



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

February 8, 2012

VIA ELECTRONIC MAIL
< minister@ec.gc.ca >
AND ORDINARY MAIL

The Honourable Peter Kent
Minister of the Environment
Environment Canada
Les Terrasses de la Chaudiere
10 Wellington Street, 28th Floor
Gatineau, Quebec K1A 0H3

Dear Minister Kent:

Re: Report of the Siloxane D5 Board of Review

We are the solicitors for four groups that were granted intervenor status in the above review process: Canadian Environmental Law Association, International Institute of Concern for Public Health, Chemical Sensitivities Manitoba, and Crooked Creek Conservancy Society of Athabasca (collectively known as the "Coalition").

We are writing to you with respect to the above report, which was released at the end of October 2011. For the reasons set out below, we urge you not to adopt all of the conclusions of the Board report and instead to recommend that the Governor in Council:

- (1) promulgate an order under section 90(1) of the *Canadian Environmental Protection Act, 1999* ("CEPA, 1999") that Siloxane D5 be added to the List of Toxic Substances in Schedule 1 of that Act; and
- (2) implement virtual elimination of D5 pursuant to section 65(3) of said Act.

Background

As you are aware, in 2008 an Environment Canada screening assessment of Decamethylcyclopentasiloxane (hereinafter "Siloxane D5" or "D5") concluded that the substance "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" thus meeting one or more of the criteria in section 64 of *CEPA, 1999*, for being a toxic substance. A 2009 proposed order by your predecessor, the Hon. Jim Prentice, and by the

Minister of Health, to place D5 in the Schedule 1, List of Toxic Substances under *CEPA*, 1999¹ was met by a request from the Silicones Environmental, Health and Safety Council of North America (“SEHSC”) to establish a board of review to inquire into the matter. In August 2010, Minister Prentice granted the SEHSC request. The terms of reference of the Board included the obligation to inquire into the “nature and extent of the danger” posed by D5.²

In October 2011, following a hearing into the matter in April and May 2011, the Board of Review issued a report that concluded as follows:

“292. The evidence presented to the Board demonstrated that Siloxane D5 exceeded the regulatory threshold for persistence. However, Siloxane D5 did not exceed the thresholds established in the [*Persistence and Bioaccumulation Regulations*] for bioaccumulation.”³

293. Siloxane D5 does not biomagnify through the food chain, although it can be accumulated into organisms from environmental matrices or food. That is, concentrations of Siloxane D5 do not increase in predators relative to their prey.

294. There is no evidence to demonstrate that Siloxane D5 is toxic to any organisms tested up to the limit of solubility in any environmental matrix. The Board is of the opinion that Siloxane D5 will not accumulate to sufficiently great concentrations to cause adverse effects in organisms in air, water, soils, or sediments.

295. Consequently, taking into account the intrinsic properties of Siloxane D5 and all of the available scientific information, the Board concluded that Siloxane D5 does not pose a danger to the environment. Furthermore, the Board concluded that, based on the information before it, the projected future uses of Siloxane D5 will not pose a danger to the environment.”

The remainder of this letter sets out the reasons why the Coalition is of the view that you should not accept certain of the above conclusions contained in the report of the Board of Review.

The Minister is Not Obligated to Adopt Report Conclusions or Recommendations

Section 333 of *CEPA*, 1999 authorizes you to establish a board of review to inquire into the matter. The section does not authorize the board to decide the matter referred to it by you.

The case law is clear that in such a context the board is not a decision-making authority and that you, as Minister, are not obliged in law to accept conclusions or implement recommendations provided to you by a board of review: *Monsanto Canada Inc. v. Canada (Minister of Agriculture)*, [1988] F.C.J. No. 1107 (F.C.A.).

¹ The Canada Gazette, Part I, May 16, 2009 contained a proposed order by the Ministers of Environment and Health adding D5 to Schedule 1 of *CEPA*, 1999.

² The Canada Gazette, Part I, August 10, 2010.

³ At paragraph 3 of the executive summary of the Board’s report there appears to be a material error and omission in stating the conclusion contained in paragraph 292, in that paragraph 3 reads: “The evidence presented to the Board demonstrated that Siloxane D5 exceeded the regulatory threshold for persistence. However, Siloxane D5 did not exceed the thresholds established in the *Persistence and Bioaccumulation Regulations* (“Regulations”).” The Coalition assumes that paragraph 292, and not paragraph 3, correctly states the Board’s conclusion on this point.

