



CANADIAN ENVIRONMENTAL LAW ASSOCIATION
L'ASSOCIATION CANADIENNE DU DROIT DE L'ENVIRONNEMENT

May 27, 2009

Vincenza Galatone
A/ Executive Director
Chemicals Management Division
and
Executive Director
Program Development and Engagement Division
Gatineau, Quebec K1A 0H3

Via email: existing.substances.existantes@ec.gc.ca, riskmanagementprograms@ec.gc.ca

Re: State of the Science and Revised Risk Management Strategy for PDBEs

Response to Canada Gazette, Part I, Vol. 143, No. 13 – March 28, 2009:

- *Draft State of the Science Report on the Bioaccumulation and Transformation of Decabromobiphenyl Ether (DecaBDE)*
- *Revised Risk Management Strategy for PBDEs*
- *Proposed Performance Agreement to Control, Monitor and Minimize the Release of Decabromobiphenylether (DecBDE) Commercial Mixture from Canadian Facilities where DecaBDE is Used or Handled*

We write in response to the consultation on the above-cited documents released via notice and related information in the *Canada Gazette*.

Introduction, Background and Context: Regulatory Lessons Remain Unlearned

The Canadian Environmental Law Association (CELA) has a long-standing interest in the regulation of toxic substances, including PBDEs. For over seven years, we have been aware of the very large and evolving body of scientific evidence pointing to the environmental and human health dangers of PBDEs, particularly the greater vulnerability of children and the developing fetus.

This scientific evidence includes an understanding about pervasive environmental contamination that will now exist for decades and to some extent will be impossible to ever reverse. It confirms what early investigators predicted about the toxicity, persistence and bioaccumulation of these chemicals. It is the reason for the recent decision at the fourth Conference of the Parties, held early this month, to add PentaBDE and OctaBDE (the commercial mixtures of each) to the international Stockholm Convention on Persistent Organic Pollutants (POPs) in order to

eliminate their use and production worldwide. Regrettably, that decision will not result in a worldwide ban of these PBDEs due to the decision to allow recycling of PBDE-containing products until a deadline of 2030. The result will be the manufacture of new products via recycling of older PBDE-containing products thus allow continued movement of toxic PBDEs into indoor house dust and extending the impact of these chemicals for many more decades into the future.

Notably, PBDEs raise multiple concerns that are very similar to those that exist for PCBs, another groups of chemicals included in the Stockholm Convention, banned since the 1970s and in need of perpetual management by regulatory agencies around the world. There are similarities in terms of environmental and human health concerns, pervasiveness and stability in the environment and in many cases a similarly common origin: multiple consumer products.

The use of lead in consumer products, particularly in paint, is another example of widespread use of a highly toxic substance for which appropriate regulatory action occurred long after a massive legacy of real and potential exposure was created, and remains, for future generations.

In responding to the revised Risk Management strategy for decaBDE, we are particularly mindful of the regulatory strategy within which this document arises. That strategy is one that demands an extremely high level of scientific proof of causation and as such, perpetuates massive mistakes. The regulatory lessons of PCBs, of lead and now of PBDEs are numerous. They have occurred in many other environmental debates and can be summarized as follows:

- ignoring early warnings (from animal evidence, occupational accidents or otherwise high levels of exposure);
- lengthy disputes over evidence of harm, often fuelled by those with a commercial interest in the production or use of the chemical in question;
- the necessity of highly complex and costly scientific investigations to understand how low-level exposures can contribute to subtle and hard-to-measure health outcomes (and for which, as with any health outcome, multiple determinants exist);
- a lengthy process of gathering information that steadily serves to confirm and expand upon initial concerns, including that harmful effects during development can result in permanent damage; and
- failure to take regulatory action until after clear evidence of harm is confirmed following widespread exposure or environmental contamination, that is either very costly, or to a large extent impossible, to clean up.¹

Finally, despite the high level of scientific evidence demanded by the current regulatory paradigm, gaping holes remain in our understanding about toxic substances. The reality of multiple exposures to multiple chemicals, that may have similar or dissimilar impacts on human health or the environment, is completely ignored.

