



Summary of Public Comments received on the proposed *Prohibition of Certain Toxic Substances Regulations, 2012*

The proposed *Prohibition of Certain Toxic Substances Regulations, 2012* were published on July 23, 2012 in *Canada Gazette*, Part I, for a 75-day public comment period. Approximately twenty organizations provided comments: Anachemia Canada Co.; Arkema Canada Inc; Assembly of First Nations; Association of International Automobile Manufacturers of Canada; Canadian Environmental Law Association; Canadian Manufacturers & Exporters; Canadian Paints and Coatings Association; Canadian Vehicle Manufacturers' Association; CCI Manufacturing IL Corp.; Color Pigments Manufacturers Association, Inc.; Dow Chemical Canada ULC; E.I. du Pont Canada Company; Ford Motor Company; Imperial Oil; Industry Coordinating Group for the Canadian Environmental Protection Act; International Chlorinated Paraffin Industry Association; Motorcycle and Moped Industry Council; R.T. Vanderbilt Company, Inc.; Solucor; Vinyl Council of Canada.

A number of stakeholders have forwarded positive comments on the Regulations such as supporting either the addition of certain substances or other administrative changes and clarifications that have been made. In addition, a number of specific comments relating to the following toxics are summarized below.

- Benzenamine, *N*-phenyl-, Reaction Products with Styrene and 2,4,4-Trimethylpentene (BNST)
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Benzenamine, N-phenyl-, Reaction Products with Styrene and 2,4,4-Trimethylpentene (BNST)

Topic	Comment Summary	Response
<i>Use in Lubricants</i>		
	Industry stakeholders have expressed that substitutes for BNST are ready and available and that the 2-year temporary permitted use exemption should be sufficient. However, should difficulty occur during the substitution process, the permitted use exemption should be extended. A non-governmental organization was concerned that 2-years was too long for temporary permitted usage.	The Government of Canada is providing a 2-year temporary permitted use exemption for the use of BNST as additive in lubricants. If required, anyone importing or manufacturing BNST for use as an additive in lubricants can apply for an annual permit after the end of the 2-year exemption period under conditions specified in the Regulations.

	An industry stakeholder proposed that the temporary permitted use period be applicable to the use of BNST as an anti-oxidant in other lubricants such as motor vehicle power steering fluids, transmission fluids, and various grease.	The intent is that the 2-year temporary permitted use exemption would apply to the use of BNST in all types of lubricants; therefore the Regulations have been modified to clarify this issue.
<i>Use in Rubber</i>		
	Some industry stakeholders have provided information indicating that BNST is used in automobile and vehicle rubber parts. They also requested an exemption for this use on the basis that the use of BNST in rubber poses less risk to the environment than vehicle engine oil.	The use of BNST in rubber parts is not expected to contribute to environmental releases. Thus an exemption has been added to the Regulations for the use of BNST in rubber products, with the exception of tires. No uses in tires were identified or reported, thus this use was not exempted to avoid introduction.
<i>Products in Use</i>		
	There should be an exemption for products containing BNST manufactured and imported prior to the coming into force of the Regulations.	An exemption has been added for the use, sale and offer for sale of products containing BNST, short-chain chlorinated alkanes, PCNs and TBTs that were manufactured or imported prior to the coming into force of the Regulations. This exemption is also applicable for products containing BNST as an additive in lubricants if manufactured or imported prior to the end of the temporary permitted use period. This is intended to allow the sale of existing products that may contain these substances and to allow on-going use of these products.
<i>Reporting Requirements</i>		

