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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Polybrominated Diphenyl Ethers Regulations

P.C. 2008-1271 June 19, 2008

Whereas, pursuant to subsection00A0;332(1) (see footnote a) of the *Canadian Environmental Protection Act, 1999* (see footnote b), the Minister of the Environment published in the *Canada Gazette*, Part00A0;I, on December 16, 2006 a copy of the proposed *Polybrominated Diphenyl Ethers Regulations*, substantially in the annexed form, and persons were given an opportunity to file comments with respect to the proposed Regulations or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

Whereas, pursuant to subsection00A0;93(3) of that Act, the National Advisory Committee has been given an opportunity to provide its advice under section00A0;6 (see footnote c) of that Act;

And whereas, in the opinion of the Governor in Council, pursuant to subsection00A0;93(4) of that Act, the proposed Regulations do not regulate an aspect of a substance that is regulated by or under any other Act of Parliament in a manner that provides, in the opinion of the Governor in Council, sufficient protection to the environment and human health;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of the Environment and the Minister of Health, pursuant to subsection00A0;93(1) of the *Canadian Environmental Protection Act, 1999* (see footnote d), hereby makes the annexed *Polybrominated Diphenyl Ethers Regulations*.

POLYBROMINATED DIPHENYL ETHERS REGULATIONS

APPLICATION

1. Subject to sections00A0;2 to 5, these Regulations apply to polybrominated diphenyl ethers that have the molecular formula $C_{12}H_{(102013;n)}Br_nO$ in which 42264;n2264;10 and that are specified on the List of Toxic Substances in Schedule00A0;1 to the *Canadian Environmental Protection Act, 1999*.

EXCEPTIONS

2. These Regulations do not apply to any polybrominated diphenyl ether referred to in section00A0;1 that is contained in a pest control product within the meaning of subsection00A0;2(1) of the *Pest Control Products Act*.

3. These Regulations do not apply to any polybrominated diphenyl ether referred to in section00A0;1, or to any resin, polymer or other mixture containing a polybrominated diphenyl ether set out in the schedule, that is for use

- (*a*) in a laboratory for analysis;
- (b) in scientific research; or
- (c) as a laboratory analytical standard.

4. These Regulations do not apply to a product 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 that product contains a polybrominated diphenyl ether referred to in section00A0;1.

5. These Regulations do not apply to any polybrominated diphenyl ether referred to in section00A0;1 that is present as a contaminant in a chemical feedstock used in a process from which there are no releases of the polybrominated diphenyl ether, provided that the polybrominated diphenyl ether is destroyed or completely converted in that process to a substance that is not a polybrominated diphenyl ether.

PROHIBITIONS

6. No person shall manufacture any polybrominated diphenyl ether referred to in section00A0;1 or any resin, polymer or other mixture containing a polybrominated diphenyl ether set out in the schedule.

7. (1) No person shall use, sell, offer for sale or import a polybrominated diphenyl ether set out in the schedule or any resin, polymer or other mixture containing such a substance.

(2) Subsection (1) does not apply to any polybrominated diphenyl ether or resin, polymer or other mixture that is to be

(a) re-processed on-site in a process from which there are no releases of the substance; or

(*b*) disposed of in accordance with the laws of the jurisdiction where the disposal is to take place.

ANALYSIS BY ACCREDITED LABORATORY

8. The presence of any polybrominated diphenyl ether shall be determined by a laboratory that is accredited under the International Organization for Standardization standard ISO/IEC00A0;17025: 2005, entitled *General requirements for the competence of testing and calibration laboratories*, as amended from time to time, and

whose accreditation includes the analysis of polybrominated diphenyl ethers within its scope of testing.

COMING INTO FORCE

9. These Regulations come into force on the day on which they are registered.

SCHEDULE (Sections 3, 6 and 7)

POLYBROMINATED DIPHENYL ETHERS WHOSE MANUFACTURE, USE, SALE, OFFER FOR SALE OR IMPORTATION IS PROHIBITED

1.00A0;Benzene, 1,12032;-oxybis-, tetrabromo derivative that has the molecular formula $C_{12}H_6Br_4O$ (tetraBDE)

2.00A0;Benzene, 1,12032;-oxybis-, pentabromo derivative that has the molecular formula $C_{12}H_5Br_5O$ (pentaBDE)

3.00A0;Benzene, 1,12032;-oxybis-, hexabromo derivative that has the molecular formula $C_{12}H_4Br_6O$ (hexaBDE)

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

Purpose

The *Polybrominated Diphenyl Ethers Regulations* (the Regulations) are made under subsection 93(1) of the *Canadian Environmental Protection Act 1999* (CEPA 1999). The purpose of the Regulations is to protect Canada2019;s environment from the risks associated with polybrominated diphenyl ethers (PBDEs) by preventing their manufacture and restricting their use in Canada, thereby minimizing their releases into the environment.