¹ Adapted from: Canadian Environmental Law Association and Ontario College of Family Physicians, 2000. *Environmental Standard Setting and Children's Health*, Chapters 4 and 8; and Canadian Partnership for Children's Health and Environment, 2005. *Child Health and the Environment – A Primer*. Chapter 5.

We barely have the scientific methods, much less the policy commitment or regulatory requirements, to ensure that this reality of multiple exposures is adequately assessed or managed. This reality alone underscores the need to take preventive and precautionary action in the face of the kind of uncertain but deeply troubling evidence we do have about toxic chemicals like PBDEs, including decaBDE.

The regulatory strategy of insisting upon a high degree of scientific evidence of causation results in a failure to prevent contamination that can cause harm. This failure is compounded by the speed at which new studies are generated in the scientific literature and the slowness of the federal government's ability to assess and/or respond to it.

CELA was among several groups that raised concerns about the government's reliance on an out-of-date review of the scientific evidence about PBDEs to support the government's decision to fully ban only the lower congeners of PBDEs and allow the continued use of decaBDE within a Risk Management framework.

In filing a Notice of Objection,² environmental groups pointed out that more recent scientific evidence had not been addressed. Indeed, ten months after filing the Notice of Objection, we filed supplementary information about additional scientific evidence pointing to the bioaccumulation of decaBDE.³

Comments on the Revised State of the Science report

A finding of bioaccumulation and debromination to banned congeners

We are gratified that the draft, revised State of the Science report reflects a more up to date review of the scientific evidence concerning decaBDE. Notably, the report concludes that decaBDE:

- “is bioavailable and may accumulate rapidly to potentially high and problematic levels in certain species” and
- “contributes to the formation of bioaccumulative and/or potentially bioaccumulative transformation products such as lower brominated BDEs in organisms and the environment”⁴

² Wilkins, H. *Notice of Objection Re: Proposed Polybrominated Diphenyl Ethers Regulation* Filed by Sierral Legal Defence Fund on behalf of the David Suzuki Foundation, Environmental Defence and Canadian Environmental Law Association. February 14, 2007. On-line at: <http://www.cela.ca/publications/notice-objection-re-proposed-polybrominated-diphenyl-ethers-regulation>

³ Ecojustice, 2007. *Supplement to Notice of Objection Re: Proposed Polybrominated Diphenyl Ethers Regulation*. Filed by Ecojustice (formerly Sierral Legal Defence Fund) on behalf of the David Suzuki Foundation, Environmental Defence and Canadian Environmental Law Association. December 8, 2007. On-line at: <http://www.cela.ca/publications/supplement-notice-objection-re-proposed-polybrominated-diphenyl-ethers-regulation>

⁴ Environment Canada, 2009. DRAFT State of the Science Report on the Bioaccumulation and Transformation of Decabromodiphenylether. Quoted from Report Summary. On-line at: http://www.ec.gc.ca/CEPARRegistry/subs_list/decaBDE/SR.pdf

Deca-BDE is a problem, but not according to the fifteen year old science underpinning the CEPA Regulation

Despite these conclusions, particularly evidence that decaBDE debrominates to those PBDE congeners that the federal government sees fit to ban, the report finds that decaBDE continues to fail to meet the numeric thresholds for bioaccumulation specified in the *Persistence and Bioaccumulation Regulations* under CEPA, 1999.⁵

We believe that the conclusion arising from the application of this CEPA Regulation to decaBDE raises serious environmental and human health concerns that will continue to occur without banning decaBDE. It also points out a similar but more far-reaching problem with this CEPA Regulation since it too relies upon a foundation of out-of-date scientific information. Indeed, the same conclusion was reached by Health Canada and Environment Canada in November of 2008. In response to a Petition about the inadequate regulation of decaBDE to the Commissioner of the Environment and Sustainable Development,⁶ the joint response from Health Canada and Environment Canada notes the following:

Criteria in the Regulations under CEPA 1999 are based on those in the Toxic Substances Management Policy [of 1995]. Given advancements in the state of the science on persistent organic pollutants (POPs) since that time, as well as changes in domestic and international policy surrounding POPs, Environment Canada is considering revisions to the *Persistence and Bioaccumulation Regulations*. Such a revision would support appropriate decision making in the development of measures for the large number of substances entering the risk management phase under the Chemicals Management Plan....

Through a potential review of the *Persistence and Bioaccumulation Regulations*, it is expected that the resultant revisions, if any, would support the development of measures that are appropriately comprehensive and based on science, to manage substances which may be highly bioaccumulative and/or biomagnify in air- and water-breathing organisms.⁷

Still broader implications for the Chemicals Management Plan

The federal government prides itself on the progress that has been made from its categorization process to identify several thousand chemicals in need of closer scrutiny and the implementation of the Chemicals Management Plan to do so.

We recognize that important progress has been made in prioritizing toxic chemicals for assessment and management and that this Canadian progress is recognized internationally. However, this progress is principally one of creating a short list of chemicals for further study and policy response. Canadian progress toward actual controls on CMP chemicals will be

⁵ *Persistence and Bioaccumulation Regulations* (SOR/2000-107). On-line at: <http://laws.justice.gc.ca/en/showtdm/cr/SOR-2000-107>

⁶ McDonald, ML, 2008. To the Auditor General of Canada, Petition Requesting a Ban of DecaBDE and a Change to the Bioaccumulation Regulations. July 15, 2008. Petition No. 262. On-line at: http://www.oag-bvg.gc.ca/internet/English/pet_262_e_32509.html

⁷ Health Canada, Environment Canada, 2008. Joint Response to Petition No. 262. Bioaccumulation assessment criteria related to the regulation of fire-retardant chemicals. November 11, 2008. On-line at: http://www.oag-bvg.gc.ca/internet/English/pet_262_e_32509.html

undermined by policy responses that are governed by a regulation developed on the basis of scientific understanding from fifteen years ago. This out-of-date regulation has the potential to apply the same inadequate controls on many more highly toxic substances.

Without requiring safer substitutes history repeats itself

Moreover, this regulation, and CEPA, 1999 itself, provides no means of ensuring that history will not repeat itself with the substitution of equally problematic substances for those being regulated. A clear example of this problem is provided in the draft State of the Science report. It includes a discussion about alternatives to decaBDE that are chemically similar, notably Decabromodiphenyl ethane (decaBD ethane).

The report notes the potential for this chemical to be used as a large-scale replacement for decaBDE. It further points out the similarity between these chemicals and the presence of decaBD ethane in Canadian wildlife. However, the conclusion reached is the need to further understand the potential environmental risks from decaBD ethane and its capacity to accumulate in wildlife and transform to potentially bioaccumulative products.

This conclusion demonstrates, once again, a regulatory paradigm that is incapable of learning the lessons of history in order to avoid repeating them. A more logical and reasonable conclusion should be that such findings about decaBD ethane should prompt a precautionary response that ensures this chemical not be allowed to be substituted for decaBDE. To not do so opens the door for creating exactly the same kind of intractable problem of allowing widespread use of a toxic substance, waiting for irreversible environmental contamination to occur so it can indeed be measured and debated at length in the scientific and policy realm, perhaps for five to ten years, and ultimately found to have been yet another costly and irreversible mistake that could have been prevented.

Human exposure information is also out of date – inadequate recognition of dust

The same problem of reliance on out-of-date science, and a narrow focus on a single group of chemicals, arises with the Health Canada State of the Science report conducted by that agency in 2004 and taking account of the literature to the end of 2003.⁸ This report underestimates the contribution of dust to PBDE exposure in humans.