	An industry stakeholder noted that there is an inconsistency between the original Section 71 notice of a 100 kg reporting threshold and the new requirement of a 1 kg reporting threshold for BNST. Environment Canada should not lower the reporting threshold of 100kg to 1kg annually.	Reporting requirements associated with regulations and Section 71 notices are intended to serve different purposes. The proposed Regulations had included a reporting requirement for the manufacture and import of BNST in quantities greater than 1kg. However given that the Regulations include a permitted use exemption and a temporary use exemption for BNST, the reporting requirements for BNST have been removed.
<i>International Jurisdictions</i>		
	Industry associations suggested that the Government of Canada should harmonize their environmental safety and trade regulations for automobiles with those of the United States and globally.	The objective of the Regulations is to protect the Canadian environment from the risks posed by BNST. 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 linked to this substance. During the development of the Regulations, consideration was given to actions taken in other jurisdictions.
<i>General Comments</i>		
	An industry association was concerned that some suppliers may not identify BNST on the MSDS for their products, thus it may be difficult to identify and capture all sources of BNST.	The expectation is that manufacturers and importers should be able to obtain information regarding the amount of BNST found in products to comply with the Regulations.
	An industry association recommended that Environment Canada undertake additional evaluation and consultation on BNST before moving forward with the proposed regulations.	The Government of Canada has consulted on the draft ecological risk assessment. Following these consultations the final risk assessment report for these substances was published. Consultations also occurred as part of the development of the Regulations. Stakeholders had the opportunity to comment on the proposed Regulations. Based on comments received, some changes have been made to address concerns raised

		by stakeholders, for example, rubber products containing BNST, with the exception of tires, have been exempted from the Regulations.
	A non-governmental organization proposed that consideration should be given for BNST released during export and disposal of stockpiles and waste.	As BNST is an antioxidant additive used in lubricants, the disposal of lubricant products containing BNST are expected to be managed throughout provincial/territorial Used Crankcase Oil (UCOs) programs. All provinces and territories classify UCOs as hazardous waste under their respective legislation and it is expected that UCOs will be disposed of by authorized facility.
	A non-governmental organization asked that the alternatives of BNST should be assessed and the results should be presented in a report and made available to the public.	Substituted diphenylamines with various degrees of phenyl or alkyl substitution are known as potential alternatives for BNST. These substances are being assessed as part of the Chemical Management Plan under the Substances Grouping Initiative. Results of any assessments will be published once they have been completed. For more information on that initiative please refer to the Chemicals Substances website under the Substance Groupings Initiative menu at: http://chemicalsubstanceschimiques.gc.ca/index-eng.php
	An industry stakeholder questioned whether BNST is really manufactured in Canada.	The manufacture of BNST occurs in Canada.

	<p>An industry stakeholder noted that caution should be taken before implementing risk management action for BNST based on modelled data.</p>	<p>The substance BNST was included in the Challenge initiative under the Chemical Management Plan as one of approximately 200 substances identified as high priorities for action. The final screening assessment report for BNST concluded that BNST is potentially harmful to the environment and meets the criteria set out under paragraph 64(a) of <i>Canadian Environmental Protection Act, 1999</i> 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 <i>Canada Gazette</i>, 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. Therefore actions are being put in place to prevent harmful effects on the environment.</p>
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Tributyltins (TBTs)

Topic	Comment Summary	Response
<p><i>International Jurisdictions</i></p>		
	<p>A non-governmental organization representative commented that other jurisdictions, such as the European Union, have adopted a decision in May 28, 2009 to prohibit the use of triorganotin compounds and dibutyltin in articles. They requested that Canada follow this approach and expand the Regulations to include prohibition of dibutyltin at a minimum or to establish clear numerical limits similar to those of the European Union.</p>	<p>The Regulations are one of several measures in place to manage the risks associated with TBTs in the Canadian environment. Other measures in place include a Code of Practice and an Environmental Performance Agreement that are intended to manage the release of these substances or of compounds that may contain these substances.</p> <p>During the development of the Regulations, consideration was given to actions taken by other jurisdictions.</p> <p>In the case of dibutyltins, Health Canada's conclusion of the human health assessment conducted in 2003 was that they</p>

