BEFORE A BOARD OF REVIEW ESTABLISHED UNDER SECTION 333(1) OF THE *CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999*

**IN THE MATTER** of the *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 33;

**AND IN THE MATTER** of a request for a board of review under section 332(2) of the *Canadian Environmental Protection Act, 1999*, in which the Silicones Environmental, Health and Safety Council of North America is the Applicant and the Minister of the Environment is the Respondent and the Canadian Cosmetic, Toiletry and Fragrance Association and the coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba and the Crooked Creek Conservancy Society of Athabasca are intervenors.

SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL OF NORTH AMERICA

Applicant

– and –

THE MINISTER OF THE ENVIRONMENT

Respondent

– and –

CANADIAN COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION and THE COALITION CONSISTING OF THE CANADIAN ENVIRONMENTAL LAW ASSOCIATION, THE INTERNATIONAL INSTITUTE OF CONCERN FOR PUBLIC HEALTH, CHEMICAL SENSITIVITIES MANITOBA AND THE CROOKED CREEK CONSERVANCY SOCIETY OF ATHABASCA

Intervenors

# REPORT OF THE BOARD OF REVIEW FOR DECAMETHYLCYCLOPENTASILOXANE (SILOXANE D5)

| | |
|---|---|
| Place of Decision: | Ottawa, Ontario |
| Date of Decision: | October 20, 2011 |
| Board of Review Chair: | Professor John Giesy, Ph.D., FRSC |
| Board of Review Members: | Professor Keith Solomon, Ph.D., Fellow ATS<br>Professor Sam Kacew, Ph.D., Fellow ATS |
| Counsel to the Board of Review | Gerry H. Stobo and<br>Steven Kennedy,<br>Borden Ladner Gervais LLP |
| Registrar: | Don Stewart |

PARTICIPANTS:

| Name: | Counsel/Representatives: |
|---|---|
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| The Minister of the Environment | Alexander Gay, Helene Robertson and Marie-Josée Montreuil |
| Canadian Cosmetic, Toiletry and Fragrance Association[1] | Beta Montemayor |
| The Coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba and the Crooked Creek Conservancy Society of Athabasca | Joseph F. Castrilli |

[1] During the hearing, the Canadian Cosmetic, Toiletry and Fragrance Association was represented by Harry Dahme and James Blonde, Gowling Lafleur Henderson LLP.

**Citation for this report:**

Siloxane D5 Board of Review. 2011. Report of the Board of Review for Decamethylcyclopentasiloxane (D5). Ottawa, ON, Canada. October 20, 2011. 83 pages.

**References to Ringtail:**

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**French translation of this report:**

This translated document is provided by the Siloxane D5 Board of Review as an informational service. In case of any discrepancy between the English and French versions of this document, the statements and conclusions in the English version entitled, "Report of the Board of Review for Decamethylpentasiloxane (Siloxane D5)" dated October 20, 2011, shall govern and supersede those contained in the French version entitled, "Rapport de la commission de révision pour le décaméthylcyclopentasiloxane (siloxane D5)".

The Board would like to thank Dr. Ève Gilroy for her review and comments on the French translation of this Report.

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# 1 Terms and Abbreviations Used in this Report

| Term/ Abbreviation | Description |
|---|---|
| BAF | Bioaccumulation factor |
| BCF | Bioconcentration factor |
| BSAF | Biota-sediment accumulation factor |
| CAS# | Chemical Abstract Service Number, a unique identifier for chemicals |
| Coalition | A coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba, and the Crooked Creek Conservancy Society of Athabasca |
| CCTFA | Canadian Cosmetic, Toiletry and Fragrance Association |
| CEPA 1999 | Canadian Environmental Protection Act, 1999 |
| dw | Dry weight |
| EC | Environment Canada |
| EQC | Fugacity-based equilibrium criterion model |
| First order | A term used to describe a chemical reaction where the rate of the reaction is dependent on the concentration of the substrate or parent material |
| HQ | Hazard quotient (Exposure concentration/Effect concentration) |
| IC50 | Concentration that causes 50% inhibition of the response |
| $K_{aw}$ | Air-water partition coefficient |
| $K_{oc}$ | Organic carbon-water partition coefficient |
| $K_{ow}$ | Octanol-water partition coefficient |
| LOD | Limit of detection |
| LOQ | Limit of quantification |
| $\mu$g | Microgram (0.000001 g) |
| mg | Milligram (0.001 g) |
| ng | Nanogram (0.000000001 g) |
| mmBAF | Multi-media bioaccumulation factor |
| NOEC | No-observed-effect-concentration |
| OC | Organic carbon |
| OECD | Organisation for Economic Co-operation and Development |
| •OH | Hydroxyl radical |
| $OH^-$ | Hydroxyl ion |

| Term/ Abbreviation | Description |
|---|---|
| Pa | Pascal |
| PCB | Polychlorinated biphenyl |
| pH | A measure of the acidity of water, acidic waters have a pH <7 and alkaline waters >7 |
| SEHSC | Silicones Environmental, Health and Safety Council |
| Siloxane D5 | Decamethylcyclopentasiloxane (CAS # 541-02-6) |
| TMF | Trophic Magnification Factor |
| UF | Uncertainly Factor |
| ww | Wet weight |
| WWTP | Waste water treatment plant |

# 2 Executive Summary

## *Conclusions of the Board of Review*

1. The Siloxane D5 Board of Review (the "Board") inquired into the nature and extent of the danger posed by decamethylcyclopentasiloxane, or Siloxane D5, (CAS # 541-02-6; D5) to the Canadian environment or its biological diversity[2].

2. 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.

3. 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").

4. 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.

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

6. 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.

## *Scope of the Mandate of the Board of Review*

7. Pursuant to the authority provided in the *Canadian Environmental Protection Act* ("CEPA 1999"), the Minister of the Environment requested that the Board inquire into the nature and extent of the danger posed by Siloxane D5. The Board consulted with the parties to these proceedings, Environment Canada, the Silicones Environmental, Health and Safety Council of North America ("SEHSC"), the Canadian Cosmetic, Toiletry and Fragrance Association ("CCTFA"), and a coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba, and the Crooked Creek Conservancy Society of Athabasca (the "Coalition"), on the proposed scope of its mandate.

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[2] Hereinafter, the term "environment" refers to the phrase "environment or its biological diversity".

8. Taking into account the issues of concern identified in the Screening Assessment conducted by government officials in 2008, the directions given by the Minister of the Environment establishing this Board, and the nature of the additional information on Siloxane D5 that has become available, the Board determined that it would focus its review on the nature and extent of the danger posed by Siloxane D5 to the environment.

9. The Board has interpreted its mandate to mean that it was to inquire into the nature and extent of the risk posed, if any, by Siloxane D5 to the environment and to determine whether detrimental effects were caused or might be caused. In other words, the Board has conducted what is, in essence, a *de novo* risk assessment of Siloxane D5 by taking into account the available scientific information. When conducting the *de novo* risk assessment, the Board was of the opinion that best scientific practice required that it consider all available information about the intrinsic physical and chemical properties of Siloxane D5, along with its toxicity, uses, exposures, and effects.

## *Fate of Siloxane D5 in the Environment*

10. When chemicals are released into the environment, they move among compartments including air, soils, water, and sediments. The ultimate distribution of a substance among these compartments and the rate at which it moves among these compartments are functions of its chemical and physical properties, and the characteristics of the environment into which it is released.

11. In addition to moving among compartments and from one location to another, chemicals can undergo transformations once released into the environment. These transformations can be due to physical, biological, and/or chemical processes, such as hydrolysis and photolysis, to form products that are different from the original chemical. The rate of transformation determines the concentrations to which chemicals can accumulate in the environment.

12. The behaviour of Siloxane D5 is different from that of other compounds of similar molecular weight and size. It has a molecular structure which consists only of carbon, silicon, oxygen, and hydrogen in a symmetrical ring structure. These physical and structural properties of Siloxane D5 result in unique patterns of distribution in the environment that need to be considered in evaluating the exposure of organisms and the potential danger posed by Siloxane D5.

13. The pathway of release of Siloxane D5 into the environment is important in determining its distribution and persistence. The unique properties of Siloxane D5 combined with its primary uses and types of releases into the environment are important when considering its potential to cause harm. Due to its relatively great vapour pressure and volatility, Siloxane D5 tends to partition primarily into air. In other words, irrespective of where Siloxane D5 is initially deposited in the environment, it will migrate mainly into the air. While it can be transported relatively long distances in the air, deposition from the air to soils or water will be very limited.

14. Once in the air, Siloxane D5 degrades relatively rapidly through a process of indirect photolysis, in which naturally occurring hydroxyl radicals, formed in the atmosphere by sunlight, degrade it into smaller molecules called silanols and ultimately to carbon dioxide, water, and silicon dioxide (the main constituent of sand). These products do not present a danger to the environment. Thus, an important aspect of the environmental fate of Siloxane D5 is that the compartment into which it is mostly released and most likely to occur is also the compartment where it also undergoes the most rapid rate of transformation.

15. Although, in the Board's view, Siloxane D5 meets the criteria to be classified as a persistent chemical under the *Persistence and Bioaccumulation Regulations* (the "Regulations"), it will only be a danger to the environment if this intrinsic property results in exposures that cause adverse effects in the environment. Thus, persistence must be accompanied by accumulation in one or more compartment(s) of the environment (or organisms) to the point that these exposures exceed the dose or concentration that causes an adverse effect. This was the principal focus of the Board's review.

16. The rate of accumulation of Siloxane D5 in air, water, soils, and sediments, as well as in organisms, is determined by its rate of release to the environment and, once there, its rates of movement to other compartments of the environment (dissipation) and transformation. Because Siloxane D5 has been used in commercial and industrial applications for a relatively long time – more than 30 years – and, given its rates of dissipation and transformation in the environment, current concentrations of Siloxane D5 are at a quasi-steady-state.

17. Concentrations of a chemical are considered to be in a quasi-steady-state in environmental compartments when concentrations remain approximately constant in the long-term, although they could fluctuate in the short-term due to sporadic releases or seasonal changes in the environment. This means that concentrations in each compartment vary within a predictable range and that concentrations of Siloxane D5 in the environment are not changing significantly over time.

18. In addition to the physical processes of degradation, there are biologically-mediated processes of transformation, referred to as biotransformation. Biotransformation can occur due to the actions of bacteria and fungi, or in the bodies of higher organisms as part of normal metabolic functions or as adaptive responses. Siloxane D5 is biotransformed into silanols, which are more soluble than Siloxane D5 and present less risk to the environment. The rate at which Siloxane D5 is biotransformed by higher animals, determines, in part, the rate of loss from the animal involving all pathways including diffusion and active transport. The rate of biotransformation in organisms also determines the concentrations that can be accumulated in plants and animals.

19. The importance of these understandings is that, at current rates of use, concentrations of Siloxane D5 in the environment will not increase significantly. If, in the future, the use and subsequent release of Siloxane D5 to the environment were to increase,

the change in concentration in the various compartments of the environment would be directly proportional to the increase in release and thus be predictable based upon current information.

## *Exposure of Organisms in the Environment*

20. Exposure measures the concentration of a chemical available to enter into an organism where it might produce adverse effects. When predicting concentrations of chemicals to which organisms might be exposed, it is also important to consider bioavailability. Bioavailability is the fraction of the total concentration of a chemical that is available to be accumulated into organisms. Siloxane D5 has a particularly strong affinity for organic particles in sediments and wet soils, and is not readily available to be accumulated into organisms.

21. When predicting concentrations of Siloxane D5 that would occur in various compartments of the environment, it is also important to consider the limits of solubility in that "matrix" and the fraction that is biologically available to organisms. It is theoretically impossible for Siloxane D5 to exceed its solubility limits in water or the organic matter in sediments or soils. Consequently, the Board advises readers of this report to be cautious about drawing conclusions with respect to bioaccumulation, persistence, and toxicity that are based upon concentrations that exceed the theoretical solubility limit.

## *Bioaccumulation in Organisms*

22. Siloxane D5 cannot produce toxicity by interacting with molecules on the outside surface of an organism. To cause effects, compounds like Siloxane D5 must enter into organisms. Siloxane D5 can enter organisms through several pathways, including inhalation from the air or across external surfaces such as the skin and gills of fish or benthic invertebrates, the roots of plants, and the lining of the gastro-intestinal system. However, the primary route of exposure for all organisms would be through the diet and/or from water.

23. There are three concepts related to the accumulation of chemicals into organisms. The first is bioaccumulation, which is the process of the chemical entering into an organism. The second is bioconcentration, where concentrations of the chemical are accumulated to values that are greater than, but proportional to, those in the surrounding medium. Finally, there is the concept of biomagnification or trophic magnification in which predators accumulate greater concentrations of the chemical than those in their prey. When expressed appropriately, concentrations of Siloxane D5 in organisms can be greater than those in the surrounding medium, i.e., it can bioconcentrate to some degree. While Siloxane D5 can accumulate in organisms, it does not biomagnify through the food-chain.

## *Toxicity of Siloxane D5*

24. Toxicity is the potential of a chemical to produce adverse effects in organisms. The severity of the effect caused is determined by the duration and magnitude of exposure to the chemical and its potency. The potency of a chemical is described by the dose-response relationship, which is derived by exposing organisms to known quantities of a chemical for known periods of time and recording the magnitude of response.

25. Once an organism has been exposed, the damage produced is related to the rates of biotransformation, depuration (excretion), and repair of any damage caused. Thus, organisms can be exposed to some concentration of a chemical for a very long period without exerting any apparent effects. In addition, animals and plants have the ability to adapt to exposures to some chemicals so that the normal functioning of the organism is not adversely affected. Such adaptive responses are not considered adverse responses.

26. In assessing the potential adverse effects and, thus, the hazard posed by a chemical, it is useful to know the mechanism of toxic action of that chemical. That is to say, how the chemical causes toxicity. There are multiple known mechanisms of toxic action. Chemicals can have a "specific" mechanism of action due to the interaction of the molecule with a particular receptor. For instance, the physical shape of some molecules is such that it fits into structures on biomolecules such as proteins. Chemicals can also elicit effects by mimicking biological molecules or blocking active receptor sites.

27. In addition to these specific mechanisms of action, all molecules have what is termed a minimal or basal toxicity. This is referred to as "narcosis" and occurs when the molecule dissolves in membranes in the body and produces changes in their structural and/or chemical properties. This process is reversible and does not necessarily result in permanent damage. For neutral (uncharged) molecules such as Siloxane D5, there is no known specific mechanism of toxicity. Toxic effects are therefore caused by narcosis.

28. In the scientific literature, there are few reports of the toxicity of Siloxane D5. However, due to its non-specific mechanism of action, it is possible to predict with acceptable certainty, the toxicity to different species and the critical body burden, or concentration required to produce an adverse effect in an organism. This is because the physiologies and membranes of animals are similar and there is little variation in sensitivity among organisms. Consequently, it is very unlikely that there will be uniquely sensitive species. For this reason, a smaller set of data on toxicity, such as that which exists for plants, fish, and mammals, is sufficiently robust to make accurate conclusions about the potential for effects on organisms.

29. Siloxane D5 has not been found to cause toxicity in any organisms tested up to its limit of solubility in any environmental compartments, or matrices. This, coupled with the fact that it is theoretically impossible for Siloxane D5 to exceed its solubility in any given matrix, led the Board to conclude that it is virtually impossible for Siloxane D5 to

accumulate to sufficient concentrations to produce adverse effects to organisms in air, water, soils, or sediments.

## *Risk Assessment*

30. Risk assessments can be conducted in tiers of increasing complexity, depending on the amount of information available. Assessments of new chemicals are restricted to the lower tiers and are based on:

- the physical and chemical properties of the compounds;
- the results of simple simulations that predict environmental fates; and,
- a few tests or models to determine toxicity.

31. However, for existing chemicals, there is more information available that can be considered in assessing the potential for harm. If chemicals have been released into the environment, as is the case with Siloxane D5, "real-world" measurements can be used to assess properties and to validate models and predictions of both exposure and effects.

32. There are two basic conditions that need to prevail for harm to occur. First, there needs to be exposure. Even for the most hazardous chemicals, no harm will occur if there is no exposure. Second, once exposure has occurred, there needs to be a detrimental or harmful effect. This is referred to as hazard. The magnitude of effect caused by exposure to a defined amount of a chemical is referred to as its potency.

33. In the 2008 Screening Assessment conducted by Health Canada and Environment Canada, government officials assessed the potential for Siloxane D5 to produce adverse effects in the environment. At that time, there was less information on environmental fate and toxicity than is currently available. Consequently, the Screening Assessment was limited to the lowest tiers of assessment, which make use of the least information and thus have the greatest uncertainty. The Screening Assessment was limited to a few basic comparisons of parameters, such as persistence and potential to bioaccumulate. There was insufficient information upon which a more detailed assessment could be made. In fact, in most cases, surrogate information based on the basic physical and chemical properties of Siloxane D5 or analogous chemicals had to be used.

34. As has already been discussed, since Siloxane D5 has unique properties for a molecule of its size, the basis for such extrapolations was uncertain. Since 2008, additional information on the basic physical and chemical properties of Siloxane D5 has become available so that more refined simulations of environmental fate can now be made.

35. Furthermore, additional information on the hazard of Siloxane D5 is now available. Most importantly, better methods for quantifying Siloxane D5 in various matrices have become available and these methods of analysis have allowed additional information to be

collected on concentrations of Siloxane D5 in environmental matrices, including air, water, soils, and sediments, as well as in organisms. Thus, a more refined assessment of the danger posed by use of Siloxane D5 can be made at this time. The Board has relied on this most recent information in making its assessment of the risks posed by Siloxane D5 to the environment.

36. Risk relates to the probability of adverse outcomes and is always related to probabilities of exposure and effects. Lower-tiered risk assessments are based on limited information and for that reason are often based on simple ratios of exposure to some threshold for effect. Because of the inherent uncertainty in these approaches, uncertainty factors are generally applied as safety factors. These factors are meant to be conservative and protective rather than being predictive. As additional information becomes available and assessments move to higher tiers, the uncertainty becomes less and the need for uncertainty factors is reduced.