Many recent studies indicate that dust is the principal exposure source for humans, particularly children, contrary to older scientific evidence that found most exposure arising from food. For example, Stapleton et. al.⁹ found dust exposure levels approximately three times higher than are predicted in the Health Canada assessment. More recent data suggest that levels could be ten or

⁸ Health Canada, 2004. *State of the Science Report for a Screening Health Assessment*. Polybrominated Diphenyl Ethers (PBDEs) [Tetra-, Penta-, Hexa-, Hepta-, Octa-, Nona- and Deca- Congeners] [CAS Nos. 40088-47-9, 32534-81-9, 36483-60-0, 68928-80-3, 32536-52-0, 63936-56-1, 1163-19-5], December 9, 2004.

⁹ Stapleton, HM, Dodder MG, et. al., 2005. Polybrominated Diphenyl Ethers in House Dust and Clothes Dryer Lint. *Env. Sci and Technol.* 39(4): 925-931.

more times higher with some people at levels fifty times higher for reasons that remain to be understood.¹⁰

The conclusions about human health risk from PBBEs in dust contained in the 2004 assessment conducted by Health Canada are out of date and, at the very least, likely provide for little to no safety margin for preventing excessive PBDE exposure via indoor dust. Moreover, while the assessment recognizes the developmental neurotoxicity of PBDEs, it takes no account whatsoever of the reality of children's exposures to multiple additional substances that are known or suspected in developmental neurotoxicity including some insecticides, metals such as lead and mercury, various solvents, legacy exposures to PCBs, etc.

We are aware that Health Canada is apparently revising its State of the Science review concerning human health risks from PBDEs, with a focus on decaBDE. Such a review is welcome and necessary and should support a conclusion that all PBDEs should be banned.

We need a Board of Review

The environmental organizations who filed the Notice of Objection concerning the PBDE regulations¹¹ sought a Board of Review under sub-section 332(2) and section 333 of CEPA, 1999. In response, we have been referred to the consultation on the revised State of the Science report and have been told by Environment Minister Prentice that a decision on whether to establish a Board of Review will be made once public comments have been considered and the State of the Science Report is finalized.¹²

As noted above, there are several issues outstanding concerning the PBDE Regulations that would benefit from a Board of Review. They include the issues discussed herein specific to the scientific review of environmental bioaccumulation of decaBDE, the toxicity and fate of decaBDE breakdown products and the accuracy of the information about human exposure sources and levels.

As well, broader and extremely important issues are illustrated by these regulations and the case of decaBDE. These broader issues include the need for ensuring that highly toxic substances like decaBDE are not replaced with equally hazardous substitutes. A fundamental issue, germane to the outcome of the entire Chemicals Management Plan, is the fact that DecaBDE also illustrates a significant problem with the *Persistence and Bioaccumulation Regulations* under CEPA, as discussed above.

Hence, despite the progress made on updating the science on the bioaccumulation of decaBDE and proposing to regulate decaBDE in line with the European ROHS approach, (discussed further below), we believe that compelling issues remain and the public interest would be well served if these issues were addressed by a Board of Review.

¹⁰ See review in: Unwelcome Guest – PBDEs in Indoor Dust. *Focus* article, *Environmental Health Perspectives*, 116(5), May 2008.

¹¹ Polybrominated Diphenyl Ethers Regulations (SPR/2008-218). On-line at: <http://laws.justice.gc.ca/en/showtdm/cr/SOR-2008-218>

¹² Letter from Hon J Prentice, Minister of Environment to Hugh Wilkins, Ecojustice Canada. April 2, 2009.