		<p>did not meet the criteria listed in paragraph 64(c) of CEPA 1999, and therefore, no risk management actions are being proposed at this time.</p> <p>Similarly, Environment Canada's conclusion of the 2009 ecological assessment for dibutyltins was that they did not meet the criteria listed in paragraph 64(a) or (b) of CEPA 1999 due to industry-wide stewardship practices in place to limit their potential environmental releases, which are being verified under an Environmental Performance Agreement.</p>
<i>General Comments</i>		
	<p>A non-governmental organization representative indicated that there should be mandatory controls on tetrabutyltin, mono- and dibutyltins in place of non-regulatory mechanisms, and that it should be released to the public for review and comments.</p>	<p>The risk management tools in place for managing potential releases of tetrabutyltin, monobutyltins and dibutyltins have been released to the public for comments prior to their finalisation.</p> <p>In the case of tetrabutyltin, the proposed Code of Practice was published for public comments in January 2011. Comments have been considered and the final Code was published on November 5, 2011. Environment Canada intends to verify the degree of implementation of the Code and to publish the results on our website. The final Code is available at the following Website: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=B5292A55-1</p> <p>As for mono- and dibutyltins, these were not concluded to be toxic; however, an Environmental Performance Agreement (EPA) was put in place to verify whether suitable management practices and procedures were in place to prevent their release into the aquatic environment. The draft EPA on tin stabilizers was published in April 2007 for public review. Apart from a clarification question, no comments were received, and the final EPA was signed in March 2008. Furthermore, annual progress reports are published on Environment Canada's website available at: http://www.ec.gc.ca/epe-</p>

		epa/default.asp?lang=En&n=980ED2A4-1
	An industry stakeholder suggested that the proposed regulations not interfere with the Code of Practice objectives and /or the development process.	<p>The Regulations and the Code of Practice do not interfere with one another.</p> <p>The Regulations prohibit the manufacture, use sale, offer for sale or import of the product tetrabutyltin containing a concentration greater than 30% by weight of TBTs.</p> <p>The existing activities involving the import, distribution, manufacture and use of tetrabutyltin are covered by the Code of Practice as they pertain to products containing less than or equal to 30% by weight of TBTs.</p>

Short Chain Chlorinated Alkanes

Topic	Comment Summary	Response
<i>Use in Paints</i>		
	An industry association stated that medium-chain chlorinated alkanes are used in paints found in pools. Since short-chain chlorinated alkanes are found in trace amounts in medium chain chlorinated alkanes, they suggested than an exemption should be provided for the use of paints found in pools.	Short-chain chlorinated alkanes are not used intentionally in paints within Canada; however they may be incidentally present in small amounts. In such instances, the prohibition on manufacture, use, sale, offer for sale and import of short-chain chlorinated alkanes would not apply.
<i>International Jurisdictions</i>		

	Several industry associations mentioned that the Government of Canada should align their Regulations on short-chain chlorinated alkanes with those of the United States, the European Union, and globally. Further consultation should be taken before continuing with the proposed prohibition.	Canada's actions on short-chain chlorinated alkanes are consistent with those of other jurisdictions. Short-chain chlorinated alkanes are already banned in Europe and the US EPA proposed new controls in March, 2012 to further address the manufacturing, processing, distribution in commerce and use of short-chain chlorinated alkanes. Short-chain chlorinated alkanes have also been added to the Protocol on Persistent Organic Pollutants to the Convention on Long-range Transboundary Air Pollution. In addition short-chain chlorinated alkanes have been nominated for addition to the Stockholm Convention on POPs.
<i>General Comments</i>		
	An industry association questioned whether there are appropriate test methods to determine whether short-chain chlorinated alkanes are present.	Environment Canada has worked in collaboration with industry on developing test methods to determine whether or not SSCAs are present. Certain test methods for metal working fluids have been completed and other test methods are under development.
	A non-governmental organization noted that based on assessments, all chlorinated alkanes meet the criteria of toxic under Section 64 of the Canadian Environmental Protection Act, 1999 (CEPA, 1999). When does the Government of Canada expect to develop options for the management of the remaining chlorinated alkanes?	The Government of Canada is in the process of evaluating potential options for the management of chlorinated alkanes containing 14-20 carbon atoms (medium and long chain chlorinated alkanes).
	A non-governmental organization suggested that regulatory measures should be developed to address the full life cycle of short-chain chlorinated alkanes and to identify safe alternatives.	The Regulations aim to minimize potential releases by prohibiting the manufacture, use, sale, offer for sale or import of short-chain chlorinated alkanes or any products containing short-chain chlorinated alkanes. Also, the monitoring of short-chain chlorinated alkanes is occurring under a comprehensive monitoring and surveillance strategy for all substances under the Chemicals Management Plan. This monitoring will be used to determine whether further action needs to be taken to

