year;

(c) the total quantity of the toxic substance manufactured, and its unit of measurement;

- (d) the total quantity of the toxic substance sold in Canada, and its unit of measurement;
- (e) the total quantity of the toxic substance imported, and its unit of measurement;
- (f) the identification of each proposed use of the toxic substance and the product, if applicable;
- (g) the annual weighted average concentration of the toxic substance in the product and its unit of measurement, if applicable;
- (h) the analytical method used to determine the concentration of the toxic substance in the product, if applicable;
- (i) the analytical method detection limit used to determine the concentration of the toxic substance in the product, if applicable; and
- (j) the name, civic and postal addresses, telephone number and, if any, email address and fax number of each person in Canada to whom the manufacturer or importer sold the toxic substance or the product.

3. The name, civic and postal addresses, telephone number and, if any, email address and fax number of the laboratory that determined the concentration of the toxic substance in the product, if applicable.

[30-1-o]

[Footnote a](#)

S.C. 2004, c. 15, s. 31

[Footnote b](#)

S.C. 1999, c. 33

[Footnote 1](#)

Pesticidal uses of TBTs are regulated under the *Pest Control Products Act* (PCPA), whereas non-pesticidal uses are proposed to be regulated under CEPA 1999.

[Footnote 2](#)

Socio-Economic Study on Chlorinated Linear Alkanes that have the Molecular Formula $C_nH_xCl_{(2n+2-x)}$ in which $10 \leq n \leq 20$ in Canada, Cheminfo Services, 2011.

[Footnote 3](#)

Hexachlorobenzene Priority Substance List Report, 1993, www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl1-lsp1/hexachlorobenzene/index-eng.php.

[Footnote 4](#)

Screening assessment report available at www.chemicalsubstanceschimiques.gc.ca/challenge-defi/naphthalenes-eng.php.

[Footnote 5](#)

www.unece.org/env/lrtap/pops_h1.htm (select "Amendments to annexes I and II").

[Footnote 6](#)

The full risk assessment for BNST is available at www.ec.gc.ca/ese-ees/default.asp?lang=En&xml=77578C0A-53F0-BE0F-1730-6CFB5E5C90B2.

[Footnote 7](#)

Environment Canada. 2009. "BNST Use and Disposition in Lubricants." Report prepared by MTN Consulting Associates for Environment Canada, Oil, Gas and Alternative Energy Division, Gatineau, Quebec K1A 0H3.

[Footnote 8](#)

Ibid.

[Footnote 9](#)

The full risk assessment is available at www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=D7D84872-1.

[Footnote 10](#)

Socio-Economic Study on Chlorinated Linear Alkanes that Have the Molecular Formula $C_nH_xCl(2n+2-x)$ in which $10 \leq n \leq 20$ in Canada, Cheminfo Services, 2011.

[Footnote 11](#)

Approximation based on the report *Analysis of Options to Mitigate Chlorinated Paraffin Releases in Canada*, Cheminfo Services, 2005.

[Footnote 12](#)

Socio-Economic Study on Chlorinated Linear Alkanes that Have the Molecular Formula $C_nH_xCl(2n+2-x)$ in which $10 \leq n \leq 20$ in Canada, Cheminfo Services, 2011.

[Footnote 13](#)

Note that the definition provided previously on PCNs, namely chlorinated naphthalenes containing more than one chlorine atom is equivalent to chlorinated naphthalenes containing two to eight chlorine atoms.

[Footnote 14](#)

Screening assessment report: www.chemicalsubstanceschimiques.gc.ca/challenge-defi/naphthalenes-eng.php.

[Footnote 15](#)

CCME, 2007, Canadian Council of Ministers of the Environment, *Review of Dioxins and Furans from Incineration in Support of a Canada-wide Standard Review*.

[Footnote 16](#)

The full risk assessment report is available at www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=B3B78BAF-1.

[Footnote 17](#)

This Environmental Performance Agreement is available at www.ec.gc.ca/epe-epa/default.asp?lang=En&n=7F317BDF-1.

[Footnote 18](#)

This Ministerial Condition is available at www.gazette.gc.ca/archives/p1/2005/2005-03-26/html/notice-avis-eng.html.

[Footnote 19](#)

Anti-fouling paints are used to coat the bottoms of ships to prevent sea life such as algae and molluscs from attaching themselves to the hull, whose attachment would slow down the ship and increase fuel consumption.

[Footnote 20](#)

Cost-Benefit Analysis Study for BNST, Final report, HDR Corporation, February 2011.

[Footnote 21](#)

Johnston, R. J., E. Y. Besedin, R. Iovanna, C. J. Miller, R. F. Wardwell, and M. H. Ranson, "Systematic Variation in Willingness to Pay for Aquatic Resource Improvements and Implications for Benefit Transfer: A Meta-Analysis" (2005), *Canadian Journal of Agricultural Economics* 53, p. 221–248.

[Footnote 22](#)

The Water Quality Ladder (WQL) index represents poor to excellent water quality that is assessed in terms of its suitability for swimming, aquatic life and safety of fish and shellfish for human consumption, and whether the water meets guidelines for drinkable water. The WQL is measured on a scale from 1 to 10 where 1 represents the worst possible water quality equivalent to raw untreated effluent and 10 represents the best water quality.

[Footnote 23](#)

This document is available at www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=98F99990-1.

[Footnote 24](#)

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NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

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