Comments on the Revised Risk Management Strategy for DecaBDE

Support for tighter controls on DecaBDE in electronics; justifies a full ban

First, we wish to express our strong support for the proposal to tighten regulatory controls on DecaBDE by aligning Canadian rules with the European Union Restrictions on Hazardous Substances (RoHS) Directive in electronics.

However, in line with the comments made above concerning the revised State of the Science report and Health Canada's apparent intention to produce a revised State of the Science report concerning human health risks, we wish to raise similar concerns about the revised Risk Management Strategy for DecaBDE.

Since we continue to dispute the legitimacy of allowing any uses of DecaBDE, we believe the Risk Management Strategy should spell out an equivalent program to phase-down and ultimately ban all remaining uses in the other sectors discussed in the document. We find it flawed logic for the report to say, on the one hand, the more recent evidence about the bioaccumulative potential of DecaBDE justifies banning its use in electronics, thus eliminating approximately 80% of its use in consumer products. On the other hand, such evidence is not used to support eliminating the remaining 20% of use in multiple consumer products for which indoor use and resulting human exposure will continue.

Worst-case estimate of human exposure is out-of-date; textiles and PBDEs in dust

In describing "The Issue" the RM Strategy refers to the Health Canada "human health risk assessment" of 2006, noting its conclusion that worst-case estimates of human exposure are acceptable. This document from 2006 was a Screening Level Risk Assessment, not a human health risk assessment. More important, as discussed above, the "worst-case estimates" in the 2006 report are out-of-date and likely in need of significant revision, particularly with respect to what is now known about much higher PBDE exposure in indoor dust (including in vehicles).

In explaining "Why We Need Action" (page 8-9) and "Presence [of PBDEs] in the Canadian Environment and Exposures Sources" (page 9-11) the draft RM Strategy consistently understates the importance of indoor dust as a repository for PBDEs, an exposure medium and a source of environmental contamination.

A partial exception is the statement on page 9 noting that potential releases of DecaBDE used in textile applications occur evenly throughout the product life cycle, with most releases being associated with textile processing/finishing and releases during the product service life. Such releases during the "product service life" are occurring indoors in our homes and making important contributions, perhaps the most significant contributions, to the levels of PBDEs in dust that recent studies are linking directly to the unacceptably high levels of PBDEs in human serum and breast milk.

Were Health Canada to bring up to date the scientific information underpinning this review of exposure sources, it would be far more reasonable to conclude that such uses should be discontinued.

Waste recovery and reuse of products containing PentaBDE and OctaBDE is overlooked

In describing the use patterns of the three commercial PBDE mixtures, the draft RM Strategy notes that the PentaBDE and OctaBDE mixtures are no longer available worldwide though they may be in older materials and products manufactured prior to 2006. While this drop in availability is true for the original manufacturing of these materials and products, the statement is misleading.

As noted above, the recent decision in Geneva concerning the decision to list these chemicals in Annex A of the Stockholm Convention on Persistent Organic Pollutants (POPs) did not prevent the recycling of products containing PBDEs. As a result, waste recovery of materials originally containing these mixtures and their reuse in the manufacture of substantially similar products can be expected for another two decades. Since the products that could contain this recovered material can often be long-lasting/durable goods such as carpets and foams, the result will mean cumulative indoor exposures to these banned PBDEs for much longer than the draft RM Strategy implies.

Misleading impression of products as sources of indoor exposure; Lack of consideration for poverty or low income circumstances

In discussing “Product Use” (page 10) of PBDEs, the draft RM Strategy downplays the significance of indoor exposure sources, particularly to children and even more so to children living in poverty. It is not the case that product use “may” result in PBDE release to the environment. It does do so.

This contribution to indoor dust levels is similarly downplayed in the statement: “particle emissions may also result from aging and wear of products.” Normal use and wear of products is clearly the source of PBDEs in dust (and dryer lint). Under low income circumstances, multiple products in the home, particularly durable goods containing PBDEs like furniture, beds, carpets, etc., will be more likely to be older (thus containing the banned PBDE commercial mixtures) and also more worn and thus able to release more PBDEs to house dust.

