Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-

(DTBSBP)

Chemical Abstracts Service Registry Number (CAS RN):
17540-75-9

Environment Canada
Health Canada

July 2010

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

1. The Government is proposing regulatory controls towards virtually eliminating releases of the substance to the environment
2. The Government is proposing a regulation to prohibit and/or limit the conditions under which the substance may be imported, manufactured or used.
3. The Government will assess the potential for DTBSBP to meet the criteria set out in section 200 of CEPA 1999 in the event that it was to enter the environment as a result of an environmental emergency.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that, in accordance with the criteria at section 73 of the Act, a) are considered to be persistent (P) or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000), and "inherently toxic" (iT) to humans or other organisms, or b) may present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets one or more of the criteria set out in section 64 of the Act[1].

[1] A determination of whether one or more of the criteria of section 64 are met and whether risk management may be required is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 on the substances in the Chemicals Management Plan (CMP) Challenge Batches 1-12 is not relevant to nor does it preclude an assessment against the hazard criteria specified in the Workplace Hazardous Materials Information System [WHMIS] *Controlled Products Regulations* for products intended for workplace use.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comments, profiles of batches containing 12 to 19 high-priority substances. New batches have been released for comments approximately every three months.

Information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-, Chemical Abstracts Service Registry Number (CAS RN)[2] 17540-75-9, also known as 2,6-Di-tert-Butyl-4-Sec-Butylphenol and referred to throughout this document as "DTBSBP", is included in Batch 8 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for DTBSBP

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for DTBSBP on July 31, 2010, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that DTBSBP is entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

The final screening assessment report also concluded that DTBSBP meets the criteria for persistence and meets the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of DTBSBP in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for DTBSBP, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-8/index-eng.php.

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the

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

substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances, the Ministers must make a specific proposal to recommend the implementation of virtual elimination. In this case, the Ministers proposed to recommend the addition of DTBSBP to the List of Toxic Substances in Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the environment from the potential effects of exposure to this substance.

In addition, the final screening assessment report concluded that DTBSBP meets the virtual elimination criteria set out in subsection 77(4) of CEPA 1999 because

- DTBSBP meets the criterion set out in paragraph 64*(a)* of CEPA 1999;
- DTBSBP is inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies;
- DTBSBP meets the criteria for persistence and bioaccumulation as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999;
- the presence of DTBSBP in the environment results primarily from human activity; and
- DTBSBP is not a naturally occurring radionuclide or a naturally occurring inorganic substance.

As a result, the process for substances targeted for virtual elimination will be followed.

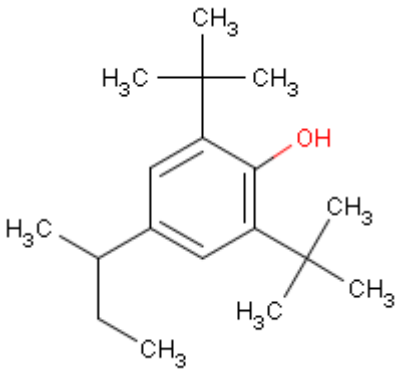
2. BACKGROUND

2.1 Substance Information

DTBSBP is part of the chemical class phenol and the chemical sub class alkylphenol. Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for DTBSBP.

Table 1. Identity of DTBSBP

Chemical Abstracts Service Registry Number (CAS RN)	**17540-75-9**
DSL name	**Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-**
National Chemical Inventories (NCI) names[1]	*Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-* (TSCA, ENCS, AICS, PICCS, ASIA-PAC) *4-sec-Butyl-2,6-di-tert-butylphenol* (DSL, EINECS, ECL) *PHENOL, 2,6-DI-TERT-BUTYL-4-SEC-BUTYL-* (PICCS)
Other names	*2,6-Di-tert-butyl-4-sec-butylphenol;* *Isonox 132;* *NSC 14460;* *Phenol, 4-sec-butyl-2,6-di-tert-butyl-;* *Vanox 1320*

Chemical Abstracts Service Registry Number (CAS RN)	**17540-75-9**
DSL name	**Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)-**
Chemical group (DSL Stream)	Discrete organics
Major chemical class or use	Phenols
Major chemical sub-class	Alkylphenols, hindered phenols
Chemical formula	$C_{18}H_{30}O$
Chemical structure	
SMILES[2]	Oc1c(cc(cc1C(C)(C)C)C(CC)C)C(C)(C)C
Molecular mass	262.44 g/mol

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based on empirical, modelled and analogue data, DTBSBP is expected to be persistent in water, soil and sediment. It is also expected to have a high bioaccumulation potential and high potential for toxicity to aquatic organisms based on analogue and modelled data.