Specifically, the Regulations:

i) prohibit the manufacture of PBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE congeners (see footnote 1)), and;

ii) prohibit the use, sale, offer for sale and import of those specific PBDEs that meet the criteria for virtual elimination under CEPA 1999 (tetraBDE, pentaBDE and hexaBDE congeners), as well as mixtures, polymers and resins containing these substances.

These Regulations target the raw materials, and do not apply to manufactured articles or final products containing PBDEs that are imported or already in use in Canada.

The Regulations come into force on the day on which they are registered.

Background

The Chemicals Management Plan, (see footnote 2) announced in December 2006, is part of the government2019;s comprehensive environmental agenda. It will further strengthen the degree of protection for Canadians and their environment against chemicals that have not yet undergone scientific assessment. Through an exercise called 201C;categorization,201D; 400A0;300 of 2300A0;000 existing substances were identified as requiring further attention by the federal government. This will take the form of further assessment, supported by research and monitoring, and will lead to the management of these priority substances.

A key element of the Chemical Management Plan includes taking immediate action on five substance categories, including PBDEs.

The Regulations represent an important first step in the risk management of PBDEs, with a focus on the PBDE congeners that meet the criteria for virtual elimination. The Regulations are also part of a more comprehensive risk management strategy for all PBDEs. (see footnote 3) Under this strategy, additional measures and activities are being developed to complement these Regulations, including:

- a regulation to control PBDEs in manufactured products;
- a voluntary approach (i.e. Performance Agreement [PA]) to minimize releases to the environment from the use of the DecaBDE commercial mixture in the manufacturing of semifinished and finished products in Canada;
- a detailed review of newly published science on decaBDE, to determine whether further controls on this form of PBDE are warranted;
- the development of a management strategy for PBDEcontaining products at end-of-life, and;
- the monitoring of Canadians2019; exposure to PBDEs and concentrations in the environment.

The risk management objective for PBDEs is to prevent the introduction of their manufacture and to minimize their release into the environment from all sources in Canada. Since there is no manufacture of any form of PBDEs in Canada, and the commercial use of tetraBDE, pentaBDE and hexaBDE congeners have been phased out internationally and in Canada since 2006, the Regulations constitute a preventative approach to ensure that these activities are not introduced in Canada.

On July 1, 2006, the Ministers of the Environment and of Health published their final decision on the screening assessment of PBDEs in the *Canada Gazette*, Part I. (see footnote 4) The screening assessment (see footnote 5) recommended that PBDEs with four or more bromine atoms be added to the List of Toxic Substances in Schedule 1 of CEPA 1999. On December 27, 2006, the order to add these PBDE congeners to the List of Toxic Substances in Schedule 1 of CEPA 1999 was published in the *Canada Gazette*, Part II. (see footnote 6)

Environment Canada2019;s Ecological Screening Assessment Report indicated that the greatest potential risks from PBDEs in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs, and effects on benthic (see footnote 7) organisms, which may result from elevated concentrations of certain PBDE congeners in sediments.

The 2006 screening assessment report also concluded that PBDEs are 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. More specifically, it concluded that tetraBDE, pentaBDE and hexaBDE congeners meet the criteria for persistence and bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* of CEPA 1999. The screening assessment also concluded that their presence in the environment results primarily from human activity (that is, releases from product manufacturing and processing, and throughout the product life cycle). As a result, tetraBDE, pentaBDE and hexaBDE congeners meet the conditions for virtual elimination, as set out in subsection 77(3) of CEPA 1999.

