Government of Canada / Gouvernement du Canada

RISK MANAGEMENT SCOPE

for

Phenol, 4,4'-(1-methylethylidene) bis[2,6-dibromo- (Tetrabromobisphenol A)

Chemical Abstract Service Registry Number (CAS RN):
79-94-7

Environment Canada
Health Canada

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Canada

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SUMMARY OF PROPOSED RISK MANAGEMENT

The Government of Canada is considering the implementation of risk management measures to address potential releases from industrial sources of Tetrabromobisphenol A to the environment.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage Tetrabromobisphenol A. Please see section 3 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Pilot Project Background

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999*[1] (CEPA 1999) (Canada 1999), the Ministers of Environment and Health has conducted a screening assessment of Phenol, 4,4'-(1-methylethylidene) bis[2,6-dibromo-, Chemical Abstract Service Registry Number (CAS RN)[2] 79-94-7, referred to by its common name "Tetrabromobisphenol A" (TBBPA) throughout this document.

TBBPA was one of the 123 substances on the Domestic Substances List (DSL) selected for a pilot project for screening assessments. During categorization of the DSL, TBBPA was identified as a high priority for a screening assessment as it met the criteria for persistence and inherent toxicity to non-human organisms.

CEPA 1999 requires the Minister of the Environment and the Minister of Health to categorize substances on the DSL. Further to this activity, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria to determine whether these substances meet one or more of the criteria set out in section 64 of the Act.

[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, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 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. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being undertaken under other sections of CEPA or other Acts.

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1.2 Draft Screening Assessment Report Conclusion

A notice summarizing the scientific considerations of the draft screening assessment report was published for TBBPA by Environment Canada and Health Canada in the *Canada Gazette*, Part I, on November 10, 2012, under subsection 77(1) of CEPA 1999. The draft screening assessment report proposes that TBBPA 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, and that TBBPA is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on human life or health.

Based on the information available, it is proposed that TBBPA meets one or more criteria set out in section 64 of CEPA 1999.

The draft screening assessment report also proposes that TBBPA meets the criteria for persistence but does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* (Canada 2000) made under CEPA 1999.

For further information on the proposed draft screening assessment report conclusion for TBBPA, refer to the Draft Screening Assessment Report. Please note that, based on comments received during the consultation process, the proposed conclusions in the draft screening assessment report could be subject to change, and will inform future risk management actions.

1.3 Current Uses

Globally, TBBPA is the highest production volume brominated flame retardant with world market production over 120 000 tonnes in 2001, over 170 000 tonnes in 2004. It is likely these numbers have continued to increase in recent years as TBBPA has been considered a substitute for certain polybrominated diphenyl ethers (PBDEs) like the commercial Octabromodiphenyl ether (OctaBDE) product. OctaBDE has been subject to a global production phase-out (DEFRA 2002) and has been prohibited in Canada under the *Polybrominated Diphenyl Ethers Regulations, 2008* (Canada 2008).

TBBPA is incorporated in polymers primarily as a reactive flame retardant for use in flame-retarded epoxy and polycarbonate resins, and to a lesser extent, as an additive flame retardant in acrylonitrile-butadiene-styrene (ABS), high impact polystyrene (HIPS) and phenolic resins. A major usage of flame-retarded epoxy resins containing TBBPA is in rigid epoxy-laminated printed circuit boards; other uses include glass-reinforced construction panels, and motor housings and terminal boards. Applications of flame-retarded polycarbonate resins include communications and electronics equipment, appliances, transportation devices, sports and recreation equipment, lighting fixtures and signs. ABS resins containing TBBPA are used in automotive parts, pipes and fittings, refrigerators and other appliances, business machines and telephones. TBBPA is also used in the production of derivative compounds which are used in specialty or niche applications.

Information gathered in 2000 through an Environment Canada use pattern survey, conducted under section 71 of CEPA 1999, indicated that although TBBPA was not manufactured in Canada in that year, between 100 000 to 1 000 000 kg were imported into Canada, including TBBPA in mixtures and products. Recent estimates based on a voluntary data submissions from industry suggest TBBPA imports to Canada remain in the 100 000 to 1 000 000 kg range, including pure TBBPA and TBBPA found in manufactured items (additive TBBPA in ABS, HIPS and phenolic resins, as well as unreacted TBBPA in printed wire boards) (Environment Canada 2011a). TBBPA is manufactured in Israel, the U.S.A., Jordan, Japan and China.

1.4 Releases to the Canadian Environment

Sources of exposure to TBBPA are anthropogenic in nature and data on the environmental release of TBBPA in Canada are not available. Releases of TBBPA into the environment (air, water, soil and sediment) may occur during manufacture, processing, use and disposal of the substance or products containing it. Models predicted that TBBPA could primarily be released to surface water during industrial processing. If the release was to a wastewater treatment facility, TBBPA is likely to be sequestered to sludge resulting in very small releases to the environment. Releases from manufactured items are expected to be minimal during use and at end-of-life upon disposal or recycling of the substance or products containing the substance.