37. Lower-tiered assessments are designed to screen out, rather than to screen in, chemicals of concern. They are meant to be conservative so as to minimise the likelihood of improperly classifying chemicals that might produce adverse effects. Exceeding one of the individual indicators of persistence or bioaccumulation does not imply that there will harmful exposures. Rather, it indicates that further, more refined assessments are warranted.

38. In the Screening Assessment of Siloxane D5, government officials followed a conservative, or precautionary, approach since there was insufficient information on toxicity and no information on concentrations in the environment. In contrast, the Board had access to monitoring information to substantiate the results of more refined estimates of both exposure and effects and was able to make use of this scientific information to conduct a more robust evaluation at higher tiers of assessment.

39. The Board considered the unique physical and chemical properties and the mechanism and potency of toxicity of Siloxane D5, and concluded that it is virtually impossible for Siloxane D5 to occur in any environmental matrix at concentrations sufficient to cause damage. Consequently, the Board has determined that current uses of Siloxane D5 do not pose a risk of danger to the environment.

40. The Board has further concluded that there is no potential for future uses of Siloxane D5 to result in danger to the environment since current concentrations of Siloxane D5 in the environment are at a quasi-steady-state. Concentrations of Siloxane D5 are unlikely to change in the future, except in direct proportion to the growth of the population.

# 3 Statement of Reasons of the Siloxane D5 Board of Review

## *3.1 Introduction and Background*

41. On August 21, 2010, the Minister of the Environment ("Minister") published a Ministerial Notice ("Notice")[3] in the *Canada Gazette* in which he established a board of review pursuant to subsection 333(1) of the *Canadian Environmental Protection Act, 1999*[4] ("CEPA 1999") to inquire into the nature and extent of the danger posed by decamethylcyclopentasiloxane ("Siloxane D5").

42. The Minister's decision followed a final screening assessment ("Screening Assessment") of Siloxane D5 (Environment Canada and Health Canada 2008 ("EC" and "HC" 2008))[5] conducted by Health Canada and Environment Canada (sometimes referred to as the "Department" or "Departments") pursuant to section 74 of CEPA 1999. The Screening Assessment was published on January 31, 2009 and concluded that, based on the available information, Siloxane D5 was entering the environment in a quantity or concentration or under conditions that may have an immediate or long-term harmful effect on the environment or its biological diversity[6] and, as a consequence, met one or more of the criteria set out in section 74 of CEPA 1999.

43. As a result of that determination, the Minister of Health and the Minister of the Environment recommended that Siloxane D5 be added to the Toxic Substances List in Schedule 1 of CEPA 1999. This decision was based on the potential for harm in the environment; concerns for humans were not identified.

44. One of the affected industry stakeholders, the Silicones Environmental, Health and Safety Council of North America ("SEHSC"), filed a Notice of Objection on July 10, 2009 pursuant to subsection 332(2) of CEPA 1999. The SEHSC requested that a board of review be established to inquire into the nature and extent of the danger posed by octamethylcyclotetrasiloxane ("Siloxane D4") and Siloxane D5.

45. The SEHSC claimed that the Screening Assessments for these substances were not conducted in a manner that was consistent with the best available science and that errors were made in the approach used by government officials when assessing them. Furthermore, the SEHSC stated that new scientific information was available to demonstrate that Siloxanes D4 and D5 did not meet the criteria for toxicity and that new risk assessments should be undertaken.

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3 Canada Gazette, vol. 144, no. 34, August 21, 2010. See section 9.1 for a copy of the Notice.

4 S.C. 1999, c. 33.

5 Bracketed references identify the author and, where relevant, the page number.

6 Hereinafter, the term "environment" refers to the phrase "environment or its biological diversity".

46. Taking into account that new scientific information with respect to Siloxane D5 had been made available since the Screening Assessment was published in 2008, the Minister of the Environment decided to establish a board of review (the "Board") pursuant to subsection 333(1) of CEPA 1999. However, the request with respect to Siloxane D4 was denied.

47. The Minister appointed Professor John Giesy, Ph.D., FRSC as Chair, and Professor Keith Solomon, Ph.D., Fellow of the Academy of Toxicological Sciences ("ATS"), and Professor Sam Kacew, Ph.D., Fellow ATS, as members of the Board. The Minister directed the Board to prepare and submit a report, together with recommendations, and the evidence that was presented, on or before March 31, 2011 (see Appendix A).

## *3.2 Procedural Steps in the Board of Review Process*

48. After the Notice was published, the Board sent notice of this proceeding to a wide range of potentially interested stakeholders and informed them that they could request intervenor status, as permitted by section 10 of the *Rules of Procedure for Boards of Review* ("Rules")[7]. The notice from the Board was sent to all stakeholders who had indicated an interest and/or participated in the Screening Assessment conducted by the Departments. The notice was also sent to several daily newspapers for publication as a public service announcement and it was posted on the Board's website.

49. The Board received two requests for intervenor status, one from the Canadian Cosmetic, Toiletry and Fragrance Association ("CCTFA"), and the other from a coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba, and the Crooked Creek Conservancy Society of Athabasca (the "Coalition"). In considering those requests and the contribution they could make to these proceedings, the Board granted intervenor status to both requestors.

50. The Coalition requested and received permission to provide written submissions. The Coalition indicated that it would not participate in the hearing unless funding for that purpose was provided. In responding to the funding request, the Board noted that, pursuant to article 4 of the Terms of Reference contained in the Notice, no funding would be provided to any person or party. Consequently, the Coalition participated by providing written submissions in this proceeding.

51. The CCTFA requested and received permission to participate fully by providing written submissions and participating in the hearing. Consequently, the CCTFA participated in all steps leading up to the hearing. However, before the hearing began in April 2011, the CCTFA informed the Board that it would be represented by counsel for the SEHSC during the hearing.

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[7] SOR/2003-28. The Rules of Procedure for Boards of Review were amended following the initiation of this review: see SOR/2011, January 11, 2011.

52. As a preliminary matter, and because it was aware that new scientific information relating to Siloxane D5 was, or would be available, the Board requested that parties provide a timeframe for the production of any new scientific information that would be pertinent to the assessment. The parties, with the exception of the Coalition, indicated that scientific information that was not available at the time the Screening Assessment was conducted would be available by the end of 2010.

53. Consequently, to ensure that the Board considered the latest scientific information relating to Siloxane D5, the Board determined that it would not be possible to complete its investigation and deliberations within the timeframe provided in the Notice. As a result, the Board communicated with the Minister on November 12, 2010 advising him that the Board would be in a position to issue its report by September 30, 2011 (a copy of this letter can be found in Appendix B below). The Minister subsequently requested that the Board issue its report in both English and French, and extended the Board's delivery date to October 31, 2011 (see Appendix C below).

## *3.3 Determination of Scope of the Board's Mandate*

54. As the Board undertook its review, an issue arose with respect to the scope of its mandate. In particular, it was suggested that the Board consider the nature and extent of the danger posed by Siloxane D5 to human health in addition to considerations related to the environment. After considering the available information, the Board was of the opinion that this issue warranted further consideration and asked the parties for their views.

55. After considering the submissions received from the parties, on November 16, 2010, the Board issued a ruling in which it stated that its mandate was to focus on the nature and extent of the danger posed by Siloxane D5 to the environment (a complete copy of this ruling can be found in Appendix D). The Board stated in part:

> 12. Taking into account the background leading up to the establishment of the Board, and the views of parties, the Board has concluded that the scope of its review should focus on the nature and extent of the danger posed by siloxane D5 to the environment or its biological diversity.
>
> 13. The Board was established following the Minister's consideration of the Notice of Objection filed by the Silicones Council. The Notice of Objection indicated that new data and information related to the effects of siloxane D5 on the environment or its biological diversity were available to cast into doubt the conclusion reached by the government in the screening assessments.
>
> 14. While the Board recognises the potentially broad scope of its mandate, at this point, it does not believe that issues related to human health should be the subject of this review. In reaching this decision, the Board took note of the preamble referred to above in the Notice dated August 21, 2010 where it stated that, according to the screening assessment, siloxane D5 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. There is no mention in the Notice to issues related to human health.

15. The Board also notes that even though the CEPA 1999 provides that a board of review may be established by the Minister of the Environment alone or in conjunction with the Minister of Health, the Notice states that the Minister of the Environment alone has established this Board.

16. Further, the Board has been advised by parties that the new data and information available following the issuance of the government's screening assessment relates only to environmental or biological diversity issues.

17. In coming to this decision, the Board has carefully considered the points that the Coalition raised in its submission where it proposed a broader scope of review. No doubt, some of the points they raise will be discussed during this process, including the precautionary principle. But other points, including the cumulative impact of siloxanes D4, D5 and D6 on human health, and their impact on vulnerable populations, as well as the human health issues they urge the Board to consider are not supported by new information and, in the Board's view, are beyond the mandate of this Board in this review.

18. While the Board will focus on issues related to the environment or its biodiversity, it reserves the discretion to revisit the scope of its inquiry following its review of the post-screening assessment data and information. Should these data and information indicate that matters related to human health should also be considered, the Board will inform the parties and provide them with an opportunity to address these issues.

56. Consequently, the Board was alerted to the possibility that scientific information relating to human health might be presented during this proceeding. However, following a review of the scientific information available, it became clear to the Board that human health issues were not engaged and the Board's focus was therefore limited to considering the nature and extent of the danger posed by Siloxane D5 to the environment.

57. In the steps leading up to the hearing, the parties, with the exception of the Coalition, provided new scientific information and analysis. All of that information, in addition to the information taken into account by government officials during the Screening Assessment, was filed with the Board and made available to the parties.

58. In addition, written submissions were received from all parties. Parties were also given the opportunity to pose interrogatory questions to opposing parties. Answers to those interrogatories were provided in writing and were, similarly, made available to all parties.

59. As a result, before the hearing began, parties and the Board had a comprehensive and extensive record relating to Siloxane D5. In the Board's view, the range and quality of

data presented was sufficient for it to conduct a meaningful inquiry into the nature and extent of the danger to the environment posed by Siloxane D5.

60. Hearings were conducted from April 26 to May 6, 2011, and final arguments were heard on May 26, 2011. Testimony was received from witnesses called by Environment Canada and the SEHSC/CCTFA, all of whom were qualified as experts in various scientific disciplines. Additionally, the Board called one witness, Dr. Steve Dungey, from the United Kingdom Environment Agency.

## *3.4 Relevant Legislation and Regulations*

61. CEPA 1999 establishes the legislative framework within which chemical substances are assessed in order to determine whether they cause or may cause harmful effects to humans or the environment. In conducting an assessment of the potential harm posed by Siloxane D5, the Board's attention was drawn to the following provisions:

Paragraph 2(1)(a):

> In the administration of this *Act*, the government of Canada shall, having regard to the constitutional laws in Canada and subject to subsection 1.1,
>
> *(a)* exercise its powers in a manner that protects the environment and human health, applies the precautionary principle that, 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, and promotes and reinforces enforceable pollution prevention approaches.

Subsection 3(1):

> "biological diversity" means the variability among living organisms from all sources, including, without limiting the generality of the foregoing, terrestrial and marine and other aquatic ecosystems and the ecological complexes of which they form a part and includes the diversity within and between species and of ecosystems
>
> "environment" means the components of the Earth and includes
>
> *(a)* air, land and water,
>
> *(b)* all layers of the atmosphere;
>
> *(c)* all organic and inorganic matter and living organisms; and
>
> *(d)* the interacting natural systems that include components referred to in paragraphs *(a)* and *(c)*

Section 64:

For the purposes of this Part and Part 6, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

*(a)* have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

*(b)* constitute or may constitute a danger to the environment on which life depends; or

*(c)* constitute or may constitute a danger in Canada to human life or health

Section 68:

For the purpose of assessing whether a substance is toxic or is capable of becoming toxic, or for the purpose of assessing whether to control, or the manner in which to control, a substance, including a substance specified on the List of Toxic Substances in Schedule 1, either Minister may

*(a)* collect or generate data and conduct investigations respecting any matter in relation to a substance, including, without limiting the generality of the foregoing,

(i) whether short-term exposure to the substance causes significant effects,

(ii) the potential or organisms in the environment to be widely exposed to the substance,

(iii) whether organisms are exposed to the substance via multiple pathways,

(iv) the ability of the substance to cause a reduction in metabolic functions of an organism,

(v) the ability of the substance to cause delayed or latent effects over the lifetime of an organism,

(vi) the ability of the substance to cause reproductive or survival impairment of an organism,

(vii) whether exposure to the substance has the potential to contribute to population failure of a species,

(viii) the ability of the substance to cause transgenerational effects;

(ix) quantities, uses and disposal of the substance,

(x) the manner in which the substance is released into the environment,

(xi) the extent to which the substance can be dispersed and will persist in the environment,

(xii) the development and use of alternatives to the substance,

(xiii) methods of controlling the presence of the substance in the environment, and

(xiv) methods of reducing the quantity of the substance used or produced or the quantities or concentration of the substance released into the environment;

*(b)* correlate and evaluate any data collected or generated under paragraph *(a)* and publish results of any investigations carried out under that paragraph; and

*(c)* provide information and make recommendations respecting any matter in relation to a substance, including, without limiting the generality of the foregoing, measures to control the presence of the substance in the environment.

Section 90.(1):

Subject to subsection (3), the Governor in Council may, if satisfied that a substance is toxic, on the recommendation of the Ministers, make an order adding the substance to the List of Toxic Substances in Schedule 1.

Section 332.(1):

The Minister shall publish in the *Canada Gazette* a copy of every order or regulation proposed to be made by the Minister or the Governor in Council under this Act, except a list, or an amendment to a list, referred to in section 66, 87, 105, or 112 or an interim order made under section 94, 163, 173, 183, or 200.1.

(2) Within 60 days after the publication of a proposed order or regulation in the *Canada Gazette* under subsection (1) or a proposed instrument respecting preventive or control actions in relation to a substance that is required by section 91 to be published in the *Canada Gazette*, any person may file with the Minister comments with respect to the order, regulation or instrument or a notice of objection requesting that a board of review be established under section 333 and stating the reasons for the objection.

(3) No order, regulation or instrument need be published more than once under subsection (1), whether or not it is altered after publication.

Section 333.(1):

Where a person files a notice of objection under subsection 77(8) or 332(2) in respect of

*(a)* a decision or a proposed order, regulation or instrument made by the Governor in Council, or

*(b)* a decision or a proposed order or instrument made by either or both Ministers,

the Minister or the Ministers may establish a board of review to inquire into the nature and extent of the danger posed by the substance in respect of which the decision is made or the order, regulation or instrument is proposed.

(2) Where a person files a notice of objection under subsection 9(3) or 10(5) in respect of an agreement or a term or condition of the agreement, the Minister may establish a board of review to inquire into the matter.

(3) Where a person or government files with the Minister a notice of objection under subsection 332(2) with respect to regulations proposed to be made under section 167 or 177 within the time specified in that subsection, the Minister shall establish a board of review to inquire into the nature and extent of the danger posed by the release into the air or water of the substance in respect of which the regulations are proposed.

(4) Where a person files with the Minister a notice of objection under subsection 332(2) with respect to regulations proposed to be made under Part 9 or section 118 within the time specified in that subsection, the Minister shall establish a board of review to inquire into the matter raised by the notice.

(5) Where a person files with the Minister a notice of objection under section 134 within the time specified in that section, the Minister may establish a board of review to inquire into the matter raised by the notice.

(6) Where a person files with the Minister a notice of objection under section 78 in respect of the failure to make a determination about whether a substance is toxic, the Minister shall establish a board of review to inquire into whether the substance is toxic or capable of becoming toxic.

Section 334.(1):

A board of review shall consist of not fewer than three members.

(2) A person is not eligible to be appointed as a member of a board of review unless the person is knowledgeable about the Canadian environment, environmental and human health or traditional aboriginal ecological knowledge.

Section 335:

A board of review shall give any person or government a reasonable opportunity, consistent with the rules of procedural fairness and natural justice, of appearing before it, presenting evidence and making representations.

62. In respect of the relevant regulatory framework, reference was made to the *Persistence and Bioaccumulation Regulations* ("Regulations")[8] and, in particular, sections 3 through 5 which read as follows:

**3.** A substance is persistent when it has at least one of the following characteristics:

*(a)* in air,

(i) its half-life is equal to or greater than 2 days, or

(ii) it is subject to atmospheric transport from its source to a remote area;

*(b)* in water, its half-life is equal to or greater than 182 days;

*(c)* in sediments, its half-life is equal to or greater than 365 days;

or

*(d)* in soil, its half-life is equal to or greater than 182 days.

**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.

**5.** The determination of persistence and bioaccumulation with respect to a substance under sections 3 and 4 must be made in accordance with generally recognised 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

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8 SOR/2000-107.

community and taking into account the intrinsic properties of the substance, the ecosystem under consideration and the conditions in the environment.

## *3.5 Framing the Board's Mandate*

63. Before turning to its analysis of the science, the Board first considered what should be the body of scientific information to inform this review and on what issues this review should be focussed.

### 3.5.1 Positions of the Parties

64. During the hearings, counsel for both Environment Canada and the SEHSC/CCTFA agreed that the Board was to conduct a *de novo* assessment of the available science in determining the nature and extent of the danger posed by Siloxane D5 to the environment. However, the positions of both parties diverged on the path that the Board should follow in conducting its review.

65. Environment Canada stated that it was not necessary for the Board to review the Screening Assessment conducted by government officials in 2008, nor would it be appropriate for the Board to pronounce on the conclusions arrived at in that assessment. The Board's review, in other words, was not an appeal *per se* of the Screening Assessment.

66. Furthermore, Environment Canada took the position that the Board was not bound by the provisions in either CEPA 1999 or the Regulations. Accordingly, the Board should not make a determination about whether Siloxane D5 is "CEPA-toxic" in accordance with section 64 of CEPA 1999. Likewise, the Board should not make a determination or recommendation that Siloxane D5 should, or should not, be added to Schedule 1 of CEPA 1999 as a toxic substance. Those matters are the prerogative of the Minister of the Environment.

67. Additionally, according to Environment Canada, the Board must not take into account factors such as socio-economic considerations or assess the value this substance might have for commercial purposes. The Board's mandate was limited to conducting a scientific review of the nature and extent of the danger to the environment posed by Siloxane D5.