		address the potential releases of short-chain chlorinated alkanes from other sources.
	An industry association stated that the raw materials used to make medium-chained chlorinated alkanes usually specify the short-chain chlorinated alkanes content to 1%, thus the 0.5% reporting threshold is difficult to meet.	The intent of this reporting requirement is to gather information on the incidental presence of short-chain chlorinated alkanes in medium-chain chlorinated alkanes. This information will be used to assess the potential need to take action to address potential exposure or release where short-chain chlorinated alkanes are incidentally present. While it may be difficult to meet the 0.5% threshold, it should be noted that the European Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals requires reporting if short-chain chlorinated alkanes are present in a concentration above 0.1%.

Polychlorinated Naphthalenes (PCNs)

Topic	Comment Summary	Response
<i>Products in Use</i>		
	An industry stakeholder noted that the Regulations should not disrupt the products already in use that contain PCNs, such as underground cables.	The Regulations take into consideration any potential issues associated with existing products containing PCNs (i.e. products in use in Canada prior to the coming into force of the Regulations such as underground cables), by including an exemption for the use, sale and offer for sale of products manufactured or imported into Canada prior to the coming into force of the Regulations.
<i>Laboratory Use</i>		
	An industry stakeholder proposed that the Regulations should allow for the continuation of the use of substances in laboratories as it would be beneficial for research and development.	The Regulations take into consideration the use of PCNs as analytical standards by exempting manufacture, use, sale, offer for sale and import of PCNS used in a laboratory for analysis, in scientific research or as a laboratory analytical

		standard.
<i>General Comments</i>		
	The Regulations should address PCN disposal methods.	<p>The Regulations aim to minimize potential releases by prohibiting the manufacture, use, sale, offer for sale or import of PCNs or any products containing PCNs.</p> <p>Furthermore, EC has undertaken research on the unintentional production of PCNs and has concluded that no additional control measures are needed at this time to control unintentional production and release of PCNs from waste disposal.</p> <p>In addition, the monitoring of PCNs is occurring under a comprehensive monitoring and surveillance strategy for all substances under the Chemicals Management Plan. This monitoring will be used to determine whether further action needs to be taken with respect to unintentional releases of PCNs in the future.</p>
	An industry stakeholder questioned whether it was premature to publish the Regulations before the completion of the consultation process for the Risk Management Approach and the addition of PCNs to CEPA Schedule 1.	<p>The Government of Canada published a Risk Management Scope for PCNs which stated that a prohibition was being considered. No comments were received regarding the proposal to prohibit these substances. In addition, stakeholders had an opportunity to provide comments on the proposed regulatory controls for PCNs when the proposed <i>Prohibition of Certain Toxic Substances Regulations, 2012</i> were published in Canada Gazette on July 23, 2011 for a 75-day public comment period. Comments received on the proposed regulations suggested that stakeholders were supportive of the proposed regulatory measures for PCNs. PCNs have been added to the List of Toxic Substances in Schedule 1 of CEPA 1999 on October 10, 2012.</p>