TBBPA is not manufactured in Canada, so estimated losses are based on estimated import quantities (Environment Canada 2011a). TBBPA released during processing activities may enter the air or be discharged into wastewater. Since major uses are in polymer production and electrical and electronic equipment, most releases would likely be in urban and industrial areas. Whether TBBPA is present in the air as dust particles or adsorbed to particulates, its relatively high specific gravity (2.18; WHO 1995) suggests that removal by settling would be relatively rapid (EU RAR 2008). TBBPA released into wastewater would likely be transported to a treatment facility. Moderately high partition coefficients suggest that most TBBPA entering a treatment plant will sequester into sludge; however, small amounts (e.g. up to 0.025 µg/L; Kuch et al. 2001) have also been measured in final effluents discharged into receiving waters. TBBPA entering surface waters would be expected to partition into bed sediments, after sorption to suspended particulates in the water column and subsequent settling.

Estimated Releases from Industrial Use

Aquatic exposure to TBBPA is expected if the substance is released from industrial manufacture, formulation or to a wastewater system that discharges its effluent to a receiving surface water body. Industrial releases of TBBPA to wastewater (before wastewater treatment) are estimated at 0.2% of quantity used (Canada 2012). Models predicted that TBBPA could be released to surface water during industrial processing. If the release was to a wastewater treatment facility, TBBPA is likely to be sequestered to sludge resulting in very small releases to the environment. During industrial use, releases of TBBPA to other environmental media are expected to be minimal.

Consumer or Commercial Release

Although TBBPA can be found in consumer or commercial products, it is expected that release to water from these products would be minimal. For products containing reactive TBBPA, the substance is chemically bound to the resin. The level of unreacted TBBPA is very low, of the order of 0.0004% to 0.06% (EU RAR 2008), limiting release into the environment. Estimates suggest that 0.02 tonnes of TBBPA is imported into Canada annually as residual and unreacted substance in printed circuit boards (Environment Canada 2011). In products where TBBPA is used as an additive, diffuse releases may occur from articles, but it is expected that the rate is very low. Potential releases from products during their service life is estimated at 0.05% per year to water if the product is for indoor use or 0.16% per year if the use is outside (OECD 2004).

1.5 Exposure and Sources of Concern in Canada

TBBPA is expected to be persistent in air, water, soil and sediment. It is expected that TBBPA may accumulate to some degree in the tissues of biota. The quantity of this substance imported into Canada, along with information on its use, indicate potential for release to the Canadian environment. Once released into the environment it is expected to be found predominantly in soil and/or sediment, depending on the compartment of release (i.e, release to air versus water). TBBPA is expected to strongly adsorb to suspended solids and settle in bed sediments or biosolids. TBBPA has been shown to degrade under anaerobic conditions to form Bisphenol A, a potentially persistent substance that has been found to meet the criteria defined in section 64 of CEPA 1999. The available aquatic toxicity data demonstrate that exposure to TBBPA can cause significant adverse effects on survival, reproduction and development of pelagic, sediment, and soil organisms at very low concentrations.

Environment

Based on the information presented in the draft screening assessment indicating increasing use, persistence in the environment, ecotoxicological hazard, potential to degrade to form bisphenol A, and potential for some accumulation in biota, as well as estimated risk for pelagic, sediment, and soil organisms, it is proposed that TBBPA is entering 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. Furthermore, TBBPA meets the criteria for persistence but does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000). Based on this information, TBBPA has the potential to cause ecological harm in Canada (Canada 2012).

Human Health

For the general population, sources of exposure to TBBPA are expected to be through environmental media and from household dust, indoor air, human milk, contaminated food and from TBBPA containing flame-retarded products. In Canada, the highest derived upper-bounding estimate of exposure was for breast-fed infants. The critical effect for the characterization of risk to human health is liver toxicity noted in female offspring of mice

following exposure to TBBPA in a reproductive toxicity study. Based on the comparison of upper-bounding estimated intake of TBBPA for breast-fed infants and the critical effect for the characterization of risk to human health, it is considered that the resulting margins of exposure are adequately protective of human health.

2. OVERVIEW OF EXISTING RISK MANAGEMENT

2.1 Existing Canadian Risk Management

There are no existing Canadian risk management measures which are specific to controlling the use or release of TBBPA to the environment.

2.2 Existing International Risk Management

United States:
In the United States, TBBPA is subject to release reporting under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), Title III, Section 313, also known as the Superfund Amendment and Reauthorization Act (SARA) (US EPA, Emergency Planning and Community Right to Know Act).

Manufacturers, users and processors need to report TBBPA released in the environment to the U.S. EPA each year. TBBPA releases must be reported to the Toxics Release Inventory, with the reporting threshold set at 100 lbs of annual releases (US EPA, TRI).