68. Finally, Environment Canada claimed that it was not necessary for the Board to determine whether harm was definitely being caused to the environment by Siloxane D5. Further, because CEPA 1999 is founded on the principles of protection and precaution, as outlined in section 2, the Board's analysis should not be based on the "average or standard use" of Siloxane D5 for commercial purposes or its uses. As counsel for Environment Canada stated, the Board's review should not be based on the "average or standard use of the chemical in products in Canada. As a result, for example, if the pure product poses a danger, that must form part of the Board's assessment" (Transcript of the Public Hearings, Vol. 9, p. 1129).

69. Counsel for Environment Canada went on to state, however, that the question of danger is "... not strictly restricted to what is currently happening. It is whether there is a danger and the danger, obviously from the ordinary meaning of that term, can mean a future potential danger. The question then becomes, what is the probability of that potential?" (Transcript of the Public Hearings, Vol. 9, p. 1117).

70. The SEHSC/CCTFA submitted that although the Board must conduct a *de novo* assessment of the science, it also needed to review the Screening Assessment conducted by Environment Canada and Health Canada and the manner in which the Screening Assessment was conducted. In view of the conclusion reached in the Screening Assessment, the SEHSC/CCTFA stated that the Board must have particular regard to paragraph 64(a) of CEPA 1999, which states:

> Section 64:
>
> For the purposes of this Part and Part 6, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter in a quantity or concentration or under conditions that
>
> (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity.

71. The SEHSC/CCTFA also urged the Board to give careful consideration to section 5 of the Regulations and determine whether the available science demonstrated that Siloxane D5 met the criteria for bioaccumulation and persistence, taking into account the "intrinsic properties" of the substance (Transcript of the Public Hearings, Vol. 9, p. 1200).

72. The SEHSC/CCTFA urged the Board to take into account "real-world" quantities or concentrations and conditions under which Siloxane D5 is used. That is to say, the assessment of the substance should be rooted in the data and information which details how and where the substance is used, the quantities used, the concentration of the substance, and the effects it currently has or might have on the environment. The Board was not, in its view, conducting a hypothetical assessment based on worst-case scenarios, where the available data or circumstances did not warrant that manner of proceeding.

73. The Board agreed with both parties that its mandate was to conduct an independent, *de novo* scientific assessment of the relevant and available science relating to Siloxane D5.

74. The Board also agreed with counsel from Environment Canada that its mandate was not to conduct this review in the manner of an appeal of the Screening Assessment. However, it was also the opinion of the Board that it could not, and should not ignore the analysis and conclusions expressed in the Screening Assessment as they provide the context and foundation upon which this review was based.

75. With respect to the review process for Siloxane D5, the Board agreed with Environment Canada that its mandate was not to pronounce on whether Siloxane D5 is

"CEPA-toxic" according to section 64, nor was it the Board's mandate to determine whether the substance should, in accordance with section 90 of CEPA 1999, be added to Schedule 1 as a toxic substance. Those are matters that are entirely within the purview of the Minister of the Environment.

### 3.5.1.1 The Meaning of "Danger" to the Environment

76. In conducting its *de novo* scientific assessment of the nature and extent of the danger posed by Siloxane D5 to the environment, the Board considered how the term "danger" should be interpreted. The term "danger" is not defined in CEPA 1999 or in the Regulations. It therefore fell to the Board to interpret the meaning of that term in the context of the Notice issued by the Minister of the Environment.

77. The Board noted that the term "danger" is found in paragraphs 64(b) and (c) of CEPA 1999. Those paragraphs contrast slightly with paragraph 64(a) which refers to "harmful effect". Section 64 reads:

> For the purposes of this Part and Part 6, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
>
> *(a)* have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
>
> *(b)* constitute or may constitute a danger to the environment on which life depends; or
>
> *(c)* constitute or may constitute a danger in Canada to human life or health
>
> [emphasis added]

78. Referring back to the Screening Assessment issued by Environment Canada and Health Canada, it concluded, in part, that:

> Based on the information presented in this screening assessment on the potential of D5 to cause ecological harm, it is concluded that decamethylcyclopentasiloxane is entering or may be 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 (EC & HC 2008).
>
> [emphasis added]

79. Although that conclusion parallels the toxicity threshold in paragraph 64(a) of CEPA 1999 (i.e., "harmful effect"), in the Notice issued by the Minister, he chose to craft the mandate in terms of the "danger", the term found in paragraphs 64(b) and (c). In

attempting to give meaning to the term "danger", the Board considered whether to interpret it to mean something different from the term "harmful effect".

80. In analysing this issue, the Board was able to draw on guidance offered by the Supreme Court of Canada in *R. v. Hydro-Québec*, [1977] 3 S.C.R. 213. Although that case revolved around the constitutionality of some provisions of the *Canadian Environmental Protection Act*, R.S.C. 1985 ("1985 Act"), the Court had an opportunity to comment on section 11, dealing with the thresholds for determining whether a substance was toxic. Section 11 of the 1985 Act stated:

> 11. For the purposes of this Part, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions
>
> (a) having or that may have an immediate or long-term harmful effect on the environment;
>
> (b) constituting or that may constitute a danger to the environment on which human life depends: or
>
> (c) constituting or that may constitute a danger in Canada to human life or health.
>
> [emphasis added]

81. It is readily apparent that section 11 is largely mirrored in section 64 of CEPA 1999. Just as in CEPA 1999, the 1985 Act establishes two toxicity thresholds: "harmful effect" and "danger".

82. At paragraph 31, the minority of the Court noted that there was no definition of the terms "danger" or "harmful effect" in section 11. Nevertheless, in looking at section 11, the Court reframed the essence of that section by stating that toxicity would be shown:

> If a substance...poses or may pose a risk to human life or health, or to the environment upon which human health depends, or to any aspect of the environment itself...
>
> [emphasis added]

83. After considering that section and its different components holistically, the minority stated that the threshold for toxicity was based on the "risk" posed by the substance to human health or the environment. In other words, it drew no meaningful distinction between the terms "danger" and "harmful effect".

84. At paragraph 141 of that decision, the majority of the Court noted that, for a substance to be found to be toxic according to section 11, it must be demonstrated that the substance is:

> ...entering or may enter the environment in a quantity or concentration or under conditions that result in the detrimental effects on the environment, human life and human health described in [11] paragraphs (a) to (c).
>
> [emphasis added]

85. The majority of the Court similarly chose not to draw any significant distinction between the toxicity thresholds of "danger" and "harmful effects" in paragraphs (a)-(c) of section 11, choosing instead to reformulate the toxicity threshold as "detrimental effects".

86. Furthermore, the majority also opined that an assessment of the toxicity of a substance should take into account the manner and quantities in which the substance is found in the environment and the effects it has or might have on the environment, human life, and human health.

87. The Board recognised that it was not mandated to determine if Siloxane D5 met the toxicity thresholds provided for in paragraphs 64(a)-(c) of CEPA 1999. But, the Supreme Court of Canada's interpretation of the meaning of section 11 of the 1985 Act did assist the Board in determining how it should approach the interpretation of the term "danger", as provided in the Notice.

88. Taking the guidance from that case into account, the Board interpreted its mandate to mean that it was to inquire into the nature and extent of the risk posed, if any, by Siloxane D5 to the environment and to determine whether detrimental effects were caused, or might be caused. In other words, the Board was mandated to conduct what was, in essence, a *de novo* risk assessment of the substance taking into account all of the available, relevant, scientific information about Siloxane D5.

89. When conducting the *de novo* risk assessment, the Board concluded that best scientific practice required that it take into account information about the "intrinsic" physical and chemical properties of the substance along with its uses, releases, dissipation, transformation, and degradation, pathways of exposures, toxicity, and effects. Additionally, the Board determined that the review should be rooted in real-world terms. That is to say, the Board decided to conduct its review taking into account the quantities or concentrations and conditions under which Siloxane D5 is used or, based on the best information available, the likely future volumes or uses. This approach permitted the Board to consider not only current patterns and methods of use, but also assess the potential changes in use and concentrations, in order to analyse the nature and extent of the risk (or danger) posed by Siloxane D5 to the environment.

#### 3.5.1.2 Persistence and Bioaccumulation Regulations

90. Before considering the scientific information related to Siloxane D5, the Board determined that another aspect of the regulatory regime needed to be addressed. During the course of these proceedings, there was considerable discussion about, and reference to,

the Regulations, in particular sections 3 to 5. For ease of reference, those sections are reproduced here:

> **3.** A substance is persistent when it has at least one of the following characteristics:
>
> (*a*) in air,
>
> (i) its half-life is equal to or greater than 2 days, or
>
> (ii) it is subject to atmospheric transport from its source to a remote area;
>
> (*b*) in water, its half-life is equal to or greater than 182 days;
>
> (*c*) in sediments, its half-life is equal to or greater than 365 days; or
>
> (*d*) in soil, its half-life is equal to or greater than 182 days.
>
> **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.
>
> **5.** The determination of persistence and bioaccumulation with respect to a substance under sections 3 and 4 must be made in accordance with generally recognised 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.

91. Environment Canada and the Coalition took the position that Siloxane D5 met, and continues to meet, the thresholds given in sections 3 and 4 of the Regulations. Keeping in mind the overarching objective in CEPA 1999 to protect the environment, Environment Canada and the Coalition argued that, those thresholds having been met, Siloxane D5 poses or may pose a danger to the environment. Later in this report, the Board comments on the persistence and accumulation characteristics of Siloxane D5 in relation to the regulatory thresholds referred to above.

92. The SEHSC/CCTFA, on the other hand, claimed that the regulatory thresholds in sections 3 and 4 of the Regulations were not met in the case of Siloxane D5. They stated

that, based on a proper analysis of the scientific information now available, those thresholds have not been met or exceeded.

93. However, the SEHSC/CCTFA went on to further state that: i) any analysis of persistence and bioaccumulation of Siloxane D5 must take into account its intrinsic properties as provided for in section 5 of the Regulations and, ii) irrespective of whether thresholds in sections 3 and 4 have been met, it is necessary to further consider the intrinsic properties of Siloxane D5 to properly assess whether it poses a danger. When the intrinsic properties of Siloxane D5 are taken into account, the SEHSC/CCTFA claims that it does not pose a danger to the environment.

94. Section 5 of the Regulations is somewhat unclear about whether the intrinsic properties of a chemical should always be considered when assessing persistence and bioaccumulation. That section might be interpreted to mean that the intrinsic properties of a substance should only be taken into account in cases where it is not possible to rely on the generally recognised methods of the OECD or other similar organisation when assessing persistence and bioaccumulation. The Board does not, however, agree with such an interpretation.

95. The Board determined that section 5 of the Regulations could and should be read to require that, when assessing persistence and bioaccumulation, evaluators should take into account the other factors referred to in section 5: the intrinsic properties of a chemical, the ecosystem under consideration, and conditions in the environment. Furthermore, the Board interpreted the term "intrinsic properties" to mean intensive properties such as vapour pressure and solubility as well as extensive properties such as toxicity.

96. An analysis of persistence and bioaccumulation performed in accordance with generally recognised methods within the scientific community can only be adequately conducted if the particular characteristics of a chemical under review, and its impact on the ecosystem or environment, are adequately considered. It would not be scientifically credible to ignore consideration of a substance's intrinsic properties where that information is available.

97. Moreover, it is important to consider how the chemical is used and how it enters into the environment. Failure to take all available scientific information about a chemical into account could lead to a flawed conclusion about its danger to the environment.

98. The Board's interpretation of section 5 appears to be consistent with the views of Environment Canada. In the State of the Science Report (EC 2011a, p. 18), when discussing the Regulations, Environment Canada stated:

> The Regulations go on to indicate that "[t]he determination of persistence and bioaccumulation...must be made...taking into account the intrinsic properties of the substance, the ecosystem under consideration and the conditions in the environment." Thus, determining whether these criteria are met involves

professional judgement which considers the intrinsic properties of the substance and ecosystem under consideration.

[emphasis added]

99. As is discussed in detail later in this report, it is the Board's opinion that Siloxane D5 is one of those chemicals whose intrinsic properties play a significant role in determining whether it is persistent and bioaccumulative and whether it poses a danger to the environment.

### 3.5.1.3 The Role of Precaution in This Review

100. Finally, in conducting its review, the Board was reminded by all parties of the importance and role of the precautionary principle provided for in paragraph 2(1)(a) of CEPA 1999. The Board does understand the importance of, and need for, precaution when assessing the impact a chemical could have on human health or the environment.

101. It is also important though, to understand the proper application of the precautionary principle and the precautionary approach to risk assessment. When conducting a risk assessment, evaluators appropriately rely on the precautionary approach to the extent warranted. Consequently, where data gaps exist, or in cases where the data are equivocal or unreliable, evaluators rightfully rely on a conservative or precautionary approach, using reasonable worst-case assumptions and uncertainty factors, when analysing information or modelling. This approach ensures an appropriate degree of caution and protection.

102. The precautionary principle comes into play when governments are determining what measures, if any, they should impose when a chemical of concern has been identified following a risk assessment. The degree to which the precautionary principle affects the government's approach to the management of a chemical will in part depend on the quality and scientific robustness of the available information, and the nature and extent of the risk revealed by that information.

103. In this case, there is sufficient credible and trustworthy scientific information about Siloxane D5 for the Board to conduct a scientifically-robust and meaningful risk assessment. In these circumstances, because it had credible and trustworthy scientific information before it, the Board did not need to rely solely on the precautionary approach in the same way as required by those conducting the Screening Assessment.

# 4 The Nature, Use, Distribution, Concentrations, and Toxicity of Siloxane D5

## *4.1 Use and Release of Siloxane D5 in the Canadian Environment*

104. Siloxane D5 is an odourless, colourless liquid that is used in consumer and industrial applications. It is mainly used in blending and formulating personal-care products and cosmetics, and is an intermediate in the production of polydimethylsiloxane silicone polymers. A few commercial dry cleaners in Canada also use Siloxane D5 as a dry-cleaning fluid. Its use in silicone polymers and in dry-cleaning is not considered to be a significant source of release to the environment (EC & HC 2008, p. 9).

105. In Canada and worldwide, the most important uses of Siloxane D5 are in the preparation of personal-care products, including antiperspirants, and hair- and skin-care products (EC & HC 2008, p. 9). Current use of Siloxane D5 in personal-care products in Canada was estimated to be 3.3 million kg/yr in 2010 (SEHSC/CCTFA 2011, p. 21). In 2010, antiperspirants and/or deodorants accounted for 72.2% of Siloxane D5 use in personal-care products. This was followed by hair-care products at 19.4%, skin-care products at 2.7%, colour cosmetics at 2.6%, sunscreens at 1.1%, and several other uses totalling 1.9% (CCTFA 2011a).

106. Due to its large vapour pressure and volatility, the major route of release of Siloxane D5 from personal-care products is to the atmosphere (CCTFA 2011b). For example, in antiperspirants, Siloxane D5 is mostly lost to the air with less than 1% available for wash-off eight hours after application and less than 0.1% available for wash-off after 24 hours.

107. Similar losses to air were observed in other uses where the product was applied directly to the skin or to hair (after washing). However, in the case of hair-care products such as hair conditioners that are rinsed off after in-shower use, approximately 40% of the Siloxane D5 enters drains and will subsequently be transported to wastewater treatment plants (WWTPs) (CCTFA 2011b).

## *4.2 Distribution and Persistence of Siloxane D5 in the Environment*

108. When released into the environment, chemicals move among compartments including air, soils, water, and sediments. The ultimate distribution of a chemical among these compartments and the rate at which it moves among these compartments is a function of its physical and chemical properties and the environment into which it is released.

109. Once released into the environment, chemicals can undergo transformations as they move from one physical location to another and/or among environmental compartments. These transformations can be due to biological and physical-chemical processes, such as hydrolysis and photolysis, and produce substances that are different from the original,

parent chemical. The rate and degree of transformation determines the volume of the chemical which is available to potentially accumulate in the environment.

110. In characterising the distribution of Siloxane D5 in various compartments and its persistence in the environment, the Board kept in mind that it is a unique chemical compound, whose behaviour is different from that of other compounds of similar molecular weight and size (Mackay 2011a).

111. Siloxane D5 consists of carbon, silicon, oxygen, and hydrogen in a symmetrical ring structure. This compound has intrinsic chemical and physical properties that result in unique patterns of distribution in the environment (EC 2011a, Tables 4 and 5, p. 21-22, SEHSC. 2011a). These properties were carefully considered in evaluating the exposure of organisms in the environment by Siloxane D5 and the danger, if any, it poses.

### 4.2.1 Use of Models and Tools for Assessing Environmental Fate and Distribution of Siloxane D5

112. When a chemical is being evaluated and where there are limited empirical measurements of concentrations in the environment, models can be used to estimate releases to the environment, as well as its fate and distribution after release. Although Siloxane D5 has been in use for over 30 years, there was limited measured information on concentrations in, or effects on, the environment. Consequently, models featured prominently in the Screening Assessment conducted by government officials.

113. The Board carefully reviewed the models and tools applied in the Screening Assessment (EC & HC 2008) and subsequent modifications made to them and to their input parameters. The Board concluded that these models and tools had several limitations and inaccuracies.

114. The Board is of the view that those shortcomings resulted in inaccurate predictions of environmental fates. Consequently, the interpretations based on these models and tools were of limited utility to this review. Now that empirical monitoring data are available, the Board gave greater weight to these measured values than the initial estimates made by the MegaFlush model (EC 2009) and MassFlow tool (EC 2008a).

115. When conducting the Screening Assessment (EC & HC 2008), the MassFlow tool and the MegaFlush model were used to estimate releases to the environment via wastewater. As an input parameter to the MassFlow tool, government officials had estimated that 12.2% of the Siloxane D5 used by industry and in personal care products was released to sewers. (EC & HC 2008 1632, Table 3, p. 12).

116. In this proceeding, the SEHSC proposed that 9-9.5% was a more reasonable estimate of the rate of release to the environment via wastewater (Cowan-Ellsberry and Mackay 2011b, p. 7) and that this was a rate that was also consistent with that specified by Environment Canada in the MassFlow tool documentation (EC 2008b).