<u>Other Comments</u>		
Topic	Comment Summary	Response
<i>Accredited Laboratories</i>	Several stakeholders stated that it is unclear whether the government or the regulatees are required to verify compliance with the Regulations using an accredited laboratory and what should be the frequency. Regulatees should not be limited only to having to use accredited laboratories.	<p>The Regulations allow for either the use of an accredited laboratory or one that meets an equivalent standard.</p> <p>Any quantities and concentrations that are required to be reported to Environment Canada under the Regulations must be obtained through accredited laboratories under the standard ISO/IEC 17025:2005 or from a laboratory that meets an equivalent standard, and in accordance with generally accepted standards of scientific practice.</p> <p>As for the frequency in which a manufacturer/seller/importer/user would conduct testing as part of an internal evaluation to verify their compliance with the Regulations there is no specific requirement in the Regulations. Nonetheless, the Regulations do prescribe the testing frequency for information that needs to be reported to Environment Canada. Environment Canada also promotes environmental audits, as set out in the <i>Compliance and Enforcement Policy for CEPA (1999) – March 2001</i>.</p> <p>For the purpose of verifying and securing compliance with the Regulations, the Government of Canada will use an accredited laboratory, as prescribed in the Regulations.</p>
<i>CAS Registry Numbers</i>		

	Several industry stakeholders and an industry association recommended that the CAS Registry Numbers be included in Regulations so that specific substances and groups of substances can be clearly identified.	It may not be possible to list the CAS Registry Numbers in the Regulations for the following reasons: not all substances have a CAS number, it can be difficult to identify an exhaustive list of CAS numbers, and CAS numbers may change over time. However, a non-exhaustive list of known CAS Registry Numbers is provided as part of the guidance materials on the Regulations.
<i>Incidental Presence</i>		
	An industry association noted that the text in the Regulations regarding the prohibition of HCB “unless incidentally present” is supported, however the text in the RIAS could be interpreted otherwise.	The description of the Regulations under section 5 of the Regulatory Analysis Impact Statement has been updated to better capture that the exemption for incidental presence applies to HCB.
<i>Reporting</i>		
	A non-governmental organization proposed that the reporting of all substances listed on the Regulations should be required regardless of threshold and also to include information on alternatives.	The Regulations prohibit the manufacture, import, use, sale and offer for sale of toxic substances or products containing them with certain exceptions. The reporting requirements focus on those areas where there may be on-going use as per one of the exemptions.
	An industry stakeholder suggested that the exemption for incidental presence should be universal, applying to all situations, including reporting for substances listed in Schedule 2, Part 4.	There are only 2 substances listed in Schedule 2, Part 4 for which reporting could be required. These reporting requirements are limited in scope and are intended to gather information that can be used to assess whether additional control measures should be considered for these substances.
<i>Record Keeping</i>		

	An industry stakeholder noticed that in Section 12 of the Regulations there is no reference to confidential business information, which may be found in submitted reports or permits. Provisions should be included in the Regulations to ensure that confidential business information will be protected.	Under Section 313 of CEPA, 1999 any person submitting information under the Act may request that it be treated as confidential.
<i>Laboratory Use</i>		
	An industry stakeholder suggested that the Regulations clarify the restrictions on the distribution of substances in research labs, schools and industrial labs.	There is an exemption for Research and Development use in the lab for analysis, scientific research or as an analytical standard. This exemption applies to manufacture, use, sale, offer for sale and import of substances intended for this purpose.
<i>Transition</i>		
	An industry stakeholder asked if section 13 in the Proposed Regulations (now section 16) transitional provisions are redundant.	The <i>Prohibition of Certain Toxic Substances Regulations, 2005</i> have been repealed, thus it is necessary to include this provision to ensure that a permit cannot be obtained for an activity that had been previously prohibited.
<i>Permits</i>		
	An industry stakeholder wanted to clarify whether permit requirements were applicable for the incidental presence of HCB in products.	The Regulations prohibit the manufacture, import, use, sale and offer for sale of HCB or products containing it unless incidentally present. Since incidental presence is exempt from the Regulations no permits would be required in these circumstances.
	An industry stakeholder raised a question regarding the meaning of the term “interested person” within section 14 of the Regulations.	The term “interested person” refers to a person who is required to submit a report as per subsections 3(2), 3(3) or 3(4) or section 12 of the Regulations or a person who submits a permit application as per section 9 of the Regulations.