The importation volume of DTBSBP into Canada (16 686 kg in 2006), along with information on its industrial and consumer uses, indicates the potential for widespread and point-source releases into the Canadian environment. DTBSBP is expected to be released mainly to water, though it is expected to reside in sediment as well.

Evidence that a substance is highly persistent and bioaccumulative as defined in the *Persistence and Bioaccumulation Regulations* of CEPA 1999 (Canada 2000), when taken together with potential for environmental release or formation and potential for toxicity to organisms, provides a significant indication that it may be entering the environment under conditions that may have harmful long-term ecological effects. Substances that are persistent remain in the environment for a long time after being released, increasing the potential magnitude and duration of exposure. Substances that have long half-lives in mobile media (air and water) and partition into these

media in significant proportions have the potential to cause widespread contamination. Releases of small amounts of bioaccumulative substances may lead to high internal concentrations in exposed organisms. Highly bioaccumulative and persistent substances are of special concern, since they may biomagnify in food webs, resulting in very high internal exposures, especially for top predators.

Given the information on the amount of DTBSBP that is imported into Canada and on the nature of its reported industrial and consumer uses, there is potential for release of this substance into the Canadian environment. Once released in the environment, because of its resistance to degradation it will remain in water, sediment and soil for long times. As it persists in the environment, and because of its lipophilic character, it will likely bioaccumulate and may be biomagnified in trophic food chains. It has also demonstrated potential for relatively high toxicity. This information indicates that DTBSBP has the potential to cause ecological harm in Canada. (Canada 2010)

4. CURRENT USES AND INDUSTRIAL SECTORS

Recent information was collected through surveys conducted for the years 2005 and 2006 under *Canada Gazette* notices issued pursuant to section 71 of CEPA 1999 (Canada 2006, Canada 2009). These notices requested data on the Canadian manufacture, import and use of DTBSBP. Three companies reported total importations of between 1000 kg and 100 000 kg of the substance into Canada in 2005 (Canada 2006). In Canada in 2006, no company reported manufacturing DTBSBP (above the reporting threshold of 100 kg). In 2006, 16 686 kg of DTBSBP was imported into Canada by five companies, including one below the reporting threshold of 100 kg/year. Six companies identified a stakeholder interest (Canada 2009).

In response to the CEPA section 71 notices, DTBSBP was identified as used in plastics product manufacturing (primarily urethane and other foam products, except polystyrene) and as an antioxidant/corrosion inhibitor used in brake fluid. Other uses were noted to be confidential business information (CBI). Although not described here, this CBI information was considered in estimating environmental releases and in risk management development.

This information is consistent with the DSL nomination data (1984 - 1986), which identified the substance as an antioxidant/corrosion inhibitor/scavenger/antiscaling agent and that the substance was used as an antioxidant in the manufacture of plastics products. It was also used as an antioxidant in other manufactured products (Environment Canada 1988).

Other Potential Uses and Industrial Sectors

The additional information below on potential uses of DTBSBP was found through searches of the available scientific and technical literature, although potential uses in Canada were not specifically confirmed.

DTBSBP is listed by the U.S. Food and Drug Administration as an effective food contact substance, which is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food (US FDA 2008).

It is specifically used as an antioxidant in plasticized vinyl chloride homo- and co-polymers (PVC) (SII 2001). For example, it may be used in PVC films for wrapping meat and produce, and in plastic hoses employed to transfer food during processing and packaging (2009 email from Food Directorate, Health Canada, to Risk Management Bureau, Health Canada; unreferenced).