There also are sound legal, statutory, and policy reasons for this jurisprudence. While the Board of Review consisted of a panel of three scientists, the inquiry they conducted took place in the context of a regulatory statute that is designed to protect the public and the environment and, in doing so, incorporates precautionary principles, provides preventive and remedial measures, and imposes administrative duties on the Government of Canada, to achieve such ends. Where science may insist that a thing is not proven unless there is 99.9 per cent certainty, a regulatory statute, such as *CEPA, 1999*, does not require proof to that degree of certainty before a conclusion may be drawn and action taken. Indeed, as this was not a criminal inquiry, but rather administrative, the standard of proof required to be met, even before consideration of the precautionary principle, is a civil one of balance of probabilities, or more probable than not or, in numeric terms, 50.1 per cent certainty. Were it otherwise, Parliament would be seen to be granting chemicals a presumption of innocence that is normally reserved for people and that runs counter to the declaration, preamble, and duties in *CEPA, 1999* respecting protection of the public and the environment.

Moreover, the precautionary principle itself, referred to in the Act's preamble, the section 2 administrative duties imposed on the Government of Canada, and the section 76.1 scientific assessment and interpretation obligations, is defined as follows: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". So you, as Minister, operating as you do with a broader array of obligations under the Act than the members of the Board of Review cannot, as a matter of law, be constrained by the Board's conclusions.

The Minister Should Not Accept all of the Conclusions of the Board

Quite apart from the legal question of whether you are bound to adopt the board's conclusions or recommendations, which the Coalition says you are not, there are sound science and policy reasons arising from just a review of the transcript evidence at the hearing as to why you should not adopt all of the conclusions in the board report. These reasons include the following:

- The transcript evidence shows that D5 meets the criteria for being judged bioaccumulative;
- The transcript evidence shows that reliance on biomagnification as a means for determining whether a substance is bioaccumulative is not a generally accepted method in the regulatory community in this or any other jurisdiction, particularly in the United Kingdom, or the European Union;
- The transcript evidence shows that certain reports indicated adverse effects in certain water or sediment dwelling organisms; and
- Accordingly, and arising from the foregoing, the Board's conclusion that D5 does not pose a danger to the environment now, or in future, does not follow.

Each of these issues is addressed below.

D5 Meets the Criteria for Being Judged Bioaccumulative

As noted above, one of the conclusions of the Board of Review was that:

“292.Siloxane D5 did not exceed the thresholds established in the [Persistence and Bioaccumulation Regulations] for bioaccumulation”.

In this regard, a scientist from Simon Fraser University (“SFU”) appearing for SEHSC testified that D5 is not a bioaccumulative substance in the environment. This witness stated that one of the reasons his assessment was different from that of Environment Canada was because he considered the intrinsic properties of D5, something recognized in the regulations, but he was not sure if this information was fully used in Environment Canada’s evaluation (Testimony of Dr. Frank Gobas, Transcript of Siloxane D5 Board of Review Hearing, May 3, 2011, Vol. 6, pages 861-862).

However, it was the testimony of the Environment Canada scientist responsible for the ecological assessment program under the Act that section 5 of the regulations allows in the assessment of whether a substance is bioaccumulative, consideration of the intrinsic properties of the substance. So in determining whether a substance is bioaccumulative, Environment Canada looks at the section 4 criteria and the intrinsic properties of the substance as per section 5 of the regulations (Testimony of Dr. Robert Chenier, Transcript of Siloxane D5 Board of Review Hearing, April 26, 2011, Vol. 1, page 67).

It was the testimony of another Environment Canada scientist in the ecological assessment program that since the screening assessment, additional information on bioaccumulation has increased the concern of Environment Canada with regard to the extent of bioaccumulation of D5 in the environment (Testimony of Dr. Don Gutzman, Transcript of Siloxane D5 Board of Review Hearing, April 26, 2011, Vol. 1, page 149).

It was the testimony of the senior science advisor at Environment Canada that the biota-sediment accumulation factor (“BSAF”), the bioconcentration factor (“BCF”), and the bioaccumulation factor (“BAF”) showed that D5 can bioaccumulate to high levels at values that exceed regulatory criteria (Testimony of Mark Bonnell, Transcript of Siloxane D5 Board of Review Hearing, April 28, 2011, Vol. 3, page 376).

It was the testimony of a scientist from Stockholm University that studies in Swedish lakes showed that the bioaccumulative properties of D5 and PCB 180 (the latter chemical known to be strongly bioaccumulative) were similar (Testimony of Dr. Michael McLachlan, Transcript of Siloxane D5 Board of Review Hearing, April 29, 2011, Vol. 4, pages 566-567).