117. This estimated rate was confirmed by apportioning the use of Siloxane D5 in Canada (26.9 mg/capita-day) and an average per capita wastewater treatment plant ("WWTP") flow of 495 L/capita-day, giving a value of 54 $\mu$g/L (Cowan-Ellsberry 2011, p. 6). This amount is in agreement with the 95$^{th}$ centile concentration measured in influents from non-industrial sources to WWTPs (approximately 47 $\mu$g/L based on tabular data from Wang et al. 2010).

118. Consequently, after considering all the data submitted during this review process, the Board agreed that 9.5% was a more reasonable, yet conservative, estimate of releases of Siloxane D5 to sewers than the value of 12.2% used in the Screening Assessment (EC & HC 2008 1632, Table 3, p. 12).

119. The Board also examined the removal rate parameters used in the MegaFlush model during the conduct of the Screening Assessment. In the Screening Assessment, removal rates for Siloxane D5 were assumed to be 0% for lagoons and 48% for primary treatment (SEHSC. 2011a).

120. Information presented during this review indicated that actual removal rates are greater. For example, data based on the ASTREAT model presented to the Board suggests that the removal rate for lagoons, primary treatment plants, and secondary treatment plants is of the order of 97% (Cowan-Ellsberry 2011, p. 6). This is similar to the actual mean removal rates of 98% recorded in the United Kingdom (Cowan-Ellsberry 2011, p. 7, CCTFA 2011b, p. 432).

121. Concentrations of Siloxane D5 were measured at WWTPs in Canada in summer and winter (Wang et al. 2010, Wang et al. 2011a). These measurements can be used to verify the assumptions used in the MegaFlush model. Although the samples were not matched to the retention time of the WWTP, the concentrations in samples of influent and effluent taken in summer suggested a mean removal rate of Siloxane D5 of 99.2% for lagoons and 96% for WWTPs when using primary treatment. Mean rates of removal of Siloxane D5 by WWTPs using secondary treatment were found to be 97.8% (based on data from Wang et al. 2010).

122. From results of similar samples taken in winter, removal rates of Siloxane D5 from WWTPs using secondary treatment were not significantly influenced by temperature (all were $\geq$95% between 10 and 25°C) (Wang et al. 2011a, Figure 3). The Board noted, however, that removal rates from lagoons were highly variable at temperatures $\leq$5°C, ranging from 25% to 99% at the 11 sites tested (Wang et al. 2011a, Figure 4). However, all rates of removal were greater than the 0% worst-case assumption used for lagoons in the Screening Assessment. Similarly, rates of removal from WWTPs using primary treatment were approximately double the assumption of 48% used in the Screening Assessment.

123. As a result, the Board has concluded that less Siloxane D5 is released to receiving waters from WWTPs than was previously estimated from various models and tools, and

that the values measured in samples from selected Canadian locations provide reasonable worst-case estimates of exposures in surface waters.

124. The Board agrees with the SEHSC/CCTFA that overall, based on its unique intrinsic properties, its uses, and the types of treatment for wastewater in Canada, a realistic scenario for Siloxane D5 releases into the environment would be 94.5% to air; 0.8% to water; and, 4.7% to soils via biosolids (Powell 2011, p. 2, Cowan-Ellsberry and Mackay 2011b, p. 4).

125. Since the Screening Assessment was completed, the fugacity-based Equilibrium Criterion simulation model ("EQC model") (CEMC 2003) has been updated. The Board concluded that the revised estimates of environmental fates and the conclusions drawn from the updated model are more accurate than the estimates used in the Screening Assessment. In particular, the revised structure and input parameters of the model provided to the Board (Mackay 2011b, Kim 2011) more accurately reflect the relative distribution of Siloxane D5 between environmental compartments.

126. Furthermore, recent modifications to the EQC model (Mackay 2011b) better estimate the distribution and residence time of Siloxane D5 (time required to degrade to half its initial concentration). These modifications also permitted the model to take into account some of the intrinsic properties of Siloxane D5 and allowed for direct input of the organic carbon-water partition coefficient (" $K_{OC}$ ").

127. In the previous version of the EQC model used by Environment Canada, the $K_{OC}$ was calculated from the octanol water partition coefficient (" $K_{OW}$ ") (Transcript of the Public Hearings, Vol. 4, p. 700), which, in the Board's opinion, was inappropriate for Siloxane D5 due to its intrinsic properties.

128. The distribution and the residence times in the various compartments of the environment are summarised below (Table 1).

**Table 1. Compartmentalisation and persistence of Siloxane D5 released into various environmental compartments**

| Emitted to: | Percentage of amount emitted in: | | | | Residence time (half-life) in days |
|---|---|---|---|---|---|
| | Air | Water | Soils | Sediments | |
| Air | 99.9 | <0.1 | <0.1 | <0.1 | 10 |
| Water | 1 | 5 | 0 | 96 | 680 |
| Soils | 71 | 0 | 29 | 0 | 11 |
| Realistic scenario to air, soils, and water | 64 | 2 | 1 | 33 | 15 |

Data from (Kim 2011, Mackay 2011b)

129. Over time, concentrations of chemicals equilibrate between compartments of the environment including air, water, soils, and sediments. The rate of accumulation of a compound such as Siloxane D5 is determined by the relative rates of release and degradation in the environment.

130. With a relatively constant rate of release, which is the case for Siloxane D5, the rate of accumulation is a function of the rates of degradation through various processes. The conditions when the absolute concentrations in the environment and relative concentrations in the various compartments do not change are referred to as steady-state.

131. As noted earlier, Siloxane D5 has been used for more than 30 years in various commercial and industrial applications. Evidence presented to the Board indicated that the concentrations in the environment as a whole and in its relative compartments were not changing, in any material sense, over time (Transcript of the Public Hearings, Vol. 4, pp. 581 & 651). Based on its rate of degradation in the environment, Siloxane D5 has attained a quasi-steady-state. Consequently, concentrations of Siloxane D5 in the environment vary within predictable ranges.

132. As a result, the Board is of the opinion that concentrations of Siloxane D5 in the environment will not increase significantly. Even if uses of Siloxane D5 were to double in the future (a scenario which is not expected to occur), this would not have a measurable impact on the risk posed to the environment (Transcript of the Public Hearings, Vol. 4, p. 656).

133. In addition to the physical processes of degradation, there are biologically-mediated processes of transformation, referred to as biotransformation. Biotransformation can occur due to the actions of bacteria and fungi, or metabolically in the organs of higher organisms. Siloxane D5 is biotransformed into silanols, which are more soluble and less active than Siloxane D5 (Environment Agency 2010) and, thus, present less risk and danger to the environment.

134. In the following sections, the fate and distribution of Siloxane D5 in various environmental compartments are reviewed. This review focuses on analyses making use of new methods of measuring concentrations. Historically, a major problem with measuring concentrations of all siloxanes in environmental compartments has been the availability of reliable analytical methods. It is only in the last few years that reliable methods have been developed which minimise sample and equipment contamination-related errors (McLachlan et al. 2010, Kierkegaard and McLachlan 2010, EC 2010c, Wang et al. 2011b). Emphasis was placed on data with respect to concentrations measured in locations in Canada.

### 4.2.2 Air

#### 4.2.2.1 Processes Affecting Fate and Distribution in Air

135. Siloxane D5 has a larger vapour pressure and is thus more volatile than other molecules of similar molecular weight and size. Consequently, Siloxane D5 tends to partition (i.e., to be released) into air. Once in air, Siloxane D5 can be transported relatively long distances, but deposition to soils or water is predicted to be limited (Table 1) (Transcript of the Public Hearings, Vol. 4, p. 742).

136. The major process of degradation of Siloxane D5 in the atmosphere is indirect photolysis. In this process, hydroxyl radicals (•OH), formed in the atmosphere by UV-B radiation, degrade Siloxane D5 to dimethylsilanediol and ultimately to carbon dioxide, water, and silicon dioxide (sand). Hydroxyl radicals are widely regarded as the cleaning agent of the atmosphere because they convert many atmospheric chemicals, including major air pollutants, into forms that are more water-soluble and therefore more easily removed from the atmosphere in precipitation.

137. The half-life of Siloxane D5 in air has been estimated to be between 0.6 and 9.8 days, depending on temperature, intensity of solar radiation, presence of precursors for •OH, and other parameters (Environment Agency 2010).

138. The Regulations classify persistent chemicals as those having half-lives in the atmosphere of more than two days. However, an important aspect of the environmental fate of Siloxane D5 is that it is released mostly into the atmosphere. The atmosphere is the compartment where Siloxane D5 predominantly occurs and where it is most rapidly degraded. Because releases are greatest in urban areas, it is noteworthy that half-lives tend to be shorter near urban areas because of the greater concentrations of •OH in these locations (Environment Agency 2010).

139. The Board also considered the question of the potential effects of Siloxane D5 on stratospheric ozone (Shao-Meng 2010). The half-life of Siloxane D5 in the troposphere is considerably less than the 2-3 months that would be required for significant amounts to reach the equatorial regions from where it would be transported to the stratosphere (Transcript of the Public Hearings, Vol. 2, p. 298, Transcript of the Public Hearings, Vol. 3, p. 446, Transcript of the Public Hearings, Vol. 4, p. 657). In addition, Siloxane D5 does not contain ozone depleting substances, such as halogens (Cowan-Ellsberry and Mackay 2011b, Cowan-Ellsberry and Mackay 2011a, Xu 2011c). Consequently, the Board has concluded that stratospheric ozone depletion is not an issue of concern.

#### 4.2.2.2 Concentrations in Air

140. Siloxane D5 has been measured in ambient air over Sweden at concentrations between 0.3 and 9 ng/m$^3$ (McLachlan et al. 2010), values that are consistent with those predicted from simulation modelling, but less than measured concentrations reported by earlier studies in Sweden (9-170 ng/m$^3$) (Kaj, 2005) and other Nordic countries (5).

141. Total concentrations of siloxanes (of which approximately 75% were Siloxane D5) in ambient air over Canada were 0.3 to 0.4 ng/m$^3$ (EC 2010a). These concentrations were less than those measured in Europe. The Board does not consider these concentrations in Canada to pose a danger to the environment.

142. Total concentrations of siloxanes (of which approximately 75% were Siloxane D5) in air near a WWTP in Canada were greater than in ambient air, with an average of 4,556 ng/m$^3$ and samples downwind from a landfill site were 4,669 ng/m$^3$ for total siloxanes (approximately 75% Siloxane D5) (EC 2010a). These concentrations are more than

80,000-times less than the No-Observed-Adverse-Effect-Level of 380,000,000 ng/m³ reported in rats (Brooke et al. 2009).

143. As for ambient air, where the margins of safety are even greater, the Board determined that these concentrations of Siloxane D5 near sources of emissions did not pose a danger to the environment.

### 4.2.3 Water

#### 4.2.3.1 Processes Affecting Fate and Distribution in Water

144. Siloxane D5 undergoes hydrolysis in water, a process of degradation that also involves the hydroxyl ion, $OH^-$. The final products of degradation of Siloxane D5 in water are carbon dioxide, silicic acid, and/or silicon dioxide.

145. The half-life of Siloxane D5 in freshwater is approximately 315 days at neutral pH and a temperature of 12 °C. Hydrolysis is more rapid at pH values greater or less than neutral and also at greater temperature. For example, the hydrolysis half-life of Siloxane D5 at pH 8 and 9°C in saltwater was 64 days (Brooke et al. 2009).

146. In addition to degradation, siloxanes can partition out of water into other environmental compartments (Table 1), which can result in decreases in concentration in the water phase.

#### 4.2.3.2 Concentrations in Water

147. Concentrations of Siloxane D5 in surface waters downstream from WWTPs processing industrial effluents in Europe were reported as less than the limit of detection ("LOD") (0.02 *μ*g/L). Concentrations in effluents from these same WWTPs ranged from 0.22 to 26.7 *μ*g/L (summarised in Brooke et al. 2009).

148. A recent study reported concentrations of Siloxane D5 in surface freshwater in locations close to WWTPs in Canada (Wang et al. 2010). In samples taken at 11 locations, from a few meters to 3.1 km away from the outfall, geometric mean concentrations ranged from less than the limit of quantification ("LOQ") of 0.004 to 1.48 *μ*g/L. The potential risks to aquatic organisms from these measured concentrations are discussed in section 5.2 below. The geometric mean concentrations of Siloxane D5 in samples of effluent from WWTPs, collected at the same time as samples from adjacent surface water, ranged from less than the LOQ (0.004 *μ*g/L) to 1.56 *μ*g/L.

149. In a follow-up study to characterise the effect of seasonality on concentrations of Siloxane D5 in influents and effluents from 13 WWTPs (Wang et al. 2011a), geometric mean concentrations measured in effluents collected in the summer ranged from less than the LOQ (0.004) to 1.56 *μ*g/L (discussed above from Wang et al. 2010), while those collected in winter ranged from arithmetic mean values of 0.53 to 466 *μ*g/L.

150. The greatest concentrations detected in winter were all associated with effluents from one WWTP, Site 8. This particular WWTP received influents from an industrial operation where Siloxane D5 is used. Measured concentrations of Siloxane D5 in influents at that site ranged from 261 to 4,400 $\mu$g/L over 16 days. This variation is consistent with unintentional releases from industrial operations. Concentrations of Siloxane D5 in the influent stream in the summer were less, with a geometric mean of 134 $\mu$g/L. Site 8 also had the greatest measured concentration of Siloxane D5 in surface waters at a location 1.26 km from the outfall of the WWTP (Wang et al. 2011a). Given the unique circumstances of Site 8, the Board is of the opinion that it represents an extreme worst-case scenario and is not representative of concentrations released into the environment in other locations in Canada.

### 4.2.4 Sediments

151. It is important to express concentrations of constituents in sediments consistently. Normalisation to dry-weight (dw) is commonly used. Because Siloxane D5 partitions into organic matter, normalisation to the amount of organic matter or the amount of organic carbon (OC) in the sediments is appropriate and allows assessment of the proportion of the total solubility that has been achieved. This approach is suitable for assessing partitioning from sediments to organisms (see section 4.3.2.3 below).

152. For the purposes of characterising risks, any method of normalisation is appropriate as long as the methods are consistent between toxicity testing and concentrations in the environment. In the following sections, normalisation to (dw) is used.

#### 4.2.4.1 Processes Affecting Fate and Distribution in Sediments

153. Siloxane D5 has a strong affinity for OC particles and tends to partition into sediments when released into water (Table 1). The Board agreed with the statements of the parties at the hearing that the greatest potential for danger would be in sediments within 3 km downstream from WWTP outfalls (Transcript of the Public Hearings, Vol. 3, p. 542).

154. In addition, Siloxane D5 is more persistent in sediments than in other environmental compartments. Measured half-lives of radiolabelled ($^{14}C$) Siloxane D5 in natural sediments from Lake Pepin, Minnesota were reported to range from 1,200 to 3,100 days (Xu 2011b). The aerobic half-life in non-sterilised sediment was the shortest (1,200 days). This is the most appropriate value for characterising the rate of dissipation of Siloxane D5 found in sediments in the environment.

#### 4.2.4.2 Concentrations in Sediments

155. Concentrations of Siloxane D5 in sediments have been measured in a number of locations. Concentrations measured in sediments from Europe and the United Kingdom ranged from non-detectable (1 $\mu$g/kg) to 280 $\mu$g/kg (dw) (summarised in Brooke et al. 2009). Concentrations in sediments collected in Sweden ranged from non-detectable (variable limits of detection or "variable LOD") to 190 $\mu$g/kg (dw) (Kaj, 2005) and from

non-detectable (variable LOD) to 2,000 μg/kg (dw) in other Nordic countries (Nordisk Ministerråd and Nordisk Råd 2005).

156. Some measurements of Siloxane D5 were made in samples of sediments from Lake Ontario in 2007 (Powell and Kozerski 2007). In five core samples, concentrations of Siloxane D5 were less than the LOD (4.7 μg/kg ww). However, one "grab" sample from Toronto Harbour contained concentrations of 358 μg/kg (ww) (equivalent to 790 μg/kg (dw)).

157. Concentrations of Siloxane D5 measured in sediments collected downstream from 11 WWTPs in Canada were reported by Wang et al. (2010). Two or more grab samples were taken at each site and these were treated as separate samples. The geometric mean concentrations of triplicate analyses of Siloxane D5 ranged from 0.021 to 7.6 μg/kg (dw).

158. The two greatest geometric mean concentrations, 4.0 and 7.6 μg/kg (dw), were measured in water downstream from Site 8, a site where Siloxane D5 is used in industrial applications (Wang et al. 2011a). These are considered worst-case and not representative of values generally found in WWTP outfalls in Canada.

159. The potential risks to benthic organisms from these measured concentrations are discussed in section 4.4.4 below.

### 4.2.5 Soils

160. Based on the evidence reviewed, the Board concluded that there will be negligible deposition of Siloxane D5 from air to soils via rainfall and/or snow. Consequently, precipitation would not represent a source of Siloxane D5 in either the near-field or the far-field (i.e., Arctic).

161. The major pathway of Siloxane D5 into soils is via application of biosolids from WWTPs. Siloxane D5 binds to biosolids which are applied to agricultural lands as an amendment to soils to improve fertility.

162. Concentrations of Siloxane D5 have been documented in biosolids and sewage sludge (summarised for Europe by Brooke et al. 2009) and ranged from 1,100 to 89,000 μg/kg (dw) in Nordic countries. Concentrations in biosolids sampled from WWTPs in Canada ranged from 28,000 to 328,000 μg/kg (dw) (Wang et al. 2010). Since biosolids are not an environmental compartment, but rather a conduit for materials to be transported to soil, the Board focused on the fate and concentration of Siloxane D5 in soils.

#### 4.2.5.1 Processes Affecting Fate and Distribution in Soils

163. There are two mechanisms by which Siloxane D5 is removed from soils (Xu and Chandra 1999). The first is partitioning to air via moisture-aided volatilisation. This is the dominant process in wet soils. The second is degradation via hydrolysis that is catalysed by clay particles. This process predominates in dry soils (Xu 2011a). The half-life for

degradation of Siloxane D5 in air-dry soil is 1.9 hours. From these data, the Board determined that Siloxane D5 will neither persist nor accumulate in soils to which biosolids have been added.