According to the North American manufacturer of DTBSBP, it is used in the following industries (SI Group 2009):

- PVC, both rigid and flexible grades – polymerization chain terminator and PVC stabilizer;
- thermoplastics, such as low-density polyethylene (LDPE)
- polyols/flexible foams – stabilizer/antioxidant
- brake fluids - stabilizer/antioxidant/corrosion inhibitor;
- ink resins - stabilizer/antioxidant;
- peroxide inhibitor for petrochemical and refinery streams - stabilizer/antioxidant;
- mineral/vegetable oils, such as turbine oil, hydraulic oil, chainsaw oil - stabilizer/antioxidant

The purity of commercially available DTBSBP is typically 98.6%. When used as an antioxidant, the concentration of DTBSBP ranges from 0.03-0.10 %wt (SI Group 2009). This substance may also be used as an antioxidant in mineral oils such as turbine oil, hydraulic oil and chain saw oil, in vegetable oils that have replaced mineral oils in some applications due to biodegradability issues, and is being tested for potential needs in bio-diesel (SI Group 2009), though there were no reported uses in these products in the recent section 71 surveys.

It was noted that DTBSBP is being used to replace the antioxidant butylated hydroxytoluene (BHT, CAS RN 128-37-0) in several of the non-food applications listed above (SI Group 2009).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

DTBSBP has not been measured in any environmental media or industrial discharge. The estimate of release to the environment, and subsequent environmental concentrations, are based on estimates of release applied throughout the lifecycle of this substance.

Results of lifecycle analysis (Environment Canada 2010) indicate that, overall, around 700kg, representing 3.9% of the total quantity in Canadian commerce is potentially released in industrial effluents (prior to any treatment) to either surface water or public or private wastewater systems. Releases to air (e.g., from processing and/or weathering) and paved and unpaved land surfaces (e.g., from leaks and/or spills) are estimated at 0.5% and 0.2%, respectively. Finally, as DTBSBP is not known to degrade or be consumed during the use of manufactured plastic and foam products, it is estimated that 93.6% of the substance is sent for waste management (landfill, incineration and recycling) from which further releases are unlikely, based on the physical and chemical properties of DTBSBP. Further details on estimated releases are presented below.

Container Handling and Industrial Releases

Of the total quantity used at facilities manufacturing polyurethane foam and confidential products, it was estimated that 0.5% may be released to air as a result of manufacturing processes. These releases are expected to react quickly with hydroxyl radicals and not redeposit. The potential for on-site industrial releases to water as a result of manufacturing processes was deemed negligible as the processes in the facilities identified are understood to be closed and dry, with containment measures in place.

To estimate possible releases related to container handling, it was assumed that 3% of the total quantity imported to Canada in drums and 0.2% of the total quantity imported in sealed totes, trucks and rail cars remains in the container as residue and can be released to wastewater systems (before any on-site wastewater treatment) as a result of spillage, drum recycling and reconditioning, and disposal. Empty drums (with residual) are sometimes used to collect flushing material and subsequently sent to hazardous waste facilities for treatment. There is currently no information available concerning the fate of this substance in drum recycling, reconditioning or disposal, whether from wastewater or other media, or with removal efficiency in wastewater treatment, in either industrial waste or hazardous waste facilities.

Brake Fluid Use and Disposal

The vast majority of brake fluid operations are assumed to be performed in commercial maintenance and service centers, where waste brake fluid is stored with used motor oil and hauled for treatment. In general, engine motor oil is highly recovered in Canada (UOMA 2009) and the proportion of this waste product sent to recycling facilities was estimated at 99% (Canada 2009b). The exact fate of DTBSBP in waste brake fluid mixed with engine oils has yet to be determined, but further releases to the environment are unlikely.

For lifecycle analysis, it was estimated that 1% of the DTBSBP contained in brake fluids in Canada could be released to paved/unpaved land surfaces (i.e., roads, driveways, parking lots) as a result of spills/leaks during use. It was assumed that half of this amount would remain on road surfaces or soil where the spill or leak occurred, and the other 0.5% could be washed into public or private wastewater systems. These infrequent and widely dispersive consumer releases would contain very small amounts of DTBSBP.

Foam Use and Disposal

Of the total quantity of DTBSBP that is contained in foam manufactured in Canada, it is estimated that 0.05% could be released to public or private wastewater systems and 0.05% released to air (in which DTBSBP is likely to be rapidly oxidized) as a result of consumer use. The entire remaining quantity (99.9%) is assumed to be sent for waste management (incineration or landfill) following disposal of the products, from which further releases to the environment are unlikely (Canada 2010).