The Health Canada Screening Assessment Report on PBDEs concluded that worst-case estimates of the exposure of Canadians to PBDEs were much less than those that caused health effects in animals. While the assessment concluded that PBDEs were not harmful to human health at current levels of exposure, Health Canada supports Environment Canada2019;s actions to limit the use of PBDEs so that future levels do not reach a point where they could potentially harm the health of Canadians. Health Canada, as part of its monitoring programs (e.g. the Canadian Health Measures Survey [CHMS]) will continue to observe PBDE concentrations in adults, infants, pregnant women, and umbilical cord blood. These monitoring activities would establish a representative baseline of PBDE concentrations in humans, help identify future trends, and allow comparisons with other countries. Various research studies continue to monitor a range of PBDE congeners in the environment.

PBDE congeners and commercial mixtures

PBDEs are sold in three commercial mixtures: PentaBDE, OctaBDE and DecaBDE. Although the three commercial mixtures vary in composition, each contains a typical mixture of diphenyl ethers with varying degrees of bromination, as summarized in Table 1 below.

Table 1 2014; Typical compositions of the PBDE commercial mixtures (see footnote 8)

Commercial PBDE Congener Groups

Mixtures

	tetraBDE	pentaBDE	hexaBDE	heptaBDE
PentaBDE	24-38%	50-62%	4-12%	trace
OctaBDE	2014;	0.5%	12%	45%
DecaBDE	2014;	2014;	2014;	2014;

PBDE congeners targeted for virtual elimination

Commercial Mixtures	PBDE Congener Groups		
	octaBDE	nonaBDE	decaBDE
PentaBDE	2014;	2014;	2014;
OctaBDE	33%	10%	0.7%
DecaBDE	trace	0.3-3%	97-98%

PBDE congeners targeted for virtual elimination

For the purposes of this Regulatory Impact Analysis Statement (RIAS), (see footnote 9) the commercial mixture Pentabromodiphenyl Ether, predominantly a mixture of pentaBDE, tetraBDE, and hexaBDE congeners, which may also contain trace levels of heptaBDE and tribromodiphenyl ether (triBDE) congeners, will be referred to as PentaBDE. The commercial mixture Octabromodiphenyl Ether, a mixture composed mainly of heptaBDE, octaBDE and hexaBDE congeners, which may also contain small amounts of pentaBDE, nonaBDE and decaBDE congeners, will be referred to as OctaBDE. The commercial mixture Decabromodiphenyl Ether, predominantly composed of decaBDE, with small amounts of nonaBDE and octaBDE congeners, as well as trace amounts of other PBDEs, will be referred to as DecaBDE.

The regulatory prohibitions placed on tetraBDE, pentaBDE and hexaBDE congeners would impact only the PentaBDE and OctaBDE commercial mixtures and will not impact the DecaBDE commercial mixture.

Use profile

Polybrominated diphenyl ethers (PBDEs) are a group of chemical flame retardants that slow the ignition and spread of fire. In general, plastics are the primary end use for flame retardants due to the inherent flammability of many polymers. As such, PBDEs can be found in many items such as building and automobile materials, carpet underlay, furniture foam and electronic equipment.

PBDEs are not manufactured in Canada, but are imported for use:

- as raw materials (e.g. chemical formulations, resins, polymers or substrates);
- in semi-finished articles, materials or components; or
- in finished products.

As noted above, PBDEs are sold in three commercial mixtures, PentaBDE, OctaBDE and DecaBDE, each containing a typical composition of PBDE congeners (see Table 1). The PentaBDE and OctaBDE commercial mixtures have been phased out internationally. The only commercial mixture, DecaBDE, currently available in the market is manufactured in the United States (U.S.). PentaBDE was used almost exclusively in flexible polyurethane foam, which is used as cushioning in upholstered furniture, automotive seating and carpet backing. OctaBDE was predominantly used in acrylonitrile butadiene styrene (ABS) as a flame retardant for computer housings, pipes, appliances and automotive parts.

Based on an Environment Canada use pattern survey, (see footnote 10) in the year 2000, the PentaBDE commercial mixture was imported in the greatest volume, followed by the DecaBDE commercial mixture. Very small quantities of OctaBDE commercial mixture were imported into Canada in 2000. Significant reformulation activity has occurred in recent years related to PentaBDE and OctaBDE. All companies that reported uses of PentaBDE and OctaBDE in 2000 have reported complete phase-out since 2006. The cessation of production by the only U.S. manufacturer of PentaBDE and OctaBDE in December 2004 has also impacted Canadian imports of PBDEs contained in these mixtures. Discussions with industry and industry associations indicate that PentaBDE and OctaBDE were phased out of use due to a number of factors, such as:

- the international regulatory climate;
- the consumer demand for PBDE-free products;
- the availability of cost-effective alternatives; and
- the unavailability of PentaBDE and OctaBDE in the global market after 2005.