#### 4.2.5.2 Concentrations in Soils

164. In Canada, concentrations of Siloxane D5 were measured in agricultural soils from 11 sites where soils had been amended with biosolids from WWTPs (Wang et al. 2010). In addition, samples of soils from two sites without amendment were also analysed.

165. Although Siloxane D5 was detected at all sites, concentrations varied among soils taken from different locations on the same farm. When sub-samples on a site were treated as independent measures, concentrations ranged from less than the LOQ (0.003 mg/kg (dw)) to 0.899 mg/kg (dw).

166. Concentrations of Siloxane D5 measured in two samples of soils amended with biosolids in Europe were less than the LOD (0.0001 mg/kg) and 0.01 mg/kg (dw) (Nordisk Ministerråd and Nordisk Råd 2005).

167. Potential risks of adverse effects on plants and soil-dwelling organisms from these measured concentrations are discussed in section 5.1 below.

## *4.3 Persistence, Bioaccumulation and Trophic Magnification of Siloxane D5 in the Environment*

### 4.3.1 Persistence

168. The Board was asked to determine if Siloxane D5 presented a danger to the environment. While persistence might be a contributor to the potential for a substance to be a danger, it is not necessarily an indicator of danger in and of itself. There are many natural and synthetic substances that are persistent but do not cause harm or danger to the environment.

169. The persistence of a chemical is an estimate of how long it will remain in the environment or an organism. There can be both global and local persistence. While some chemicals are not transformed or degraded in the environment, others undergo various processes through which they are transformed to other chemicals or are degraded in a manner that they are ultimately mineralised or decomposed into their constituent elements.

170. Whether chemicals degrade, how rapidly they degrade, and into what components they degrade are all important considerations when conducting a risk assessment. Chemicals can also persist in organisms by binding to proteins or being stored in fat tissue from which they are released slowly, enabling the chemical to remain in the body for extended periods of time. In the case of Siloxane D5, this chemical does not bind to molecules in the organism and is not soluble in fats or lipids.

171. In the Screening Assessment, government officials determined that, pursuant to the Regulations, Siloxane D5 was persistent. Based upon the thresholds in the Regulations (see section 3.4 above), a persistent chemical is one for which its half-life is ≥2 days in air; ≥182 days in water; ≥365 days in sediments; or ≥82 days in soils. Those thresholds were established because, during those periods of time, a chemical could possibly contribute to local or widespread effects.

172. From the information in section 4.2, the half-lives of Siloxane D5 in air, water, and sediments exceeded the threshold values in section 3 of the Regulations. The only compartment of the environment where the half-life did not exceed the threshold was for soils. All parties at the hearings and the Board agreed with this characterisation of persistence.

### 4.3.2 Accumulation

173. Although Siloxane D5 meets the thresholds for persistence pursuant to the Regulations, it will only be a danger to the environment if its persistence results in exposures that cause adverse effects in the environment.

174. Consequently, persistence must be accompanied by accumulation in one or more compartment(s) of the environment (or organisms) to the point that these exposures exceed the dose or concentration that causes an adverse effect. Whether this occurs depends upon other intrinsic properties of the chemical and its environment. In this report, the Board discusses how these properties interact with persistence and whether this results in danger to the environment.

175. To cause an effect, a chemical must enter into an organism or at least interact with its external membranes (i.e., skin, gills, etc.). Siloxane D5 can enter organisms through several pathways, including inhalation, or across the integument such as the skin or gills of fish or benthic invertebrates, or the lining of the gastrointestinal tract. However, the primary route of exposure for all organisms is via the diet and/or water. Following this exposure, the process by which neutral, unreactive molecules, such as Siloxane D5, enter into organisms is by molecular diffusion.

176. Diffusion, by definition, is a first-order process that is dependent on the difference in concentration (gradient) and some rate constant that is a function of the physical and chemical properties of the molecule and the membranes of the organism. There are two rates that need to be considered, the rate of accumulation and the rate of depuration, or loss from the organism across all pathways.

177. Under conditions of constant exposure, which is the case when chemicals are considered to be at a steady-state, the concentration that can be achieved in an organism is determined solely by the depuration rate (see section 4.3.2.6 below).

178. There are three mechanisms by which a chemical can be accumulated into organisms. The first is bioconcentration, where the chemical is accumulated in organisms

in concentrations that are greater than those in the surrounding environmental compartment. The bioconcentration factor ("BCF") is the ratio of the concentration in the organism to that in the matrix surrounding the organism.

179. The second mechanism is bioaccumulation, the process by which chemicals accumulate in organisms from the medium surrounding the organisms, including sources such as food. The bioaccumulation factor ("BAF") is the ratio of the concentration in the organism to that in the surrounding environmental medium. If sediments are included as a matrix, this ratio is the biota-sediment accumulation factor ("BSAF").

180. The BSAF is defined as the ratio of the concentration in an animal, such as a benthic invertebrate or a fish, normalised to lipid content of the animal, divided by the concentration of the chemical of interest in the sediment, normalised to the OC content of the sediment.

181. The BSAF is a thermodynamic constant that allows the prediction of concentrations in organisms from that in sediments by correcting for the effects of lipids and OC on the distribution characteristics of a chemical. The BSAF has the units of kg OC divided by kg lipid (kg OC/kg lipid). BSAF values tend to be site-specific due to the many environmental factors that affect it. For this reason, the BSAF is better used in a comparative, rather than a predictive, manner.

182. The BSAF can best be used to interpret the degree to which a chemical will likely be accumulated into organisms from sediments. Since some Siloxane D5 is expected to partition to sediments, the BSAF is a relevant parameter to use in assessing the behaviour of Siloxane D5 in the environment, particularly for organisms associated with sediments, such as benthic invertebrates. Chemicals with BSAF values of about 500 would normally be expected to biomagnify (Gobas et al. 2011 pp. 26-28).

183. The third mechanism is biomagnification, or trophic magnification, in which concentrations in organisms become greater with successively higher trophic levels in the food chain. In this process, the organism at the higher trophic level, such as a predator, accumulates a greater concentration than the organism at the lower trophic level, such as the prey.

184. Biomagnification occurs for persistent compounds such as certain polychlorinated biphenyls ("PCBs") that are slowly, or not, biotransformed. This causes concentrations of more persistent residues that associate with lipids in the prey to increase which, in turn, results in a concentration gradient that forces the more persistent compound into the organism eating the prey. This concentration gradient and the resulting propensity of the chemical to migrate from the greater to the lesser concentration are referred to as fugacity (see the discussion beginning in paragraph 189 below).

185. At steady-state, the ratio of the concentration of the compound in an organism to that in its food is the biomagnification factor ("BMF"). The relationship between

concentrations of a chemical in organisms at various trophic levels in a food chain and their position in the food chain is the trophic magnification factor ("TMF").

186. Information about BMF and TMF is important for assessing exposures in organisms higher on the food chain. In characterising bioaccumulation and trophic magnification of Siloxane D5, the primary focus of the Board was on aquatic organisms, for which measured data were available.

187. TMFs are derived under field conditions from analyses of organisms at various trophic levels for the chemical in question as well as from the ratio of two isotopes of nitrogen, $^{15}N/^{14}N$. Organisms higher on the food chain concentrate the $^{15}N$ isotope and this is used as a surrogate for trophic level.

188. TMF values less than 1.0 indicate biodilution where organisms biotransform the chemical more rapidly than they accumulate it and the concentrations decrease with increasing trophic level. A TMF greater than 1.0 is indicative of biomagnification up the food chain.

189. Fugacity is a concept that relates to movement of chemicals among compartments of the environment. At steady-state, while individual molecules are still moving between and among compartments, concentrations of a chemical of concern in each compartment do not change.

190. Fugacity can be thought of as a forcing function with the units of pressure (Pa). That is to say, fugacity is the tendency for a substance to move from one compartment into another. The fugacity capacity ($Z$) of a system allows comparison of concentrations of a chemical in different compartments by expressing them on a common basis.

191. The fugacity ratio is an indicator of the propensity of a chemical to bioconcentrate. More specifically, it is the ratio of the fugacity of a chemical in an organism relative to that in the compartment of the environment to which it is exposed, such as water or sediments. A chemical which biomagnifies has a fugacity ratio that exceeds 1.0.

192. When determining the potential for a chemical to produce adverse effects, it is important to assess whether organisms are likely to be exposed to the chemical. One aspect of this exposure assessment is to estimate the potential for the compound to enter into organisms by examining the BCF, BAF, BSAF, and/or TMF. Several approaches can be taken depending on the information available and the tier of the risk assessment. Accumulation factors can be measured under either controlled laboratory conditions, estimated from field exposures, or predicted by models.

193. If a chemical is being assessed and little information is available, its accumulation or persistence profile could be predicted by the use of simple linear free-energy models (correlations) from first or second principles. These are measures of the physical and chemical properties of the compound of interest and can include measures of properties in

its pure form, such as water solubility, and distribution between water and organic solvents, such as the $K_{OW}$.

194. In the simplest approach, the values of BAF, BCF, or some surrogate estimator such as $K_{OW}$ are compared to reference values. Based on historical information for other classes of chemicals, section 4 of the Regulations establishes threshold values of 5,000 for the BAF and BCF. In circumstances where measured values are available, such as in this case for BCFs, it is not necessary to consider the $K_{OW}$.

195. If a chemical meets a threshold, it is identified as a chemical of concern because of its potential for accumulating into organisms and in the environment. These thresholds should be used primarily to screen chemicals out from further consideration or to prioritise chemicals for further study. Simply because the BCF or BAF of a chemical exceeds the reference value does not, in and of itself, determine that the chemical will pose a danger. It is instead an indicator of the potential to accumulate.

196. As the Board noted earlier, section 5 of the Regulations requires consideration of the intrinsic properties of a chemical. In the case of Siloxane D5, this would include:

- its unique physical and chemical properties;
- how it enters the environment;
- how it moves among compartments; and,
- the manner by which it is degraded.

197. These additional factors are important in determining the exposure and potential for effects of Siloxane D5 in the environment. Consequently, the Board considered two aspects of accumulation:

- Do the values of BAF or BCF for Siloxane D5 meet the bioaccumulation thresholds according to the Regulations?
- Do the intrinsic properties of Siloxane D5 affect the analysis of its bioaccumulation characteristics?

198. Since the Board has the mandate to assess the nature and extent of the danger (or risk) posed by Siloxane D5 to the environment, the Board considered bioaccumulation, trophic magnification, and the intrinsic properties of Siloxane D5 as they relate to its distribution and fate in the environment. The Board therefore considered how Siloxane D5 is released to the environment, its distribution into the various compartments of the environment, how it is degraded, and the toxicity of the molecule once it reaches a site of action in an organism.

199. In conducting this assessment, the Board considered all the relevant scientific information available, including that information which was available in 2008, when the Screening Assessment was conducted.

200. The Board considered bioaccumulation and trophic magnification in relation to the exposures that organisms in the environment could experience to determine if these would pose a danger to the environment. The Board also recognised that accumulation of a substance from the matrix or food in an assay, or test, for toxicity (acute or chronic) inherently considers BCF or BMF, as well as the relevance of the concentrations that accumulate in an organism, even if these are not measured.

201. If toxicity is not observed in a long-term assay, then the accumulation that occurred in an organism as a result of that exposure did not produce adverse effects. Therefore, the exposure tested in the assay represented a *de minimis* risk.

202. In essence, accumulation in and of itself is not necessarily harmful. It is only harmful when the accumulation results in a concentration in the organism that exceeds its threshold of toxicity, or that of its predators.

203. Before turning to the Board's analysis of bioaccumulation in relation to Siloxane D5, it is important to note that section 4 of the Regulations, which guided the Board, establishes a hierarchical order for considering the appropriate bioaccumulation metric.

204. The first metric prescribed in the Regulations is the BAF. If that factor cannot be determined, then evaluators shall assess the chemical's BCF. If neither the BAF nor the BCF can be determined, evaluators shall then assess the $K_{OW}$. As noted earlier, because the BCF was measured, it was not necessary to consider the $K_{OW}$.

#### 4.3.2.1 Bioaccumulation Factor

205. As established in the Regulations, the BAF is the first factor to be considered in assessing bioaccumulation. The Screening Assessment cited BAFs which were calculated from models. This is because no empirical BAFs were available (EC & HC 2008). However, as noted in the Screening Assessment, government officials were unable to conclude that Siloxane D5 met the regulatory threshold for bioaccumulation (BCF or BAF ≥5,000) due to conflicting evidence. (EC & HC 2008, p. iii, EC 2011a, p. 3). Environment Canada reiterated this conclusion in its January 20, 2011 State of the Science Report where it stated that it "considers the BAF modelling for D5 to be equivocal" (EC 2011a, p. 67-68).

206. Even though no additional BAF data were provided to the Board during this review, Environment Canada, in its closing submissions, took the position that "D5 is bioaccumulative chemical and exceeds the Canadian criterion of BAF and/or BCF ≥5,000 set out in the Regulations. This determination is based on a weight of evidence that considered 15 bioaccumulation metrics" (EC 2011b, p. 7).

207. This statement is at odds with the position taken in the Screening Assessment and in the more recent State of the Science Report. Nevertheless, having considered the submissions of the parties and the relevant scientific information, the Board has concluded that the values for BAF are equivocal and do not support a conclusion that the regulatory threshold for BAF has been met.

208. Due to the absence of measured BAF values, the Board also considered alternative methodologies of expressing bioaccumulation. These included the multimedia BAF ("mmBAF") and the relative BAF (McLachlan 2011). However, neither method is currently in use in a regulatory or risk assessment context (Transcript of the Public Hearings, Vol. 3, p. 476 and Transcript of the Public Hearings, Vol. 4, p. 613). Furthermore, the techniques are new and have not been validated against other approaches to estimate bioaccumulation. Consequently, the Board was of the opinion that it would not be appropriate to rely on either mmBAF or relative BAF in the context of this inquiry.

#### 4.3.2.2 Bioconcentration Factor

209. According to the Regulations, the BCF is the second factor to consider in assessing bioaccumulation. Estimates of potential to accumulate into organisms can be used in initial assessments or the lower tiers of a tiered risk assessment process by comparing empirical values to thresholds. Paragraph 4(b) of the Regulations establishes a value of 5,000 as the screening level threshold for the BCF.

210. At the time that the Screening Assessment was conducted, there were three values available for the BCF (EC & HC 2008). These values ranged from 1,950 to 13,300 L/kg wet weight (ww) (Annelin and Frye 1989, Drottar 2005, Opperhuizen et al. 1987).

211. To supplement those empirical data, the Arnot-Gobas model (2003) was used in the Screening Assessment to estimate the BCF for middle trophic-level fish. All values calculated using that model were less than 5,000 (EC & HC 2008, Table 9b).

212. The only new information about the BCF that was provided to the Board during this review was the results of an early-life-stage chronic toxicity test conducted on fathead minnows. The authors of the study reported values that ranged from 4,000 to 5,000 L/kg (ww) (EC 2010d).

213. The Screening Assessment concluded that, "while D5 has the potential to accumulate in biota, it is not possible to conclude at this time that D5 meets the criteria for bioaccumulation as set out in the Regulations based on considerations of the conflicting evidence from laboratory studies and predictive models" (EC & HC 2008, pp. ii-iii). Furthermore, the January 10, 2011 State of the Science Report (EC 2011a, p. 55) found the data on BCF for Siloxane D5 to be "equivocal", even considering the early-life-stage fathead minnows chronic toxicity test study discussed above.

214. However, in its closing submissions, Environment Canada stated that Siloxane D5 has a BAF and/or BCF ≥5,000 (EC 2011b, p.7). Here again, the Board noted that

Environment Canada had changed its position with respect to BCF from that in the Screening Assessment and in the more recent State of the Science Report. Nevertheless, having considered all parties' submissions and the relevant scientific information, the Board has concluded that the values for BCF are equivocal and do not support a conclusion that the regulatory threshold for bioconcentration has been met.

#### 4.3.2.3 Biota-sediment Accumulation Factor

215. The BSAF was not considered in the Screening Assessment (EC & HC 2008). However, during the hearings, this parameter was raised by Environment Canada and the SEHSC/CCTFA. BSAFs of Siloxane D5 have been measured in a number of studies on sediment-dwelling organisms under laboratory and field conditions (Wildlife International 2008, Norwood et al. 2010, Dow Corning Corporation 2009). All values were less than 10 kg OC/kg lipid. These values are less than 500 kg OC/kg lipid, which is the normal threshold of concern for persistent, neutral, organic molecules.

216. In the case of Siloxane D5, the BSAF would need to exceed approximately 725 kg OC/kg lipid before it would be expected to biomagnify to a concentration that would exceed the threshold for an adverse effect (Gobas et al. 2011, p. 28). Siloxane D5 has a greater threshold of total concentration because it tends to partition more to OC in sediments than other neutral, organic molecules of similar molecular size (see discussion of $K_{OC}$ in section 4.2.1 above).

#### 4.3.2.4 Biomagnification Factor

217. Of the two studies which measured BMFs for Siloxane D5, the Environment Agency in the United Kingdom considered only one, that of Drottar (2007) to be valid (Brooke et al. 2009). Drottar studied rainbow trout and reported a BMF of 0.22 (ww) and 0.63 when normalised to lipid (Drottar 2007).

218. Biomagnification does not occur when values of BMFs are less than 1.0. This is discussed in detail with respect to depuration rates in section 4.3.2.6 below. Having reviewed the available scientific information respecting the BMF, the Board is of the opinion that Siloxane D5 does not biomagnify.

#### 4.3.2.5 Trophic Magnification Factor

219. No information on the TMF was available when the Screening Assessment was conducted. Information has now become available that allowed TMF values to be calculated.

220. TMF values for Siloxane D5 measured using nitrogen isotopes in Lake Pepin, in the Mississippi River, south of Minneapolis-St Paul, Minnesota, were less than 1.0, which indicates trophic dilution. Based on all species analysed, the TMF was 0.18. When aggregated into feeding habits (trophic guilds), the TMF for all species was 0.11 (Dow Corning Corporation 2009).