Confidential Product Use and Disposal

For the confidential use, it was estimated that of the total quantity of the substance contained in the confidential product, nothing would be released to public or private wastewater systems and 0.05% could be released to air during product use. An additional consideration regarding the confidential use was that some of the products manufactured in Canada were exported. The majority of the used products are ultimately sent for waste management, from which further releases to the environment are unlikely (Canada 2010).

5.2 Exposure Sources

DTBSBP is not reported to be naturally produced in the environment. No environmental monitoring data for DTBSBP from Canada or elsewhere have been identified (Canada 2010).

Air emissions can lead to atmospheric exposure as the substance tends to remain in air, however it will be rapidly oxidized there. As the effectiveness of sewage treatment operations is unknown, releases of DTBSBP to public or private wastewater systems may eventually be discharged to surface water. The substance released to paved/unpaved land surfaces during consumer use of brake fluid can be transported to nearby soil or into the sewer, resulting in soil or aquatic exposure. Because of its resistance to degradation and partitioning behavior, DTBSBP will remain in sediment and soil for long periods after it is released. Due to the expected release pattern for this substance, exposure of both aquatic and terrestrial organisms to DTBSBP is possible. The lipophilic character of DTBSBP indicates that, following exposure, it is likely to bioaccumulate in organisms and may be biomagnified in trophic food chains (Canada 2010).

Evaluation of risk to human health involves consideration of data relevant to estimation of exposure (non-occupational) of the general population, as well as information on health hazards. The final assessment report indicated that human exposure to DTBSBP through dietary intake, if any, in Canada would be minimal. The general population may be exposed to DTBSBP used in polyurethane foam products in bedding, furniture and automotive trim materials (Chinn et al. 2006, Meyer-Ahrens 2005) and possibly plasticized PVC for food packaging applications (2009 email from Food Directorate, Health Canada, to Risk Management Bureau, Health Canada; unreferenced). Based on the information available, the margins between upper-bounding estimates of exposure through food (i.e. migration from food packaging) and consumer products and levels associated with effects in experimental animals are considered to be adequately protective of human health (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Currently, there are no known risk management measures related specifically to DTBSBP in Canada. Used brake fluids (some of which may contain DTBSBP) and empty containers are already sent to appropriate facilities for disposal in many locations.

The safety of all materials used for packaging foods is controlled under Division 23 of the Food and Drugs Regulations, Section B.23.0001 of which prohibits the sale of foods in packages that may impart harmful substances to their contents. Because of the general nature of this requirement, and in the absence of positive lists delineating permitted ingredients, packaging materials intended for use with foods may be submitted voluntarily to the Food Directorate for a premarket assessment of their chemical safety in relation to Section B.23.001. This applies to any type of material, whether it is in the form of a finished product, such as a laminated film, a container (Canada 1985).

6.2 Existing International Risk Management

DTBSBP is included in the U.S. EPA's *Toxic Substances Control Act* inventory and has been identified as an High Production Volume (HPV) chemical under the United States Environmental Protection Agency's HPV Challenge Program. This program challenged companies to make health and environmental effects date publicly available for chemicals produced in high quantities (US EPA 2009).
DTBSBP is listed by the U.S. Food and Drug Administration (FDA) as an effective food contact substance subject to FDA Code of Federal Regulations Title 21, section 175.105 (US FDA 2009) as an antioxidant at a maximum concentration of 0.06% by weight of the finished polymer in PVC under certain conditions of use (US FDA 2008).

DTBSBP is present on the European Inventory of Existing Commercial Chemical Substances. It is considered hazardous as per the Safety Data Sheets Directive (91/155/EC) as amended, with EU symbols Xi – Irritant and N – Dangerous for the environment.