Public education should be included in risk management considerations

As we submitted in response to the first draft of the Risk Management Strategy (in November of 2006), levels of PBDEs in dust constitute a primary exposure medium. The fact that PBDEs have been incorporated into so many varied consumer products for approximately 30 years presents a legacy of contamination that has multiple implications for public health and safety. Similar to the legacy created by many decades of lead-containing paint, ongoing public awareness is necessary about these indoor exposure sources and pathways, particularly for children and pregnant women. PBDE releases will continue for many years, perhaps decades, from the millions of products that currently sit in every room of every house and building in Canada, and in just about every vehicle.

The draft RM Strategy only refers to the disposal of these products. Some products will release more PBDEs than others, especially if in a deteriorated condition (as can occur under conditions of poverty, as noted above) such as carpet backing as well as foam in many types of beds and

furniture. Public awareness about contaminants in dust and simple means of avoiding exposure is very important and is a legitimate and necessary component of a Risk Management Strategy.

Alternative chemicals should be inherently safer

The RM Strategy refers to various ways in which alternatives might be used as a substitute for decaBDE, including reference to the innovations in Design for the Environment programs. However, these are presented simply as “considerations.” As discussed above, with respect to the context for regulating PBDEs, the draft RM Strategy adopts a very narrow focus thus missing an opportunity to ensure that the mistake of using highly toxic substances as flame retardants is not repeated.

In noting alternatives as “considerations,” the draft RM Strategy opens a door to choosing a safer approach and then does nothing with it. Section 7 (page 17) outlines environmental and risk management objectives focused solely on PBDEs. Section 8 (pages 18-21) addresses risk management instruments, tools, and complementary measures. Neither of Section 7 or 8 offers any means of preventing such a huge problem from being repeated with other toxic chemicals nor even a program for warning the public about ongoing exposure and how they can reduce or prevent it.

Monitoring should address the indoor environment and be coordinated with increased labelling and inspections of imported products

The draft RM Strategy provides insufficient assurance that the monitoring to be conducted by the federal government, particularly Health Canada, will address indoor exposures, particularly via dust. Any environmental monitoring, including of the indoor environment, should be closely linked to monitoring and inspection of imported products to determine PBDE levels and regulatory compliance.

In proposal to adopt an approach similar to the EU RoHS Directive for DecaBDE in electronics, the draft RM Strategy does not mention labeling or other certification requirements to ensure regulatory compliance. Labelling to denote compliance with the new regulations will be necessary for several reasons – to provide information to consumers, to ensure the effectiveness of waste recovery and recycling operations and to allow for inspections to ensure regulatory compliance.

Comments on the Draft Performance Agreement

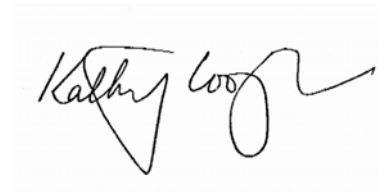
Further to our comments above, we believe any approach that allows the continued use of DecaBDE should be framed within a strategy of requiring a progressive phase-down to an ultimate ban. During this effort, DecaBDE should be substituted with inherently safer alternatives. The draft performance agreement does little more than apply a non-binding veneer of government approval of the status quo. The scientific evidence is sufficient to ban 80% of the use of DecaBDE in electronics. It is not logical or supportable to allow this additional 20% of use to continue in products for which direct and ongoing exposure to DecaBDE will occur during

the product life cycle. The draft Performance Agreement serves the purpose of political expediency, not scientific credibility or the public interest.

All of which is respectfully submitted.

Yours very truly,

CANADIAN ENVIRONMENTAL LAW ASSOCIATION

A handwritten signature in black ink, appearing to read "Kathleen Cooper", with a stylized flourish extending to the right.

Kathleen Cooper
Senior Researcher