221. The use of nitrogen isotopes to characterise trophic levels in terrestrial and freshwater environments might be confounded by inputs of nitrogen from anthropogenic sources or by difficulties in measuring concentrations of lipids in some organisms (Powell and Seston 2011), and this could have influenced the measurements of TMF for Siloxane D5. However, a similar characterisation of the food web in Lake Pepin was undertaken with a number of PCBs, which are known to biomagnify in the food chain. All TMFs for the PCBs were greater than 1.0 (from 1.5 to 5.1, depending on the congener of PCB) (Powell and Seston 2011) and were consistent with the behaviour of these well-studied compounds in other systems.

222. When considering these results, the Board concluded that these measurements add confidence to the TMF values for Siloxane D5 and that it does not undergo trophic magnification. The Board also agreed with the suggestion that a benchmark chemical that is not biotransformed, such as PCB 153 or PCB 180, could be used a reference to allow the estimation of a relative TMF (Powell and Seston 2011). This method compensates for potential sources of error and allows for better characterisation of trophic magnification of chemicals such as Siloxane D5 in freshwater food-chains.

223. In Lake Pepin, concentrations of Siloxane D5 were greater in the lowest trophic level (detritivores) than they were in sediments. However, concentrations of Siloxane D5 were inversely proportional to the ratio of nitrogen isotopes in all the other trophic levels. Trophic magnification did not occur. Trophic dilution of Siloxane D5 was also observed in Oslo Fjord (Powell 2009), the Humber Estuary, and the Baltic Sea (Gobas 2011, slides 11&12).

224. After reviewing all of the scientific information with respect to TMFs and taking into account the uncertainties noted by the parties, the Board concluded that Siloxane D5 does not biomagnify.

#### 4.3.2.6 Depuration Rates

225. The rate at which Siloxane D5 is biotransformed by higher organisms determines, in part, the rate of accumulation and depuration (loss from the organism along all pathways including diffusion, active transport, and degradation).

226. As food is consumed, some of the OC is degraded and accumulated into the organism where it is converted to energy. Thus, the OC content, and in particular the lipid content, of the food decreases as it is digested and biotransformed. Under conditions of constant exposure, which is the case at steady-state, the concentration that can be achieved in an organism is determined only by the depuration rate.

227. Information on the rate of depuration can be used in two ways. First, it can be used to interpret whether a compound, such as Siloxane D5 is biotransformed. Siloxane D5 is biotransformed, to varying degrees, in mammals (Varaprath et al. 2003) and in fish (Springer 2007). The rate constants for depuration that have been reported for two species of fish and one species of worm and range from 0.029 to 0.25/day (Gobas 2011, slide 4).

These measured rates of depuration are greater than those predicted from models in which it was assumed that Siloxane D5 is not biotransformed. This confirms that Siloxane D5 is biotransformed by organisms.

228. Second, the depuration rate can also be compared to the uptake rate. If the rate of depuration (expressed in units of mass of chemical per mass of animal per unit time) exceeds the rate of uptake (expressed in the same units), then the chemical cannot be biomagnified.

229. In the case of Siloxane D5, if it is assumed that an animal eats 4% of its body mass in food per day (a high rate) and that the assimilation efficiency is 50% (which is a typical value for neutral organic chemicals in fish), a maximum uptake rate can be calculated (Gobas et al. 2011, p. 3 ). When this was done, a rate constant of 0.02 /day was calculated (Gobas 2011, slide 4). The fact that the measured depuration rates all exceed this value also indicates that Siloxane D5 does not biomagnify.

230. Based on the available information on the BMF, measured concentrations in the environment, and the pathways and processes of degradation, the Board concluded that Siloxane D5 does not biomagnify. From this conclusion, it follows that organisms at higher trophic levels will not be exposed to greater concentrations of Siloxane D5 than organisms below them in the food web.

#### 4.3.2.7 Fugacity Analysis

231. As noted above, fugacity is the tendency of chemicals to move from one compartment into another in the environment and/or organisms. When the fugacity ratios for Siloxane D5 were calculated, they were all less than 1.0 (Gobas et al. 2011, Figure 3, p. 59). For bioaccumulative organic compounds, such as the non-biotransformed PCBs, the fugacity ratios are always greater than 1.0. The evidence indicated that Siloxane D5 is biotransformed as its fugacity ratios were less than 1.0.

232. Analyses of fugacities can also be used to determine whether Siloxane D5 would cause adverse effects. Based on calculations made for some average environmental conditions, the maximum fugacity that Siloxane D5 could achieve at its solubility limits would be approximately 33 Pa (Gobas et al. 2011, p. 32-39, Figures 2 and 3, p. 58-59).

233. When fugacities of Siloxane D5 were calculated for a range of environmental compartments and organisms, the fugacities were always less than 33 Pa and decreased with increasing trophic level. The fugacity values ranged from a maximum of 10 Pa in effluent from WWTPs to 0.0000001 Pa in marine mammals (Gobas et al. 2011, Figure 3, p. 59). The no-observed-effect-concentration ("NOEC") values for all organisms tested were at fugacity magnitudes that exceeded 33 Pa. These fugacity magnitudes are thermodynamically impossible to attain in the environment (Gobas et al. 2011, Figure 3, p. 59).

234. The results of this analysis are consistent with the conclusion of the Board that Siloxane D5 does not bioconcentrate and, based on its solubility limits, Siloxane D5 cannot exceed concentrations that could give rise to adverse effects in organisms.

### 4.3.3 Conclusions on Persistence, Bioaccumulation and Trophic Magnification of Siloxane D5 in the Environment

235. From the scientific information before it, the Board has concluded that Siloxane D5 meets the criteria to be classified as a persistent chemical under the Regulations. However, it will only be a danger to the environment if Siloxane D5 persists in such a way as to result in adverse effects in the environment. Thus, persistence must be accompanied by accumulation in one or more compartment(s) of the environment (or organisms) to the point that these exposures exceed the dose or concentration that causes an adverse effect. The Board's conclusions with respect to adverse effects are described in the following sections.

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

237. The Screening Assessment did not consider all of the intrinsic properties of Siloxane D5 and their effect on fate and transport in the environment and subsequent exposure to organisms. The Screening Assessment concluded, in part, that Siloxane D5 should be classified as bioaccumulative simply by comparing the values of the BCF and/or BAF to the regulatory threshold of 5,000, even though the data were equivocal. Such an approach might be appropriate in less robust, lower-tiered screening assessments and in the absence of additional information about the intrinsic properties of a substance. However, given the availability of additional information, the Board conducted a refined assessment of the potential danger posed to the environment from Siloxane D5 and concluded that it does not biomagnify through the food chain.

## *4.4 Toxicity of Siloxane D5 to Receptor Organisms in the Environment*

238. Toxicity is the potential of a chemical to produce adverse, or detrimental, effects in organisms. The magnitude of the adverse effect is determined by the concentration and duration of exposure to the chemical and how it interacts with the organism.

239. The interaction of the chemical with the organism includes toxicokinetic and toxicodynamic factors. Toxicokinetic factors include the rates of absorption, distribution, biotransformation, and, finally, excretion. Toxicodynamic factors also include the rate at which damage is caused and the rate of recovery, if any, from the damage.

240. There are many processes in organisms that affect the amount of the chemical reaching target sites in tissues. Indeed, organisms can be exposed to some concentration of a chemical for a very long period without any adverse effect. This is referred to as the

incipient effective concentration. Organisms, including humans, are continuously exposed to toxic chemicals, but it is only when the critical incipient effect concentration is exceeded for a sufficient period of time for damage to accumulate, that adverse effects will occur.

241. Knowledge of the mechanism of action of a chemical is useful in assessing its hazard to organisms. A chemical can have a specific mode of action due to its interaction with a particular receptor. For instance, the shape of some molecules is such that they fit into structures on biomolecules such as enzymes or receptors on the surface of a cell. Chemicals can elicit effects by mimicking biological molecules or blocking key receptors. Chemicals can interact with other chemicals enabling inactive chemicals to become active. It also should be emphasised that, in the environment, chemicals do not exist as sole entities but are part of a mixture.

242. In addition to these specific mechanisms of action, all chemicals have what is termed the minimal or basal toxicity. This is referred to as narcosis and is caused when the molecule partitions, or dissolves, into the membranes of the cells of the organism and produces changes in their structural or chemical properties. This process is generally reversible and does not cause permanent damage unless exposures are of sufficient duration and magnitude. For neutral (uncharged) molecules such as Siloxane D5, there is no known specific mechanism of action, so adverse effects can only be induced by narcosis (Transcript of the Public Hearings, Vol. 3, p. 516, Transcript of the Public Hearings, Vol. 7, p. 992).

243. Concentrations of Siloxane D5 required to produce adverse effects would be expected to vary little among species because the physiologies and membranes of most organisms are quite similar. Consequently, it is unlikely that there will be uniquely sensitive species. For this reason, a smaller set of data on toxicity is sufficiently robust to make meaningful conclusions about the potential for adverse effects on organisms.

244. The evidence available indicates that Siloxane D5 is not toxic to mammals (Environment Agency 2010). Adverse effects on other species are only observed at very large concentrations which, based on the evidence before this Board, cannot be attained in the environment as a result of normal releases.

245. In some studies on benthic organisms (summarised in EC 2011c, Table 2, p. 19), adverse effects were noted. However, in these studies, concentrations exceeded the theoretical solubility limits of Siloxane D5 in the OC component of the sediments. It is the opinion of the Board that these studies do not accurately represent concentrations of Siloxane D5 that are likely to be found in the environment.

246. There is no toxicity information available for some classes of animals such as amphibians or birds (EC & HC 2008, Brooke et al. 2009). There were no data available as to whether Siloxane D5 interacted with other chemicals in the environment as part of a mixture. However, the Board is of the opinion that this lack of information would not

change its conclusion, nor does it introduce an unacceptable level of uncertainty about hazard and risk.

247. Results of studies of the toxicity of Siloxane D5 to terrestrial and aquatic organisms that were conducted after the Screening Assessment was released have added to the understanding of the sensitivities of several groups of organisms. The toxicity data contained within these new studies are summarised and discussed in the following sections. These data represent the values associated with the most sensitive response observed in each study.

### 4.4.1 Terrestrial Animals

248. Toxicity concentrations from studies conducted after 2008 were available for earthworms and springtails and are summarised in Table 2. The most sensitive organism tested was the springtail with an IC50 based on production of young at 767 mg/kg (dw).

Table 2. Most sensitive toxicity values for effects of Siloxane D5 in terrestrial animals

| Test organism | Duration (days) | Endpoint and Response[a] | Value (mg/kg (dw))[b] |
|---|---|---|---|
| Earthworm (*Eisenia andrei*) | 56 | IC50 (production of young) | >4,074 |
| Springtail (*Folsomia candida*) | 28 | IC50 (production of young) | 767 |

[a] IC50 is the concentration that causes 50% inhibition of the response.
[b] Toxicity concentrations are based on measured concentrations at the initiation of the study.
Data from (EC 2010b).

249. During preliminary tests, after 14 days, concentrations of Siloxane D5 decreased to 50% of the initial, nominal concentrations. These losses were due to degradation and volatility. However, the values in Table 2 above are based on concentrations of Siloxane D5 measured in soils at the beginning of the study, the only time when concentrations were measured (EC 2010b). Despite some of the uncertainties associated with the study, the Board concluded that the results of these tests were appropriate for assessment of risks.

### 4.4.2 Terrestrial Plants

250. Information on toxicity was available for four species of plants (Table 3). All these data were generated after 2008. As for terrestrial animals (above), IC50 values for effects of Siloxane D5 on terrestrial plants are based on the concentrations of Siloxane D5 measured in soils at the beginning of the study. The Board determined that this did not invalidate the results of the tests since this dissipation would occur in the field after the addition of biosolids containing Siloxane D5 to the soil.

Table 3. Most sensitive toxicity values for effects of Siloxane D5 in terrestrial plants

| Test organism | Duration (days) | Endpoint and Response[a] | Value (mg/kg (dw))[b] |
|---|---|---|---|
| Barley (*Hordeum vulgare*) | 14 | IC50 (dry mass of roots) | 209 |
| Red clover (*Trifolium pratense*) | 14 | IC50 (all responses) | >4054 |
| Durum wheat (*Triticum durum*) | 14 | IC50 (all responses)[c] | >3533 |
| Radish (*Raphanus sativus*) | 14 | IC50 (all responses)[c] | >4306 |

[a] IC50 is the concentration that causes 50% inhibition of the response.
[b] IC50s are based on measured values at the initiation of the study.
[c] IC50s based on lack of observed response in the range-finding study.
Data from (EC 2010b).

251. The most sensitive plant was barley with an IC50 value based on dry mass of roots of 209 mg/kg (dw). This value was used in the risk assessment discussed below (section 5.1 below).

### 4.4.3 Aquatic Organisms

252. Although some information on toxicity was available when the Screening Assessment was conducted (EC & HC 2008), additional data have been presented to the Board and are included in this review. The concentration values for all of the studies are summarised (Table 4) and include two studies on early life-stage.

Table 4. Most sensitive toxicity values for Siloxane D5 in aquatic organisms

| Test organism | Duration (days) | Endpoint | Value (μg/L) |
|---|---|---|---|
| Rainbow trout (*Oncorhynchus mykiss)* | 14 | NOEC | ≥16 |
| Water flea *(Daphnia magna)* | 21 | NOEC | ≥15 |
| Rainbow trout (*O. mykiss)* | 90 (early life-stage) | NOEC | ≥14 |
| Rainbow trout (*O. mykiss)*[a] | 45 | NOEC | ≥17 |
| Fathead minnow (*Pimephales promelas*) | 65 (early life-stage) | NOEC | ≥8.7 |

NOECs are based on measured concentrations except for [a], which is based on nominal concentrations in a flow-through assay.
Data from (EC 2011c).

253. No adverse effects were observed in any of the studies. In all cases, the NOECs were the greatest concentration tested or measured in the studies. The concentrations were all greater than or equal to the maximum solubility of Siloxane D5 in water (17 μg/L) (EC 2011a, Table 5, p. 22).

254. In several of these studies, it was not possible to maintain concentrations of Siloxane D5 that were close to or greater than its maximum solubility. For example, in the study on the fathead minnow (EC 2010d), the greatest nominal concentration tested (17 μg/L) was measured to be 8.7 μg/L. This is consistent with the vapour pressure and the air-water partition coefficient, $K_{aw}$, of Siloxane D5 and its tendency to dissipate from water to air (section 4.2 above).

255. Because the mechanism of action of Siloxane D5 is narcosis (Transcript of the Public Hearings, Vol. 3, p. 546), the Board determined that the toxicity values available for Siloxane D5 in aquatic organisms were representative of other aquatic species. The Board further concluded that no adverse effects would be expected at concentrations less than or equal to its maximum solubility in water (17 $\mu$g/L).

### 4.4.4 Sediment-dwelling Organisms

256. Toxicity data for sediment-dwelling organisms were available for the mud-worm (*Lumbriculus variegatus*), and larvae of the midge (*Chironmus riparius*) in 2008. Additional data for these species and the scud (*Hyalella azteca*) were made available subsequently. All of the data are summarised in Table 5 and are presented relative to dry-weight of sediments and relative to the amount of OC in the sediments.

Table 5. Most sensitive toxicity values for effects of Siloxane D5 in sediment-dwelling organisms

| Test organism | Duration (days) | Endpoint | Value ($\mu$g/g dw) | Value ($\mu$g/g OC) |
|---|---|---|---|---|
| Scud (*Hyalella azteca*) | 28 | NOEC | 62 | 12400 |
| Scud (*H. azteca*) | 28 | NOEC | 130 | 2708 |
| Scud (*H. azteca*) | 28 | NOEC | 841 | 5827 |
| Midge (*Chironmus riparius*) | 28 | NOEC | 69 | 3450 |
| Midge (*C. riparius*) | 28 | NOEC | 70 | 2188[a] |
| Mud-worm (*Lumbriculus variegatus*) | 28 | NOEC | >336 | >6720 |
| Mud-worm (*L. variegatus*) | 28 | NOEC | >1272 | >34378 |

[a] This is the only value where the concentration of Siloxane D5 is less than saturation in the OC component of the sediment.
Data from (Fairbrother et al. 2011).

257. The Board noted that all but one of the NOECs in Table 5 were at concentrations greater than the maximum solubility limit in the OC fraction of the sediment used in the test. Based on the measured $K_{OC}$ for Siloxane D5, the concentration at saturation would be 2,516 $\mu$g/g OC (Mackay 2011a). Unless an unintentional industrial release occurred, concentrations greater than this value could not result from normal diffusion and partitioning in the environment.

### 4.4.5 Conclusions on Toxicity of Siloxane D5 to Receptor Organisms in the Environment

258. From the scientific information presented to the Board, Siloxane D5 is not toxic to any organisms tested up to and greater than the limit of solubility in the environmental matrix through which they were exposed. As noted above in section 3.3.7, it is theoretically impossible for Siloxane D5 to partition into any matrix to such an extent that its concentration is greater than its maximum solubility in that medium. Consequently, the Board is of the opinion that Siloxane D5 will not accumulate to sufficiently great

concentrations to produce adverse effects in organisms in air, water, soils, or sediments. Moreover, Siloxane D5 does not appear to interact with other chemicals in the environmental mixture to cause harm to the environment or organisms.

# 5 Assessment of the Nature and Extent of the Danger to the Environment Posed by Siloxane D5

259. There are several acceptable methods used to assess the potential for adverse effects of chemicals released into the environment. The methodology used to assess chemicals depends upon whether the substances are new or whether they have been used for some time. For a chemical that has been present in the environment for as long a period of time as Siloxane D5, it is possible to conduct a risk assessment based on actual, measured concentrations and any observed effects on the environment.

260. Two basic conditions need to prevail for adverse effects to occur. First, there needs to be exposure. Even for the most hazardous chemicals, if there is no exposure, no harm will be manifested.

261. Second, once exposure has occurred, there needs to be a detrimental or adverse effect. This is referred to as hazard. The magnitude of effect caused by exposure to a defined amount of the chemical is referred to as its potency. The potency of a chemical is described by the dose- or concentration-response relationship, which is derived by exposing organisms to known amounts of the chemical for known periods of time and recording the magnitude of response(s).