It was also the testimony of a scientist with the United Kingdom Environment Agency that in Europe the basic criterion applied is BCF and the agency knows that D5 does meet the BCF criterion for being a very bioaccumulative substance under REACH (the European Union chemical law) (Testimony of Dr. Steve Dungey, Transcript of Siloxane D5 Board of Review Hearing, May 6, 2011, Vol. 8, page 1060).

The transcripts reveal that there was a serious disagreement between Environment Canada scientists, scientists from Sweden, and regulators from the United Kingdom, on the one hand, and scientists appearing for the industry on the other, about whether D5 bioaccumulates in the environment. The division in the evidence about whether D5 bioaccumulates appears to have been resolved, at least in part, by the Board of Review on the basis of whether the substance biomagnifies through the food chain (See Report of the Board of Review on Siloxane D5, page 52, paragraph 237). For the reasons set out here and in the next segment of this letter, the Coalition submits that the Board conclusion on bioaccumulation is not one that should be adopted by your office and, therefore, should not prevent you from recommending to the federal cabinet that D5 be listed in Schedule 1 of the List of Toxic Substances under *CEPA, 1999* and subjected to risk management measures.

Biomagnification is Not a Necessary Condition for a Determination that a Substance is Bioaccumulative

As noted above, another conclusion of the Board of Review was that:

“293. Siloxane D5 does not biomagnify through the food chain, although it can be accumulated into organisms from environmental matrices or food. That is, concentrations of Siloxane D5 do not increase in predators relative to their prey”.

In this regard, a scientist from Simon Fraser University appearing for SEHSC testified that there is no real evidence that D5 biomagnifies in the environment (Testimony of Dr. Frank Gobas, Transcript of Siloxane D5 Board of Review Hearing, May 3, 2011, Vol. 6, pages 854, 861-862, 866, 868, 872, 953-954).

However, it was the testimony of several Environment Canada scientists responsible for the ecological assessment program under the Act that the concern about bioaccumulation is not just about biomagnification. You do not have to have biomagnification in order to have concern with respect to bioaccumulation. Furthermore, the s. 4 criteria under the *Persistence and Bioaccumulation Regulations* are with respect to bioaccumulation, bioconcentration, and octanol-water coefficient. The concern is not with biomagnification as it relates to those criteria (Testimony of Dr. Robert Chenier, Transcript of Siloxane D5 Board of Review Hearing, April 26, 2011, Vol. 1, pages 68, 72; Testimony of Dr. Don Gutzman, Transcript of Siloxane D5 Board of Review Hearing, April 26, 2011, Vol. 1, pages 151-152).

Furthermore, a Table contained in the Environment Canada State of the Science Report on D5 does not indicate a single jurisdiction listed therein relying on biomagnification as an indicator or criterion for determining bioaccumulation (Table 1: Common Bioaccumulation Indicators and Criteria Used Among Jurisdictions, in Environment Canada, Siloxane D5 – Draft State of the Science Report, January 2011, page 17).⁴ This document was an exhibit at the hearing before the Board of Review.

⁴ The jurisdictions listed in Table 1 include: Canada, the United Nations (Globally Harmonized System), European Union, United States, UNEP (Stockholm Convention), UNEP (POPs Protocol), OSPAR (Commission for the

It was also the testimony of a scientist from Stockholm University in Sweden that biomagnification alone is insufficient, in and of itself, in assessing the bioaccumulative nature of D5 because biomagnification explores the transfer of the chemical between organisms and within a food web. Bioaccumulation also includes bioconcentration into the base of the food web, and the biomagnification assessment does not capture that. Even though we have D5 biodiluting in a food web, and PCB 180 biomagnifying in a food web, we can still have the concentration of D5 being higher in fish. If we just looked at the biomagnification results, we would conclude that D5 was a much better chemical, from a bioaccumulation perspective, than PCB 180. But if we look at the whole picture, then we actually come to the opposite conclusion (Testimony of Dr. Michael McLachlan, Transcript of Siloxane D5 Board of Review Hearing, April 29, 2011, Vol. 4, pages 560-561).

It was the further testimony of a scientist with the United Kingdom Environment Agency that REACH Technical Guidance Documents say that the absence of biomagnification potential cannot be used to conclude a chemical is not either bioaccumulative or very bioaccumulative, although the lack of biomagnification is a legitimate consideration in the overall final decision about what risk management measures should be employed (Testimony of Dr. Steve Dungey, Transcript of Siloxane D5 Board of Review Hearing, May 6, 2011, Vol. 8, pages 1072-1075).

