July 8, 2013

Office of the Auditor General of Canada
Commissioner of the Environment and Sustainable Development
Attention: Petitions
240 Sparks Street
Ottawa, Ontario K1A 0G6

Email: **petitions@oag-bvg.gc.ca**

Attention: Petitions

Dear Commissioner**:**

Re:* Petition to the Office of the Auditor General – Regarding review of the *Persistence and Bioaccumulation Regulations* of *CEPA 1999

Ecojustice and the Canadian Environmental Law Association (CELA) request information regarding Canada's review of the *Persistence and Bioaccumulation Regulations SOR/2000-107* ("the regulation") of *Canadian Environmental Protection Act, 1999*, SC 1999, c. 33 ("*CEPA 1999*"). As you are aware, this regulation is integral to the effective functioning of *CEPA 1999* in order to realize the Act's purposes of protecting the environment and human health from the impacts of toxic substances.

The regulation is flawed for two reasons.

- The definitions and criteria are limited to assessing bioaccumulation in aquatic species and thus fail to assess bioaccumulation in terrestrial species through means such as inhalation and diet.

- The criteria set out in the regulation were intended for determining if a substance should be designated for virtual elimination, but are used in other contexts such as substance assessments under the Act for determining if a substance is 'CEPA toxic' setting an unreasonably high bar.

According to the government response to Petition 262[i], "Bioaccumulation assessment criteria related to the regulation of fire-retardant chemicals" submitted in July 2008, "Environment Canada is considering revisions to the Persistence and Bioaccumulation Regulations**."** In addition, a comparison of criteria values for persistence and bioaccumulation for different jurisdictions or selected international agreements on chemicals management was completed in

2009, which demonstrated that criteria set in the regulations under *CEPA 1999* are significantly less stringent than other jurisdictions.[ii]

Therefore, we request the response of Environment Canada and any other relevant departments to the questions posed below.

Background

Limitation of the regulation to finding a substance to be bioaccumulative through only water based exposures (aquatic species)

The regulation under CEPA 1999 sets out criteria under section 4 to determine if a substance is bioaccumulative.

> *"**4.** A substance is bioaccumulative*
>
> *(*a*) when its bioaccumulation factor is equal to or greater than 5 000;*
>
> *(*b*) if its bioaccumulation factor cannot be determined in accordance with a method referred to in section 5, when its bioconcentration factor is equal to or greater than 5 000; and*
>
> *(*c*) if neither its bioaccumulation factor nor its bioconcentration factor can be determined in accordance with a method referred to in section 5, when the logarithm of its octanol-water partition coefficient is equal to or greater than*
>
> ***5.** The determination of persistence and bioaccumulation with respect to a substance under sections 3 and 4 must be made in accordance with generally recognized methods of the Organisation for Economic Co-operation and Development (OECD) or of some other similar organisation or, if no such methods exist, in accordance with generally recognized methods within the scientific community and taking into account the intrinsic properties of the substance, the ecosystem under consideration and the conditions in the environment."*

Petitioner no. 262 of July 2008 raised a number of concerns regarding the regulation. In particular, petitioner no. 262 noted the regulation's inability to assess bioaccumulation in terrestrial animals. This position is supported by academic literature.[iii] The petitioner describes the regulations as "water based", which is an accurate portrayal given the definitions of bioaccumulation factor and bioconcentration factor in Section 1 of the regulation as reproduced below.

> *"bioaccumulation factor"*
>
> *"bioaccumulation factor" means the ratio of the concentration of a substance in an organism to the concentration in water, based on uptake from the surrounding medium and food. (facteur de bioaccumulation)*
>
> *"bioconcentration factor"*

> *"bioconcentration factor" means the ratio of the concentration of a substance in an organism to the concentration in water, based only on uptake from the surrounding medium. (facteur de bioconcentration)*

In their response Environment Canada and Health Canada more or less agree with the petitioner on the limitations of the regulation. The following is an excerpt from the joint Health Canada and Environment Canada response to a question regarding this issue:

> *"The current bioaccumulation criteria identified in the* Persistence and Bioaccumulation *Regulations were developed from the science of chemical bioaccumulation in fish and are mainly applicable to water-breathing organisms. As the science of bioaccumulation has progressed, researchers have demonstrated the usefulness of a variety of other measures for establishing whether food web biomagnification is occurring. Additional measures of bioaccumulation that can also be used to address the potential for chemicals to biomagnify in food webs include BMFs, trophic magnification factors (TMFs, sometimes referred to as food-web biomagnification factors), biota sediment application factors (BSAFs), and soil BAFs. However, these alternative measures are not relevant to the criteria identified in the Regulations, which are focused on aquatic BCF and BAF measures.*
>
> *In particular, for terrestrial and aquatic/marine birds and mammals, air inhalation and diet are important sources of chemical uptake as you noted in your petition. While partitioning based on the K_{ow} is the main chemical property affecting chemical uptake and elimination of neutral organics in aquatic water-breathers, this is not the case for air-breathers. Organism–air exchange involves lipid–air partitioning and is expected to depend on K_{oa}. K_{oa} provides an indication of the tendency of a chemical to accumulate in the tissues of air-breathing organisms."*

Furthermore, in their response below Environment Canada and Health Canada referred to the *Toxic Substances Management Policy* ("TSMP") as a possible vehicle for action, where the regulation is deficient. However policy cannot trump regulation.

> *"Although the* Persistence and Bioaccumulation Regulations *under CEPA 1999 do not explicitly refer to measures of BMF, TMF or BSAF and do not refer to measures like K_{oa}, concerns of very bioaccumulative substances, including those which biomagnify, are captured by the Toxic Substances Management Policy* ***(see references 2 and 3)***. *Developed during the early 1990s, the purpose of the Policy is to manage very bioaccumulative substances and substances which biomagnify regardless of whether the organisms are aquatic or terrestrial. Criteria in the Regulations are based on those in the Policy that guide the Government of Canada in determining whether substances should be identified for virtual elimination, or life cycle management. In keeping with this policy, actions may be taken to control substances which are shown to biomagnify, or accumulate from sources other than those which are aquatic based. This policy also provides latitude for the federal government to take action on a substance should it be shown to transform in the environment to forms which are bioaccumulative."*

In response to a question asking for the regulation to be changed to employ additional criteria to recognize uptake of a substance through media other than water, and species other than aquatic, the government responded in November 2008 with the following;

> *"As mentioned previously, criteria in the Regulations under CEPA 1999 are based on those in the Toxic Substances Management Policy. 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.*** *These discussions would give consideration to other measures which recognize uptake of a substance through media other than water (e.g., through air and diet) and organisms who breathe air, rather than water; as well as to other methods like modelling.****[emphasis added]"***

It is worth noting that the European Community REACH legislation[iv] recognizes the other means of bioaccumulation. Section 3.2.2 of REACH states the following.

> *3.2.2. Assessment of B or vB properties*
>
> *(a) Results from a bioconcentration or bioaccumulation study in aquatic species;*
>
> *(b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:*
>
> *— Results from a bioaccumulation study in terrestrial species;*
>
> *— Data from scientific analysis of human body fluids or tissues, such as blood, milk, or fat;*
>
> *— Detection of elevated levels in biota, in particular in endangered species or in vulnerable populations, compared to levels in their surrounding environment;*
>
> *— Results from a chronic toxicity study on animals;*
>
> *— Assessment of the toxicokinetic behaviour of the substance;*
>
> *(c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.*

Any revisions to the regulation should accommodate bioaccumulation through media other than water, as well as biomagnification, but **NOT** as an additional requirement for designating a substance as bioaccumulative, but as an alternate measurement for assessing the bioaccumulation of a substance such that evidence of only one of many factors (ex. BAF, BCF, Kow, BMF) is required for a designation of bioaccumulative.

Existing Thresholds are Too High

Setting aside the issue of the deficiency of the regulation to address bioaccumulation through exposures other than water based, such as inhalation exposure or diet in terrestrial species, also of concern are the actual threshold levels for BCF and BAF of 5,000 set under section 4 of the regulation. By comparison to other jurisdictions these thresholds are inordinately high. Under other jurisdictions, such as the EU and US, the values set for bioaccumulation under the regulation would suggest that a substance is 'very bioaccumulative'.

While we note that the 5000 BCF and BAF thresholds are used to determine if a substance should be on track for virtual elimination (when coupled with the assessment of the persistence of a substance), the BCF and BAF thresholds are also used in screening risk assessments under *CEPA 1999* and under the Chemicals Management Policy to determine if substances are toxic, or capable of becoming toxic, under *CEPA 1999* section 64.