262. Risk assessments can be conducted in tiers of increasing complexity, depending on the amount of information available. Assessments of new chemicals are restricted to the lower tiers and are based on:

- the physical and chemical properties of the compounds;
- the results of simple simulations that predict environmental fates; and,
- a few tests or models to determine toxicity.

263. When the Screening Assessment was conducted, Siloxane D5 had been in use and entering the environment for more than 30 years. Despite this, there was little information on environmental fate or toxicity available at that time. As a result, the Screening Assessment (EC & HC 2008) focused on a few parameters, such as persistence and potential to bioaccumulate, which, in the Board's opinion, represents a lower-tiered assessment.

264. Subsequent to 2008, additional information on the basic physical and chemical properties of Siloxane D5 has become available. Furthermore, additional information on the toxicity of Siloxane D5 has also become available.

265. Most importantly, information on concentrations of Siloxane D5 in a number of environmental matrices, including air, water, soils, and sediments is now available. Thus, a more refined assessment of the danger to the environment posed by the use of Siloxane D5 can be made.

266. Risk relates to the probability of adverse outcomes and necessarily relates to the likelihood of exposure and sensitivity to the substance. The lower tiers of ecological risk assessments are based on limited information and, for that reason, are often based on simple ratios of exposure to some threshold for effect (Hazard Quotients or "HQs"). Because of the inherent uncertainty in these approaches, uncertainty factors ("UFs") are generally applied to reduce the likelihood of a false-negative conclusion that there is little risk when it is, in fact, large.

267. In the lower tiers of assessments, HQs greater than 1.0 suggest that there is the potential for adverse effects while HQs of less than 1.0 suggest little chance of an adverse effect. The HQ is calculated as the ratio of the exposure concentration or dose (multiplied by an UF) to the effect concentration or dose (Equation 1).

$$Hazard\ \ Quotient\ \ (HQ)\ = \frac{Exposure\ \ concentration\ \ or\ \ dose \times UF}{Effect\ \ concentration\ \ or\ \ dose} \qquad (Equation\ \ 1)$$

268. These UFs are meant to be conservative and protective rather than being predictive. Assessments move to higher tiers as additional information becomes available and the uncertainty and the need for UFs is reduced.

269. Thus, lower-tiered assessments are intended to identify, and possibly screen out, chemicals that are not of concern. Simply exceeding a HQ of 1.0, or any regulatory threshold, does not necessarily indicate that there will be harm. Rather, it indicates that further, more refined assessments are warranted to better characterise the hazard and/or the risk. This was the case for Siloxane D5.

270. The initial HQs calculated in the Screening Assessment (EC & HC 2008, Figure 1, p. 40) were based, in the Board's opinion, on incorrect assumptions and parameters in models used to predict concentrations at sites receiving effluents from WWTPs (see section 4.2 above). When these errors and uncertainties are taken together, they resulted in an overly conservative estimate of the risk of Siloxane D5.

271. Given the scientific information now available, the Board was able to conduct a more comprehensive or refined risk assessment into the nature and extent of the danger posed by Siloxane D5 to the environment.

272. The Board considered risks in a probabilistic context wherever sufficient data were available. This probabilistic approach is consistent with the views of Environment Canada (Transcript of the Public Hearings, Vol. 9 p. 95) and the SEHSC/CCTFA (Fairbrother et al. 2011). This approach makes use of all of the available data and, while it might not include all possible values for concentrations in Canada, the data were sufficiently representative and robust to use in a probabilistic assessment.

273. Although the Board focused on exposures that were estimated or measured in the Canadian environment, it also took into account relevant data from other jurisdictions.

## *5.1 Danger to Terrestrial Animals and Plants*

274. To assess risks of Siloxane D5 to terrestrial animals and plants, the Board examined concentrations of Siloxane D5 measured in soils amended with biosolids from WWTPs (Wang et al. 2010). Because samples of soil were taken at different locations within a field on each farm and analysed separately, individual concentrations were treated as independent values that were representative of the spatial variation in concentrations between farms and within fields.

275. Cumulative frequency distributions were used to compare measured concentrations of Siloxane D5 in the environment to toxicity values. The distributions were constructed as probability plots by plotting the concentrations in a log scale on the X-axis of a graph and then plotting the ranks of the values on the Y-axis using a % probability scale. The plotting position on the Y-axis was calculated using the Weibull formula.[9] A probability plot of concentrations measured in soils (Figure 1) showed that greatest measured concentration was 100-fold less than the IC50 (Table 3) for the most sensitive terrestrial organism (barley). The probability of exceeding this concentration was less than 1% and the risk was determined by the Board to be *de minimis* for soils. This is because soils amended with biosolids represent a maximum or worst-case scenario for concentrations of Siloxane D5 in this matrix. Concentrations of Siloxane D5 in unamended soils would all be less than those where biosolids have been added.

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[9] The Weibull formula ($p = i/n+1 \times 100$, where $p$ is the plotting position, $i$ is the rank of the data point and $n$ is the total number of data points in the set) is used to calculate plotting positions for the purposes of constructing a cumulative frequency distribution. The Weibull formula is normally used with larger data sets (n >10).

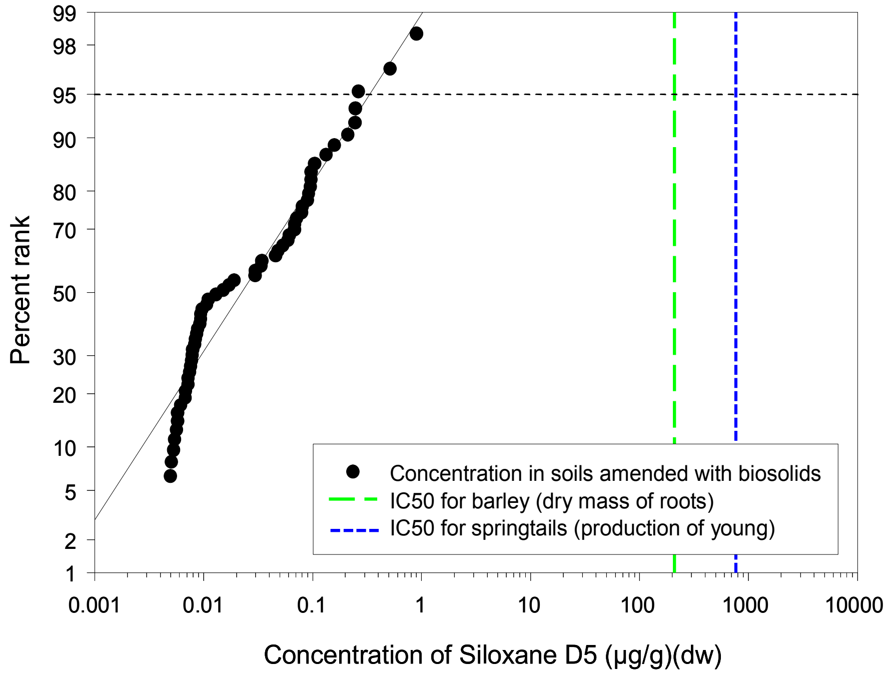


**Figure 1.** Concentrations of Siloxane D5 in Canadian soils amended with biosolids compared to toxicity values for the most sensitive terrestrial plants and animals. The 95th centile is indicated by the horizontal dashed line

276. The Board concluded that concentrations of Siloxane D5 would not increase in soils over time and that this route of exposure did not present a danger to terrestrial animals and plants. This is conclusion is based upon:

- the volatility of Siloxane D5;
- its short half-life in dry soils (0.1 to 13 days, Environment Agency 2010) and combined measured data for all soils (2.7 to 83 days, Brooke et al. 2009); and,
- the amount and frequency of application of biosolids to farmlands authorised throughout Canada (CCME 2010).

## *5.2 Danger to Aquatic Organisms*

277. Concentrations of Siloxane D5 measured in surface waters near discharges from WWTPs were available for selected sites in Canada (Wang et al. 2010). These samples were taken at sites ranging from 5 m to 3.1 km from the point of discharge and are representative of sites close to the release. Concentrations of Siloxane D5 at five of these locations were less than the LOQ, and the greatest geometric mean concentration in all of the sites measured was 1.48 µg/L.

278. In reviewing data from other countries, the Board noted that concentrations in surface waters ranged from less than the LOD to 0.4 $\mu$g/L (EC 2011c). These data suggest that concentrations are generally small and all are less than the maximum solubility in water of 17 $\mu$g/L.

279. In addition, none of the concentrations of Siloxane D5 measured in effluent from WWTPs in Canada (Wang et al. 2010) exceeded its maximum solubility in water. This is noteworthy because some of the WWTPs in this study were selected from a much larger dataset to represent worst-case scenarios of release in Canada (Wang et al. 2010).

280. Taking into account the evidence before it, the Board prepared a probability plot of the concentrations measured in surface waters (Figure 2). The greatest measured concentration was 10-fold less than the maximum solubility of Siloxane D5 in water, which is also the NOEC for aquatic organisms. This is consistent with observations reported from other jurisdictions.

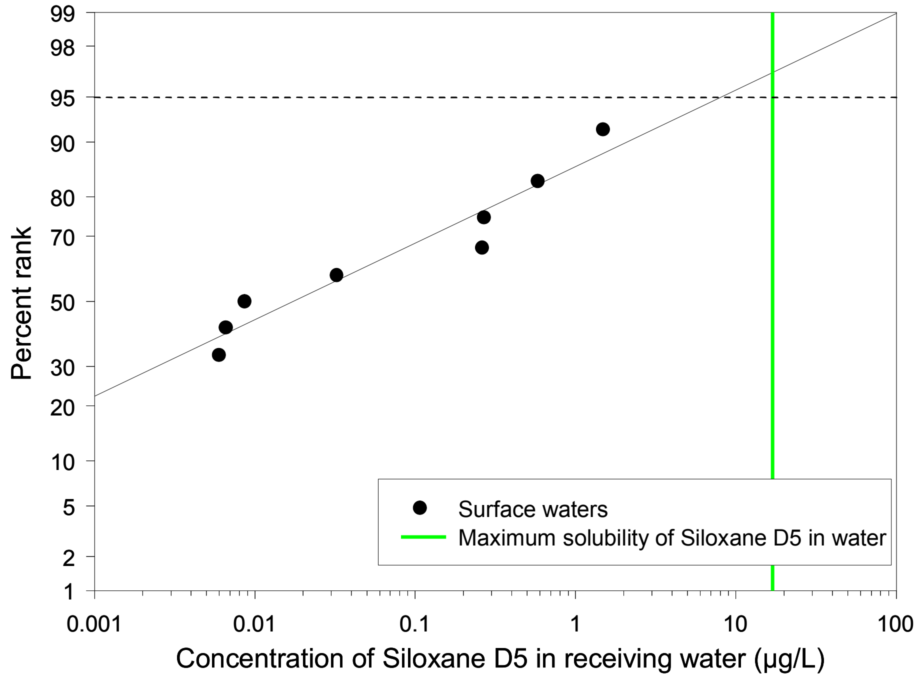


**Figure 2.** Concentrations of Siloxane D5 in Canadian surface waters within 3.1 km of discharges from waste-water treatment plants compared to the maximum solubility in water. The 95th centile is indicated by the horizontal dashed line.

281. Adverse effects of Siloxane D5 are not expected in aquatic organisms exposed to concentrations equal to or less than its maximum solubility in water. The Board has therefore concluded that concentrations of Siloxane D5 in surface waters present minimal risk and are not a danger to aquatic organisms, even in surface waters in proximity to discharges from WWTPs.

282. Based on an analysis of all the information presented to it, the Board concluded that there is no risk posed by Siloxane D5 to aquatic organisms. Indeed, no adverse effects were observed in aquatic organisms at concentrations equal to the solubility of Siloxane D5 in any matrix, which is the maximum concentration that can occur in the environment.

## *5.3 Danger to Sediment-dwelling Organisms*

283. Because of the strength of binding of Siloxane D5 to sediments and its relatively long half-life in this compartment of the environment (Xu 2011b), sediment-dwelling organisms are more likely to be exposed to Siloxane D5 than other organisms.

284. To assess risks to these organisms, the Board examined data on concentrations of Siloxane D5 in sediments sampled in close proximity (5 m to 3.1 km) to discharges from WWTPs in Canada (Wang et al. 2010). These samples of sediment were taken at the same time as the samples of water discussed in section 5.2 above and, from the tabulated values (Wang et al. 2010, Table 3), two or three separate samples of sediment were taken at each site. Each sample was analysed in duplicate or triplicate.

285. The geometric means of the replicated analyses were used to characterise concentrations of Siloxane D5 in the sediments. The multiple samples from each site were treated as independent so that the distribution of values obtained represented the spatial variance between and within sites. Because all samples of sediments were taken at about the same time, it was not possible to characterise temporal variance, such as seasonality.

286. Using the data in Table 5, the Board characterized the probability of concentrations of Siloxane D5 in sediments to exceed thresholds for toxicity to sediment-dwelling invertebrates. These are displayed in Figure 3. As there were multiple values for all of the species tested, the geometric mean was used to represent a single NOEC value for each species.

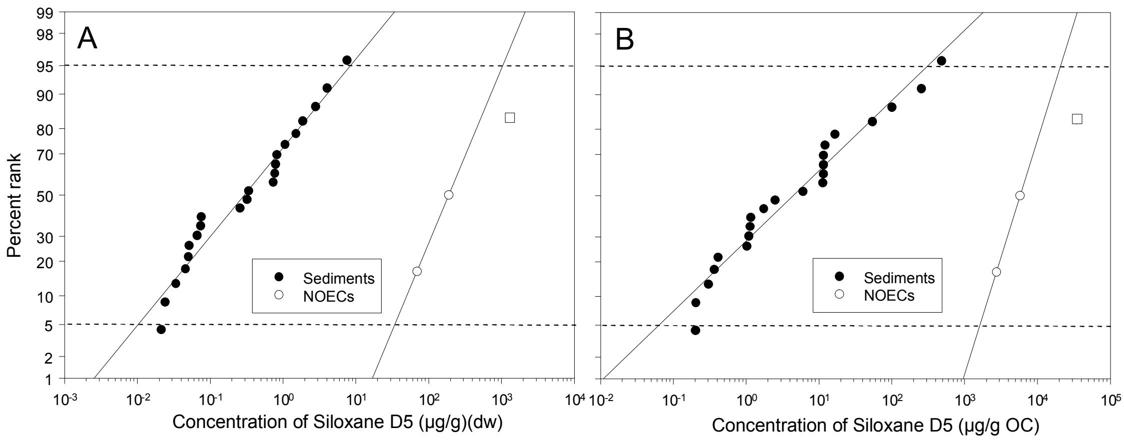


**Figure 3** Concentrations of Siloxane D5 in sediments from Canadian surface waters sampled within 3.1 km of discharges from waste-water treatment plants compared to NOECs for sediment-dwelling organisms. The 5th and 95th centiles are indicated by the horizontal dashed lines.

287. It was not possible to calculate a geometric mean for the mud-worm, *L. variegatus* ( symbol on graph), as both of the NOEC values were greater than the maximum concentration tested. However, these data for the mud-worm were included in the ranking but not included in the regression of the toxicity data. The Board used the Hazen equation to calculate the plotting positions.[10]

288. Regardless of the units of expression of exposure concentrations, the Board determined that risks were *de minimis*. For concentrations expressed in µg/g (dw), there is a 1% probability that the 5th centile of the distribution of NOECs will be exceeded (Figure 3A, Table 6). For concentrations expressed in µg/g OC, there is a 1.1% probability that the 5th centile of the distribution of NOECs will be exceeded (Figure 3B, Table 6).

**Table 6. Regression coefficients and intercepts for the *distribution* of NOECs for chronic exposures of sediment-dwelling organisms to Siloxane D5 and exposure concentrations in sediments from surface waters receiving effluents from WWTPs in Canada.**

| Parameter (units) | | | y = ax + b | | Centile intercepts (µg/g (dw) or OC) | | Probability of exceeding the 5th centile of the distribution of NOECs | |
|---|---|---|---|---|---|---|---|---|
| | n | r ² | a | b | 5% | 95% | (dw) | (OC) |
| NOECs (µg/g (dw)) | 3 | 1.00 | 2.22 | -5.05 | 34 | | | |
| NOECs (µg/g OC) | 3 | 1.00 | 2.98 | -11.21 | 1627 | | | |
| Conc. in sediments (µg/g (dw)) | 22 | 0.96 | 1.13 | 0.60 | | 8.4 | 1.0% | |
| Conc. in sediments (µg/g OC) | 22 | 0.96 | 0.89 | -0.58 | | 311 | | 1.1% |

In the above regression formula, "a" is the slope of the function and "b" is the y-intercept of the function. Data from (Wang et al. 2010).

289. These conclusions are based only on concentrations in sediments at locations in Canada. However, similar results were obtained when data from locations in other jurisdictions were included in the characterisation of exposures by use of a similar methodology to that discussed above (Fairbrother et al. 2011). Again, because a probabilistic approach was used, it is theoretically impossible to say there was no overlap between the distributions of measured concentrations in sediments and the toxicity values. Since no adverse effects were observed in any of the toxicity tests conducted up to the limit of solubility of Siloxane D5 in sediments, the Board concluded, based on the evidence before it, that there is no risk posed by D5 on sediment-dwelling benthic invertebrates.

## *5.4 Conclusions on the Nature and Extent of the Danger of Siloxane D5 to the Environment*

290. Taking into account the nature of Siloxane D5, its intrinsic properties, and all of the available scientific information, the Board concluded that Siloxane D5 does not pose a

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10 The Hazen equation (*p = (i – 0.5)/n x 100*) is used for smaller data sets (n <10).

danger to the environment. The Board also concluded that current concentrations of Siloxane D5 in the environment are at a quasi-steady-state. Consequently, concentrations of Siloxane D5 are expected to remain approximately constant over the long-term.

291. Due to its unique chemical and physical properties, mechanism of action, and lack of toxicity at concentrations less than its limit of solubility, it is virtually impossible for Siloxane D5 to occur in any environmental matrix at concentrations sufficient to produce harm to the environment. Thus, the Board concluded that Siloxane D5 does not currently pose a danger to the environment and that, based on the best available information, future uses of Siloxane D5 will not pose a danger to the environment.