Accordingly, biomagnification of D5 is not a necessary condition for a determination that the substance bioaccumulates. Put another way, just because D5 may not biomagnify does not mean it does not bioaccumulate.

Adverse Effects Were Observed

As noted above, a further conclusion of the Board of Review was that:

“294. There is no evidence to demonstrate that Siloxane D5 is toxic to any organisms tested up to the limit of solubility in any environmental matrix. The Board is of the opinion that Siloxane D5 will not accumulate to sufficiently great concentrations to cause adverse effects in organisms in air, water, soils, or sediments”.

In this regard, a scientist from the University of Michigan appearing for SEHSC testified that there was no toxicity associated with D5 to aquatic organisms, or adverse effects from D5 on sediment benthos (Testimony of Dr. Allen Burton, Transcript of Siloxane D5 Board of Review Hearing, May 4, 2011, Vol. 7, pages 963-965).

However, another scientist appearing for SEHSC acknowledged the existence of a United Kingdom report that concluded that D5 is still found in the liver of fish after long-term (35-days) exposure and that the effects of this accumulation are not known. The SEHSC witness added that the effects referred to are any adverse effects relating to survival, growth, or reproduction but that an increase in liver size, which was found in the UK study, would not be considered an

adverse effect from an ecological perspective. In response to Board questioning this witness acknowledged that an increase in liver size would not be beneficial to fish, that they did not do a full life cycle fish study, so they cannot speak to the full life cycle of reproduction, and she could not comment on the lifespan of a fish that has an enlarged liver and whether it would be the same as a fish with a normal-size liver (Testimony of Dr. Anne Fairbrother, Transcript of Siloxane D5 Board of Review Hearing, May 4, 2011, Vol. 7, pages 996-1000). However, her colleague testified that from an ecologically relevant endpoint (i.e. can the fish population reproduce and is it a healthy population), an enlarged liver is not an effect and he appeared to suggest that early life-stage studies would suffice to show that there are no full lifespan survival effects on fish (Testimony of Dr. Allen Burton, Transcript of Siloxane D5 Board of Review Hearing, May 4, 2011, Vol. 7, pages 999-1000). The issue of enlarged fish liver reported in the UK study and the possible role of D5 with respect thereto does not appear to have been addressed in the Board report.

Moreover, it was the testimony of an Environment Canada scientist that a substance that is bioaccumulative indicates that it is biologically active, that there is uptake of the substance, and there is internal exposure in organisms. So in the case of bioaccumulative substances there is always the potential for inherent toxicity. The lack of studies demonstrating toxicity is not a demonstration that such effects are not possible because a bioaccumulative substance is biologically active (Testimony of Dr. Robert Chenier, Transcript of Siloxane D5 Board of Review Hearing, April 26, 2011, Vol. 1, pages 58, 60, 63).

Furthermore, it was the testimony of another Environment Canada scientist that adverse effects from D5 were found with respect to growth, development, and survival for certain sediment organisms. The most sensitive endpoint was that of survival of an amphipod attached to DNA in lower organic carbon sediment. This was the most sensitive endpoint measured, but in combination with that, there were at least three other studies for benthic invertebrate organisms that all showed effects with medium lethal concentrations around 250 to 450 milligrams per kg (Testimony of Dr. Marc Fernandez, Transcript of Siloxane D5 Board of Review Hearing, April 27, 2011, Vol. 2, page 220).

It was also the testimony of the senior science advisor at Environment Canada that there is some evidence for effects of D5 in sediment organisms, and that D5 produced some lethality in the BCF test with respect to fish (Testimony of Mark Bonnell, Transcript of Siloxane D5 Board of Review Hearing, April 28, 2011, Vol. 3, pages 417, 479).

Overall, while the evidence for the toxicity of D5 may not have been sufficient to satisfy the Board some adverse, as well as unexplained, effects were observed and deserved further investigation.

The Board Conclusion That D5 Does Not Pose a Danger to the Environment Does Not Follow

As noted above, a final conclusion of the Board of Review was that:

“295. Consequently, taking into account the intrinsic properties of Siloxane D5 and all of the available scientific information, the Board concluded that Siloxane D5 does not pose a danger to the environment. Furthermore, the Board concluded that, based on the information before it, the projected future uses of Siloxane D5 will not pose a danger to the environment.”