European Union:
TBBPA is currently in the pre-registration phase of the European Commission's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (no action required by industry to date).

A risk assessment conducted by the European Union on TBBPA concluded that TBBPA, reacted with other substances in epoxy and polycarbonate products, does not pose a risk to human health or the environment at current levels of exposure in Europe. However, the assessment identified an environmental risk for soil, sediment, and aquatic organisms when TBBPA was used in the processing stage with ABS plastics. Rather than proposing legislative restrictions as a result of this environmental risk, the recommended strategy was to continue monitoring releases and continued implementation of existing risk reduction strategies, such as the Voluntary Emissions Control Action Programme (VECAP). Since 2004, VEPCAP has been undertaken by the European industry to control release levels of 5 brominated flame retardants, including TBBPA. VECAP 2008 and 2009 survey results show considerable and demonstrable reduction in TBBPA releases due to identification and reduction of new sources and implementation of codes of good practice, which are mandatory for participants.

TBBPA, like all other brominated flame retardants, is subject to Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic

equipment (WEEE), which states that plastic containing brominated flame retardants must be removed from separately collected WEEE.

TBBPA is on the List of Chemicals for Priority Action of the Oslo/Paris convention (for the Protection of the Marine Environment of the North-East Atlantic (OSPAR). The objective stated in the OSPAR Strategy with regard to Hazardous Substances, including TBBPA, is: *"to prevent pollution of the OSPAR maritime area by continuing to reduce discharges, emissions and losses of hazardous substances, with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances"* The Strategy also includes a timeframe which states that every endeavour will be made, *" to move towards the targets of cessation of discharges, emissions and losses of hazardous substances by the year 2020"* (OSPAR Commission)

TBBPA is on the Danish List of Undesirable Substances, 2004 (Danish EPA). The purpose of the list is to provide guidance as well as a signal to industry that the use of the listed substances should be reduced or eliminated in the long run.

There are no international existing regulatory environmental controls which are specific to controlling the use or release of TBBPA to the environment.

3. PROPOSED RISK MANAGEMENT

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 substance to the List of Toxic Substances in Schedule 1 of the Act.

If the final screening assessment report concludes that TBBPA meets one or more of the criteria under section 64 of CEPA 1999, but does not meet the conditions set out in subsection 77(4) of CEPA 1999, TBBPA will not be subject to the virtual elimination provisions under CEPA 1999 and may be managed using a lifecycle approach. Based on the information outlined in the draft screening assessment report, the Government of Canada is considering the implementation of risk management measures to reduce releases of TBBPA from industrial source if required, while maintaining the use of TBBPA where deemed necessary.

In accordance with the Government of Canada's *Cabinet Directive on Streamlining Regulation*[3] (TBS 2007), the proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration the information that has been received from industry and other information available at this time.

[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."

The Government of Canada is moving forward with the implementation of a "One-for-One" Rule to control administrative burden on business, following the release of the Red Tape Reduction Commission's Recommendations Report in January 2012. It provides specific advice to departments and agencies on how to reduce unnecessary burdens on business. It also proposes that the Government make systemic changes to the way it regulates businesses while ensuring that the environment and the health and safety of Canadians are not compromised.

The "One-for-One" Rule will reduce administrative burden (i.e. the time and resources spent by business to show compliance with government regulations) in two ways:

- It requires regulators to remove a regulation each time they introduce a new regulation that imposes administrative burdens.
- When a new or amended regulation increases administrative burden on business, regulators will be required to offset—from their existing regulations—an equal amount of administrative burden costs on business.

4. NEXT STEPS

Industry and other interested stakeholders are invited to submit comments on the content of this risk management scope. Although all submitted information will be considered, specific information of the type described below would help inform decision making:

- changes in import/manufacture/use quantities and use patterns since the 2000 reporting year, and expected future trends;
- transportation and handling practices (e.g., types of containers used, how it is transferred, what is done with empty containers, etc);
- operational conditions (e.g., frequency/duration of related processes over a given year);
- existing practices for managing industrial release of this substance ;
- potential alternatives (substitutes or technologies) and their feasibility;
- potential control technologies or processes (e.g., closed-loop, recirculation, sequestration, on-site treatment, etc) that would reduce the release of this substance in industrial effluents;
- the removal efficiency of TBBPA in industrial wastewater treatment systems and disposition of residual sludge;
- detection methods and measured concentrations of TBBPA in industrial effluents and/or sludge; and,
- costs associated with potential alternatives and control technologies.

Please submit comments prior to January 9, 2013, since the risk management for TBBPA will be moving forward after this date. The proposed risk management approach will be released simultaneously with the publication of the final screening assessment report. There will be opportunity for further consultation at that time. Comments and information submissions on the risk management scope should be submitted to the address provided below:

Program Development and Engagement Division
Gatineau QC, K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155

Email: Substances@ec.gc.ca

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