The DecaBDE commercial mixture was and continues to be used primarily in polystyrene (PS), particularly High Impact Polystyrene (HIPS), and a number of other resins. The DecaBDE flame retarded resins are predominantly used in electrical and electronic products, as well as upholstery and drapery textiles. As noted above, only the manufacture of decaBDE is prohibited by the Regulations and not the use, sale or import of decaBDE.

International initiatives

The PBDE Regulations represent a first step in aligning Canada with legislative actions taken on PBDEs in the U.S. and Europe. As outlined in Canada2019;s Risk Management Strategy on PBDEs,

additional actions will further align Canada with key international initiatives in the U.S. and Europe (such as the European Union2019;s Restrictions on Hazardous Substances Directive [RoHS Directive]).

These international initiatives generally prohibit the manufacture, processing, or distribution of a product or part of a product treated with flame retardants that contain more than 0.1% (by mass) of PentaBDE or OctaBDE, with some exemptions. In response to these restrictions on PBDE use, many North American manufacturers have shifted to PBDE alternatives.

The major international legislative actions with respect to PentaBDE, OctaBDE and DecaBDE are presented in Table 2.

Table 2: Key International Initiatives Relevant for PentaBDE,OctaBDE and DecaBDE

Jurisdictio	Legislation/	Details	Deadline	PBDEs
n	Action		for	Impacte
			Compliar	nc d
			e	

EU	EU 24th amendment to the Marketing and Use Directive 76/769/EEC	Prohibits marketing and use in the EU in concentrations higher than 0.1%.	August 15, 2004	PentaBD E OctaBDE
	Restriction of Certain Hazardous Substances to Electrical and Electronic Equipment (RoHS)	Prohibits use in new electrical and electronic equipment, ¹ with a provision to grant exemptions. Later amended to establish 0.1% as the maximum PBDE concentration.	July 1, 2006	PentaBD E OctaBDE
	Waste from Electrical and Electronic Equipment (WEEE) Directive	Separation of BFR plastics from electric and electronic equipment prior to recovery and recycling.	December 31, 2006	PentaBD E OctaBDE Other BFRs
	Directive 2000/60/EC	Establishes a list of priority substances in the field of water policy that includes PentaBDE, OctaBDE and DecaBDE.	Not applicable	PentaBD E OctaBDE DecaBD E
Sweden		Partial ban of DecaBDE at levels higher than 0.1% in textiles, furniture and some cables.	January 1, 2007	DecaBD E
Norway	Product Regulations	Prohibit the manufacture, import, export, sale and use of substances that contain more than 0.1% of	September 2005	PentaBD E OctaBDE DecaBD E

PentaBDE or OctaBDE.

Waste	Products
Regulations	containing more
	than 0.25%
	PentaBDE,
	OctaBDE or
	DecaBDE are
	classified as
	hazardous waste
	and require
	special
	treatment.

2004

U.S.	Significant New Use Rule	Requires notification of, and evaluation by, the U.S. EPA of any new use of PentaBDE or OctaBDE commercial mixtures.	January 1, 2005	PentaBD E OctaBDE
	California prohibition	Bill prohibits manufacture, processing or distribution of a product containing more than 0.1% PentaBDE or OctaBDE. DecaBDE removed before signing into law.	June 1, 2006	PentaBD E OctaBDE
	Hawaii prohibition	Legislation prohibits manufacture, processing or distribution of a product containing more than 0.1% PentaBDE or OctaBDE.	January 1, 2006	PentaBD E OctaBDE
	Illinois prohibition	Bill prohibits manufacture, processing or distribution of a product containing more than 0.1% PentaBDE or OctaBDE, with some exemptions.	January 1, 2006	PentaBD E OctaBDE
	Maryland prohibition	Bill prohibits manufacture, processing, sale or distribution of a product containing more than 0.1% of PentaBDE or OctaBDE.	October 1, 2008	PentaBD E OctaBDE

NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



Important notice <u>s</u>



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