In this regard, it was the submission of counsel for SEHSC and CCTFA that there is no danger to the environment or risk of danger to the environment at the concentrations in which D5 is entering the environment, the weight of evidence discloses that D5 is not bioaccumulative, and that D5 cannot enter the environment in concentrations that are causing or likely to cause harm to the environment or its biological diversity. To the extent there is any concern over the release of D5 and potential harm SEHSC and CCTFA believe that is simply limited to whether there is the potential for harm to sediment dwelling organisms in close proximity to lagoon system waste treatment plants. Apart from Toronto Harbour, D5 is not detected in sediment (Closing Submissions of Harry Dahme, Counsel, SEHSC and CCTFA, Transcript of Siloxane D5 Board of Review Hearing, May 26, 2011, Vol. 9, pages 1158, 1196, 1200-1203).

However, it was the submission of counsel for Environment Canada that D5 is bioaccumulative, persistent, has the potential for toxicity, and is a high-volume chemical with wide availability in the environment.⁵ Siloxane D5 is one of the highest import chemicals surveyed in the Industry Challenge under the Chemicals Management Plan. Cumulatively, these factors point to a finding that D5 does pose a danger to the environment. If the problem is caused by a low removal rate of D5 from certain waste water (lagoon) treatment plants, as suggested by the industry, then the problem is D5. The nature and extent of the danger can be in relation to a small number of such sites. That has to do with the extent of the danger, not its existence. The industry suggestion that the D5 found in sediment in Toronto Harbour should be treated as an outlier and, in essence, ignored, should not be accepted. The fact that D5 is found in sediment in field testing is something that should be considered whether it occurs in one location, or all locations, when considering the nature and extent of the danger posed by the substance (Closing Submissions of Helene Robertson, Department of Justice Counsel for Environment Canada, Transcript of Siloxane D5 Board of Review Hearing, May 26, 2011, Vol. 9, pages 1127-1128, 1133, 1139, 1222-1224).

Overall, it is the submission of the Coalition that *CEPA, 1999* will not protect the public, the environment, or biological diversity if the Government of Canada insists on absolute scientific certainty that substances are toxic before taking action. It was to avoid such inaction under the former statute that Parliament amended the law to include the precautionary principle in *CEPA, 1999*. The weight of evidence approach required by section 76.1 also does not require that absolute proof be established linking a substance to the potential harm it may cause before action may be taken. The scope of *CEPA, 1999* is further supported by the 1995 federal Toxic Substances Management Policy (“TSMP”) that established criteria for, and a goal of virtual elimination of, persistent and bioaccumulative substances, which criteria were adopted in 2000 in the *Persistence and Bioaccumulation Regulations*.

⁵ The Board of Review reported that the current use of Siloxane D5 in personal-care products in Canada was estimated to be 3.3 million kg/yr in 2010. See Report of the Board of Review, page 33.

Finally, the Coalition notes that the Government of Canada has the legislative authority to promulgate regulations having limited geographical application. Section 330(3.1) of *CEPA, 1999* is authority for the promulgation of regulations that can be made applicable in only part or parts of Canada in order to protect the environment, its biological diversity, or human health. Siloxane D5 may warrant such an approach in the circumstances.

Impact on Future Assessments of Substances Under CEPA, 1999

The Siloxane D5 Board of Review was the first established under the Act. As such, the outcome of this process is of significant importance to regulators, the public, and industry. Your recommendation and the eventual decision of the federal cabinet may set a precedent for the conduct of future assessment of substances under *CEPA, 1999*.

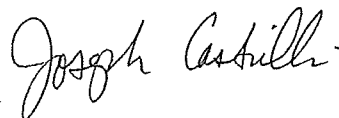
Action Requested

Accordingly, and arising from the foregoing, the Coalition repeats its request that you not adopt all of the conclusions of the Board report, namely conclusions 293-295 and the second sentence of conclusion 292, and instead recommend that the Governor in Council:

- (1) promulgate an order under section 90(1) of the *Canadian Environmental Protection Act, 1999* (“*CEPA, 1999*”) that Siloxane D5 be added to the List of Toxic Substances in Schedule 1 of that Act; and
- (2) implement virtual elimination of D5 pursuant to section 65(3) of said Act.

Should you have any questions please do not hesitate to contact the undersigned.

Yours truly,



Joseph F. Castrilli
Counsel

c.c. Harry Dahme, Counsel, Silicones Environmental, Health and Safety Council of North America and Canadian Cosmetic, Toiletry and Fragrance Association

c.c. Alexander Gay, Department of Justice, and Counsel, Environment Canada

c.c. Don Stewart, Registrar for Siloxane D5 Board of Review