DTBSBP is also included on the Oslo-Paris (OSPAR) Commission's list of substances of possible concern. Although OSPAR lists the functional use category of DTBSBP as a pesticide, it is further stated that there is no authorized use in the European Union in plant protection products (OSPAR 2006). It is not registered for use as a pesticide active ingredient (PMRA 2009) or formulant in Canada (PMRA 2007).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

DTBSBP is considered part of a broader category of substances known as alkylphenols (US EPA 2009) that are commonly used as anti-oxidants and chemical intermediates. Some substances in this same broad category of hindered phenolic substances could be substitutes for DTBSBP. However, they will all possess to a slightly greater or lesser extent the same environmental characteristics of DTBSBP. In addition, some of these substances may also be subject to assessment in an upcoming phase of the Chemicals Management Plan.

As noted in section 4, DTBSBP is used as an alternative to BHT in several applications as it is solid at room temperature and can be heated slightly to a liquid state, facilitating industrial processing and providing a benefit in lower overall capital cost for control technologies, and reduces the exposure potential of workers to dust invariably created in solids handling activities. (SI Group 2009).

7.2 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining*

Regulation (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

Socio-economic considerations for DTBSBP include

- Suitability and impact of possible alternatives
- The facilities that reported importing or using the substance are primarily concentrated in one geographic region and consumer products are used across Canada

7.3 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.
The ultimate environmental objective for DTBSBP is virtual elimination (VE). CEPA 1999 requires that substances targeted for VE under section 77 be added to the Virtual Elimination List along with their Level of Quantification (LoQ). The LoQ is the lowest concentration that can be accurately measured using sensitive but routine sampling and analytical methods.

According to CEPA 1999, virtual elimination means, in respect of a toxic substance released into the environment as a result of human activity, the ultimate reduction of the quantity or concentration of the substance in the release below the LoQ specified in the Virtual Elimination List.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). In this case, the risk management objective is to minimize releases of the substance to water and soil to the greatest extent practicable.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*[3] and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulations were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the environmental objective, the risk management being considered for DTBSBP is the implementation of regulatory controls toward virtually eliminating releases of the substance to the environment. A regulation to prohibit and/or limit the conditions under which the substance may be imported, manufactured or used is being considered.

The Government will also assess the potential for DTBSBP to meet the criteria set out in section 200 of CEPA 1999 in the event that it was to enter the environment as a result of an environmental emergency.

9.2 Other Information Gathering/Research

Monitoring and surveillance for DTBSBP in the environment will be considered under a comprehensive monitoring and surveillance strategy under the Chemicals Management Plan. Monitoring has been identified as a key pillar in the Chemicals Management Plan, and will serve the following functions: to collect and generate human health and environmental data to inform decision-making; to identify the need for any further risk management measures; and to measure the efficacy of preventive and mitigation actions for DTBSBP.

Further study is required regarding container handling, washing, reconditioning and recycling practices, collection rates and ultimate disposal methods of waste brake fluid, and the removal efficiency in hazardous waste facilities.

The above information will be used to inform the federal government on releases of DTBSBP to the environment, and guide further risk management if additional measures are deemed necessary.

[3] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

9.3 Implementation Plan

The proposed regulation respecting preventative or control actions in relation to DTBSBP will be published in the *Canada Gazette*, Part I, by July 30 2012, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope document for DTBSBP, which summarized the proposed risk management under consideration at that time, was published on January 30, 2010. Industry and other interested stakeholders were invited to submit comments on the risk management scope document during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the risk management approach will involve publication on July 31, 2010, and a 60-day public comment period.

The primary stakeholders include

- Industrial users (including Polyurethane Foam manufacturing and confidential users);
- Container reconditioners and recyclers
- Brake fluid importers and distributers
- Importers of the substance and of products containing the substance
- Hazardous waste management industry
- Provincial and territorial governments
- Non-governmental organizations

There will be additional opportunities for public consultation during the development of the risk management instrument.

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	July 31, 2010, to September 29, 2010
Response to comments on the proposed risk management approach document	At time of publication of proposed instrument
Consultation on the draft instrument	Spring/summer 2011
Publication of the proposed instrument	No later than July 2012
Formal public comment period on the proposed instrument	No later than Fall 2012

Publication of the final instrument	No later than January 2014

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to September 29, 2010, since the risk management of DTBSBP will be moving forward after this date. During the development of regulations, instrument(s) and tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Existing.Substances.Existantes@ec.gc.ca

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