	<p>An industry stakeholder stated that the use of the term “insufficient” in paragraph 10(2)(b) is too subjective and should be deleted.</p>	<p>Paragraph 10(2)(b) describes the conditions under which the Minister must refuse to issue a permit. This provision states that the Minister must refuse to issue a permit if the information required under subsection 9(4) has not been provided or is insufficient to enable the Minister to process the application. “Insufficient” therefore includes where an incomplete permit application is submitted, or if there is not enough information provided to demonstrate that the conditions of issuance identified under subsection 10(1) are satisfied.</p>
	<p>An industry stakeholder stated that the phrase in paragraph 10(1)(a) “...other than a substance regulated under these Regulations...” is not clear.</p>	<p>Paragraph 10(1)(a) outlines one of the conditions under which the Minister must issue a permit. This condition is that there is no technically or economically feasible alternative available or substitute available. Within this context, “...other than a substance regulated under these Regulations...” excludes other substances listed in the Regulations from consideration as technically or economically feasible alternatives or substitutes.</p>
	<p>An industry stakeholder noted that they were supportive of the proposed permit provisions in general. However they asked whether an activity prohibited under the Regulations could be allowed to continue while a permit application is being processed.</p>	<p>The Regulations do not enter into force until three months after they are registered. This three month period allows time for an activity to continue while potential permit applications are being evaluated against the conditions of issuance outlined in Section 10 of the Regulations.</p>
	<p>An industry stakeholder suggested that the intent of the requirement in Section 4, paragraph 2(c) be clarified.</p>	<p>This provision of the Regulations is to gather information on either the estimated quantity manufactured or imported. This has been clarified in the Regulations.</p>
	<p>An industry stakeholder asked whether sellers at a retail level would be required to obtain a permit.</p>	<p>The Regulations streamline the permit provisions by specifying that only persons who are manufacturing or importing a toxic substance subject to the Regulations or a product containing it, on the day on which the Regulations come into force may continue that activity if they have been issued a permit under section 10 of the Regulations.</p> <p>Furthermore, the prohibition on use, sale or offer for sale of a toxic substance or a product containing it, does not apply if</p>

		they were manufactured or imported by a person to whom a permit has been issued.
	An Aboriginal organization reinforced that if a permit could potentially impact Aboriginal rights, the Government of Canada must first consult First Nations.	Consultations with First Nations will be undertaken as per existing policies relating to Aboriginal consultations, such as the Updated Guidelines for Federal Officials to Fulfill the Duty to Consult, available at: http://www.aadnc-aandc.gc.ca/eng/1100100014664 .
<i>Cost-Benefit</i>		
	An industry stakeholder noted that the RIAS did not provide a total cost estimate of benefit expected by the prohibition of BNST. This raises concern because it is not certain that the Regulations would be guaranteed to result in positive results.	BNST was assessed to be persistent, bioaccumulative, and inherently toxic to the environment. It has potential to harm aquatic organisms and may biomagnify in food chains. Prohibiting BNST is expected to result in net benefits.
	An industry stakeholder commented that the RIAS discussion of 0.5 cents per litre being negligible should be worded differently as different markets react to costs differently.	The wording in the RIAS has been reviewed and the incremental costs to consumers are now described as minimal; however, as described in the cost benefit analysis, this price increase is not expected to place a significant burden on consumers because the magnitude should be small relative to the overall price of the product.
	An industry stakeholder mentioned that monitoring costs will be more than the estimated \$13,000.	
	An industry stakeholder stated that since new reporting systems will be created for the substances added to the Regulations, there will be additional costs and compliance risks. Both of these factors should be recognized in the RIAS.	It is expected that new reporting requirements would not result in significant additional costs since many organizations, such as laboratories are already submitting reports for substances that were included in the former Regulations. In addition, the costs associated with new reporting requirements for short-chain chlorinated alkanes are expected to be limited.