The lack of a lower threshold for labelling a substance as bioaccumulative has significant implications for taking steps necessary to manage chemicals. In Canada, measures may not be considered if a chemical does not equal or exceed the values for bioaccumulation in the regulation. More specifically, substances that are bioaccumulative enough to be of environmental concern such that management may be required, but not bioaccumulative enough to exceed the thresholds in the regulation used for assessing for virtual elimination, may not be designated as toxic or flagged for further assessment due to bioaccumulation concerns.

Other jurisdictions such as the US and Europe have set much lower thresholds for designating substances as bioaccumulative, but a similar threshold to that under the *CEPA 1999* regulation for an outright ban, See for example the US and Europe information summarized below.

US TSCA[v]	Bioaccumulative	Ban pending testing
Bioconcentration factor	>= 1,000	>5,000

EU REACH[vi]	Bioaccumulative	Very Bioaccumulative
Bioconcentration factor	>2,000	>5000

In light of the above background information we are asking the following questions regarding the *Persistence and Bioaccumulation Regulations* under *CEPA 1999*.

Questions and Requests

1. With respect to the consideration of revisions to the *Persistence and Bioaccumulation Regulations* mentioned above by Environment Canada and Health Canada in response to petition 262, please indicate if such a review has been, or is being. undertaken? If so, can you provide us with an update and details of that review, timing of completion if not yet completed, or the outcome of the review if completed? Please also include how, if any, public engagement was undertaken in this process.

2. If a review has not been undertaken, given the issues raised in petition no. 262 five years ago are still of concern, would Environment Canada undertake a review at this time to ensure that the regulation is strengthened to ensure all modes of bioaccumulation are recognized and assessed under the regulation? If not, please provide reasons?

3. Would Environment Canada revise the regulation to adopt lower thresholds to match the criteria applied by other jurisdictions to identify substances as bioaccumulative for the purpose of assessing toxicity and developing management measures without necessarily having such a threshold tied to a virtual elimination designation? Please provide the government's position on lowering the values for bioaccumulation to harmonize with other jurisdictions by establishing lower thresholds for bioaccumulation.

4. If Environment Canada does not agree to the revisions as requested in question 3, please provide reasons and explain how substances that are bioaccumulative, but not to such an extent that they exceed the regulatory thresholds, are managed under *CEPA 1999* for harmful environmental effects?

5. Please provide the name of substances that have met the criteria of the regulation. Of these substances, which ones have been virtually eliminated?

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We hereby submit this petition to the Auditor General of Canada under section 22 of the Auditor General Act.

Thank you for your attention to this important issue, and we look forward to your response. If you have any questions or concerns, please do not hesitate to contact the undersigned.

Yours truly,

ECOJUSTICE

Elaine MacDonald, Senior Scientist

Canadian Environmental Law Association

Fe de Leon, Researcher

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[i] Available at <http://www.oag-bvg.gc.ca/internet/English/pet_262_e_32509.html>

[ii] See: Canadian Environmental Law Association and Lowell Center for Sustainable Production, University of Massachusetts. 2010. The Challenge of Substances of Emerging Concern in the Great Lakes Basin: A review of chemicals policies and programs in Canada and the United States. A report prepared for the International Joint Commission Multi-Board Work Group on Chemicals of Emerging Concern in the Great Lakes Basin . Appendix A. Accessed at <http://www.cela.ca/sites/cela.ca/files/667IJC.pdf>

[iii] See J. Arnot and F. Gobas, 'A Review of Bioconcentration Factor (BCF) and Bioaccumulation Factor (BAF) Assessments for Organic Chemicals in Aquatic Organisms', 14 *Environ. Rev.* (2006), 257, at 292. In addition to the other literature cited in petition 262.

[iv] Section 3.2.2 of Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20121009:EN:PDF>

[v] Environmental Protection Agency [OPPTS-53171A; FRL-6097-7] Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. IV. Final TSCA New Chemicals Program Policy for PBT Chemical Substances. Available at <http://www.epa.gov/fedrgstr/EPA-TOX/1999/November/Day-04/t28888.htm>

[vi] Section 1.2.2 of Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20121009:EN:PDF>