# 6 Conclusions of the Board of the Review

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 Regulations for bioaccumulation.

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.

# 7 Costs

296. While the Board has the authority to award costs to a party in accordance with the Rules, the parties at the hearing indicated that costs were neither being sought nor were they appropriate in this case (Transcript of the Public Hearings, Vol. 9, pp. 1151 and 1213). In the circumstances of this case, the Board has decided not to award costs to any party.

# 8 Strengths and Uncertainties

297. Risk assessments will, by their very nature, contain some measure of uncertainty. New data provided by Environment Canada and the SEHSC/CCTFA have enabled the Board to conduct a more refined assessment.

298. The probabilistic nature of risk is such that absolute certainty of safety or of danger is not possible. However, the amount of information, scientific and other, now available for Siloxane D5 adds considerable strength to the assessment of risks posed to the environment. The additional data on toxicity and on concentrations in the environment have similarly allowed for better characterisation of these two critical parameters to the assessment of risk.

299. That said, the Board acknowledges that some uncertainties remain. Although the physical and chemical properties of Siloxane D5 strongly suggest that its only mechanism of toxicity is via general narcosis and physical interference with membranes, it could interact with unknown receptors or transport proteins or other chemicals present in the environment (mixture effect). The lack of effect in mammals and all other organisms, even at high doses or concentrations above the threshold for solubility, supports a conclusion that narcosis is the mechanism of action for Siloxane D5. This might not be true for classes of organisms other than those tested, but the Board considers this to be unlikely considering the similarities between species with respect to membranes, structures, and receptors.

# 9 Observations and Recommendations

300. During the course of this review, the Board was made aware of several matters about which it would like to offer comments. These comments are intended only to offer guidance to government and industry officials with respect to the framework within, and the conduct of, risk assessments.

## *9.1 Persistence and Bioaccumulation Regulations*

301. The Board encourages the Department(s) to regularly review, and update as appropriate, the Regulations. As evidenced by the new information that the Board was able to consider in this proceeding, advancements in sampling, measurement, and analysis provide new and refined techniques available to determine whether substances pose a danger to the environment (or human health). The Regulations should be reviewed periodically to ensure that they reflect current scientific standards and risk assessment methodologies.

302. The Board also is of the opinion that a guidance document should be issued by the Department(s) describing how parameters such as persistence, bioaccumulation, and intrinsic properties are examined in a risk assessment. Such a document should be developed in consultation with stakeholders and would provide a clear understanding of how the Department(s) interpret(s) the Regulations and would guide the conduct of science needed to address these requirements.

## *9.2 Availability and Transparency of the Models*

303. As discussed in section 4.2.1, models can be used to estimate releases to the environment, as well as their fate and distribution after release. Models can be of particular assistance when a chemical is being evaluated and there are limited empirical measurements of concentrations in the environment.

304. In the scientific community, it is generally accepted practice that models are fully specified and, to the extent possible, transparent. Consequently, the algorithms are fully described and the source code is accessible. Further, all input data provided to the model or tool and the output generated should generally be made available, subject to considerations respecting confidential information. When inputs to a model or tool do include confidential information, government officials should attempt to find ways that the model or tool and their inputs can be disclosed without revealing confidential information. In addition, the model or tool should be validated against measured data for the substance or for similar substances to those being tested.

305. The Board encourages Environment Canada to update its models or tools regularly and to seek the input of subject matter experts both within and outside the government to ensure the integrity of their models or tools and to ensure that both users and stakeholders are aware of the strengths and weaknesses of models or tools.

## *9.3 Conduct of Screening Assessments*

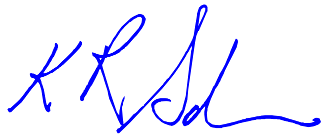
306. It was not within the Board's mandate to pronounce on the process followed by government and industry in the Screening Assessment. However, the Board did have some observations:

- It is appropriate for government officials to adopt a conservative or precautionary approach to ensure the protection of the environment and human health in the absence of a comprehensive data set and analysis.

- The Board strongly encourages industry and interested stakeholders to work diligently with government officials when screening assessments are being conducted in order to fill data gaps and provide relevant commentary and analysis.

DATED this 20th day of October, 2011

John P. Giesy, Ph.D., FRSC
Chair, Siloxane D5 Board of Review



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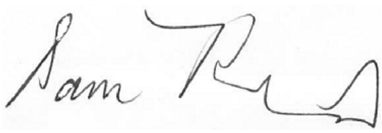
Member, Siloxane D5 Board of Review



Sam Kacew, Ph.D., Fellow ATS
Member, Siloxane D5 Board of Review

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# Appendices

## A. *Ministerial Notice Establishing the Board*

Canada Gazette, Vol. 144, No. 34 — August 21, 2010

*Establishment of a board of review for Decamethylcyclopentasiloxane (D5)*

Whereas a final screening assessment of Decamethylcyclopentasiloxane (D5), Chemical Abstracts Service Registry Number 541-02-6 ("the substance"), conducted pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* ("the Act"), was published pursuant to subsection 77(6) of the Act in the *Canada Gazette*, Part I, on January 31, 2009, and concluded, based on the available information, 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 meets one or more of the criteria set out in section 64 of the Act;

Whereas the Minister of the Environment ("the Minister") and the Minister of Health, pursuant to subsection 77(2) of the Act, recommended the substance be added to Schedule 1 to the Act;

Whereas the Minister and the Minister of Health, pursuant to subsection 332(1) of the Act, published in the *Canada Gazette*, Part I, on May 16, 2009, the proposed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999* ("the proposed Order") listing the substance and seven other substances to be added to Schedule 1;

Whereas the Silicones Environmental, Health and Safety Council of North America, pursuant to subsection 332(2) of the Act, filed with the Minister a notice of objection to the proposed Order and requested that a board of review be established under section 333 of the Act;

Whereas scientific information respecting the substance has been made available since the conduct and publication of the final screening assessment,

Therefore the Minister hereby establishes a board of review ("the Board") under subsection 333(1) of the Act, consisting of Dr. John Giesy as Chair, as well as Dr. Keith Solomon and Dr. Sam Kacew, to inquire into the nature and extent of the danger posed by the substance taking into account the Terms of Reference below.

TERMS OF REFERENCE

1. The Board shall inquire into the nature and extent of the danger posed by the substance and will be governed by the *Rules of Procedure for Boards of Review* established pursuant to section 341 of the Act.

2. The Board may conduct hearings and accept evidence or representations provided in person, in writing or in electronic form, including by teleconference or videoconference.

3. Hearings conducted in person shall be held in the National Capital Region described in the Schedule to the *National Capital Act*.

4. No funding to any person or party to the inquiry shall be provided.

5. The Board shall use the automated document management program specified by the Minister for the purpose of its inquiry.

6. The Board shall submit, on or before March 31, 2011, a report, together with its recommendations and the evidence that was presented to it, to the Minister.

## *B. Letter to the Minister of the Environment Extending the Deadline for the Board's Report*

The Honourable John Baird
Minister of the Environment
10 Wellington St.
Gatineau, Québec, K1A 0H3

November 12, 2010

Dear Mr. Minister:

I am writing to you with respect to the Siloxane D5 Board of Review ("Board") which was established on August 21, 2010 in the Canada Gazette, vol. 144, No. 34. In the Terms of Reference, the Board was directed to submit a report to you, together with its recommendation and the evidence that was presented, on or before March 31, 2011.

The Board has recently been informed by the Parties that important data and research will not be available for the Board, or opposing Parties, to review until the end of 2010 or early in the new year. The Board is committed to concluding a thorough and comprehensive review of the nature and extent of the dangers posed by Siloxane D5. To do so, the Board, and the Parties, will need an adequate period of time to review the data and research currently being prepared.

In view of this, the Board has determined that an extension of the time for submitting its report and recommendations to you is required. Therefore, the Board will deliver its report and recommendations, along with the evidence presented, on or before September 30 2011.

I want to assure you, Minister, that the Board is committed to discharging its mandate as expeditiously as the considerations of science and fairness permit. In my view, the extended timeframe will not have a significant impact on the costs associated with the review.

Yours truly,

John P. Giesy, PhD, F.R.S.C.
Chair, Siloxane D5 Board of Review

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

## C. *Letter from the Minister of the Environment received August 30, 2011*

Minister of the Environment     Ministre de l'Environnement

Ottawa, Canada K1A 0H3

RECEIVED
AUG 3 1 2011

Dr. John Giesy
Chair
Siloxane D5 Board of Review
269 Laurier Street West
6th Floor, Office 075
Ottawa ON  K1A 0K9

Dear Dr. Giesy:

I understand that the Siloxane D5 Board of Review is nearing completion of its report. As you know, the *Canadian Environmental Protection Act, 1999* requires that the report be made public immediately upon receipt.

In order to discharge that obligation and to respect the language rights of Canadians, please submit the report in English and French. Doing so will also ensure that all parties and the public will have access to the report at the same time.

Environment Canada can provide you with the necessary contract support for the translation. We are also prepared to provide you with the services of a fluently bilingual scientist of your choice, who would work under your direction and perform a comparative reading of both versions to ensure the accuracy and quality of the translation. You may also wish to apply a disclaimer to the French document indicating that it is a translation, and that in case of any discrepancy between the two versions, the authoritative report is the English one.

I am aware that the necessity of providing a translation may delay the delivery of the report by approximately three weeks. Therefore, I hereby extend the due date for its submission to October 31, 2011.

Sincerely,

The Honourable Peter Kent, P.C., M.P.

Canada

## *D. The Board's Interpretation of its Mandate*

BEFORE A BOARD OF REVIEW ESTABLISHED UNDER SECTION 333(1) OF THE *CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999*

**IN THE MATTER** of the *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 33;

**AND IN THE MATTER** of a final screening assessment of Decamethylcyclopentasiloxane (D5), Chemical Abstracts Service Registry Number 641-02-6, conducted pursuant to section 74 of the *Canadian Environmental Protection Act, 1999*;

**AND IN THE MATTER** of a recommendation by the Minister of the Environment and the Minister of Health that Decamethylcyclopentasiloxane (D5) be added to Schedule I to the *Canadian Environmental Protection Act, 1999* under section 77(2) of same;

**AND IN THE MATTER** of a proposed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999*, C. Gaz. 2009. I. Vol. 143, No. 20 in relation to Decamethylcyclopentasiolxane (D5);

**AND IN THE MATTER** of a request for a board of review under section 332(1) of the *Canadian Environmental Protection Act, 1999*, in which the Silicones Environmental, Health and Safety Council of North America is the Applicant and the Minister of the Environment is the Respondent and the Canadian Cosmetic, Toiletry and Fragrance Association and the coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba and the Crooked Creek Conservancy Society of Athabasca are intervenors.

SILICONES ENVIRONMENTAL, HEALTH AND SAFETY COUNCIL OF NORTH

AMERICA

Applicant

– and –

THE MINISTER OF THE ENVIRONMENT

Respondent

– and –

CANADIAN COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION and THE COALITION CONSISTING OF THE CANADIAN ENVIRONMENTAL LAW ASSOCIATION, THE INTERNATIONAL INSTITUTE OF CONCERN FOR PUBLIC HEALTH, CHEMICAL SENSITIVITIES MANITOBA AND THE CROOKED CREEK CONSERVANCY SOCIETY OF ATHABASCA

Intervenors

# SCOPE OF THE MANDATE OF THE BOARD OF REVIEW

| | |
|---|---|
| Board of Review Members: | John Giesy |
| | Keith Solomon |
| | Sam Kacew |
| Counsel to the Board of Review: | Gerry H. Stobo and |
| | Steven Kennedy, |
| | Borden Ladner Gervais LLP |
| Registrar: | Don Stewart |

## 1) Introduction and Summary Conclusion

1. On October 28, 2010, the Siloxane D5 Board of Review (the "Board") held a conference with the parties to the Review. In attendance were counsel representing Canada and the Silicones Environmental, Health and Safety Council of North America ("Silicones Council").

2. At the outset of the conference, the Board noted the broad mandate from the Minister of the Environment to inquire into the nature and extent of the danger posed by siloxane D5 and invited all parties to provide submissions as to their respective views on the scope of the Board's mandate. Counsel provided their views at that time. Subsequent to the conference, the Board requested the views of the two interested persons who were granted intervenor status, the Canadian Cosmetic, Toiletry and Fragrance Association ("CCTFA") and the coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba and the Crooked Creek Conservancy Society of Athabasca (the "Coalition").

3. The Board has considered the submissions of all parties in reaching its decision and has concluded that its inquiry will focus on the nature and extent of the danger posed by siloxane D5 to the environment or its biological diversity.

## 2) Background and Steps Leading to the Establishment of the Siloxane D5 Board of Review

4. A brief outline of the steps leading up to its establishment will help to provide context to the work of this Board. In 2008, the Ministers of Health and the Environment issued screening assessments of siloxane D4 and siloxane D5. The screening assessments considered whether, based on the information available at that time, siloxane D4 and/or siloxane D5 posed a danger to the environment and/or human health.[11] The screening assessment with respect to siloxane D5 concluded that:

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[11] The Environment Canada screening assessment of siloxane D4 concluded that the substance was "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

> Based on the available information on its potential to cause ecological harm, it is concluded that D5 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. Based on the available information on its potential to cause harm to human health, it is concluded that D5 is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.[12]

5. Following that screening assessment, an Order was issued in the *Canada Gazette, Part I*[13] on May 16, 2009 in which it was proposed that both siloxane D4 and siloxane D5 be added to Schedule 1 of the *Canadian Environmental Protection Act, 1999*,[14] ("CEPA"). On July 10, 2009, the Silicones Council filed a Notice of Objection requesting that a board of review be established pursuant to section 333 of CEPA for both siloxane D4 and siloxane D5.

6. On July 20, 2010, the Minister of the Environment wrote to the Silicones Council stating that he would not establish a board of review to consider the conclusions reached with respect to siloxane D4. However, the Minister went on to say that a further inquiry into the nature and extent of the danger posed by siloxane D5 was warranted considering the "...advent of information and data not previously examined."

7. Consequently, on August 21, 2010, the Minister issued a Notice in the *Canada Gazette, Part I*[15] (the "Notice") establishing the Board. That Notice stated, in part:

> Whereas a final screening assessment of Decamethylcyclopentasiloxane (D5), Chemical Abstracts Service Registry Number 541-02-6 ("the substance"), conducted pursuant to section 74 of the Canadian Environmental Protection Act, 1999 ("the Act"), was published pursuant to subsection 77(6) of the Act in the Canada Gazette, Part I, on January 31, 2009, and concluded, based on the available information, 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 meets one or more of the criteria set out in section 64 of the Act;

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diversity, but are not entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health." See Canada, Environment Canada & Health Canada, "PROPOSED RISK MANAGEMENT APPROACH for Cyclotetrasiloxane, octamethyl-(D4) Chemical Abstracts Service Registry Number (CAS RN): 556-67-2 Cyclopentasiloxane, decamethyl-(D5) Chemical Abstracts Service Registry Number (CAS RN): 541-02-6" (January 2009), online: Environment Canada, < http://www.ec.gc.ca/ese-ees/7026FB59-A1FD-4A3B-82EE-CA8180660867/batch2_556-67-2_rm_en.pdf> at 4.

[12] Canada, Environment Canada & Health Canada, "Screening Assessment for the Challenge Decamethylcyclopentasiloxane (D5) Chemical Abstracts Service Registry Number 541-02-6," (November 2008) online: Environment Canada <http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_541-02-6.cfm> [Screening Assessment].

[13] Vol. 143, No. 20 (16 May 2009).

[14] S.C. 1999, c.33.

[15] Vol. 144, No. 34 (21 August 2010) [*Notice*].

> Whereas the Minister of the Environment ("the Minister") and the Minister of Health, pursuant to subsection 77(2) of the Act, recommended the substance be added to Schedule 1 to the Act;
>
> Whereas the Minister and the Minister of Health, pursuant to subsection 332(1) of the Act, published in the Canada Gazette, Part I, on May 16, 2009, the proposed Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999 ("the proposed Order") listing the substance and seven other substances to be added to Schedule 1;
>
> Whereas the Silicones Environmental, Health and Safety Council of North America, pursuant to subsection 332(2) of the Act, filed with the Minister a notice of objection to the proposed Order and requested that a board of review be established under section 333 of the Act;
>
> Whereas scientific information respecting the substance has been made available since the conduct and publication of the final screening assessment,
>
> Therefore the Minister hereby establishes a board of review ("the Board") under subsection 333(1) of the Act, consisting of Dr. John Giesy as Chair, as well as Dr. Keith Solomon and Dr. Sam Kacew, to inquire into the nature and extent of the danger posed by the substance taking into account the Terms of Reference below.[16]
>
> [emphasis added]

8. While the Notice provides Terms of Reference for the Board's review, there is nothing in the Terms of Reference that specifically defines the scope of the Board's mandate. Accordingly, the Board decided to consider this matter and issue its determination on what it believes to be the scope of its mandate.

## 3) Positions of the Parties

9. In its submissions, Justice Canada stated that the broad powers granted to the Board by the CEPA allows it to carry out its mandate as a *de novo* review of the nature and extent of the danger posed by siloxane D5 and could encompass both issues of the environment and human health. That said, Justice Canada further noted that the Board could more effectively deliver on its mandate by narrowing its scope.

10. For its part, the Silicones Council stated that the Board's mandate should be restricted to issues of the nature and extent of the danger posed by siloxane D5 to the environment, as the screening assessment concluded that, based on the information available, siloxane D5 did not pose a danger to human health. Neither the Notice of Objection nor any new scientific evidence of which the Silicones Council was aware called this conclusion into question.

11. Both intervenors provided their respective views on the scope of the Board's mandate as well. CCTFA takes the position that the review should be limited to "elements of the environmental risk assessment for which new information is available". The Coalition stated that the Board should apply the Precautionary Principle in all aspects of its review, and should consider, *inter alia*, whether siloxane D5 biomagnifies up the food chain, the impact on the environment and human

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[16] *Ibid*. [emphasis added].

health of siloxane D5 and any other chemicals associated with its disposal and the long-term, cumulative impact of siloxanes D4, D5 and D6 on human health, and in particular, on vulnerable populations.

### 4) Analysis and Conclusion

12. Taking into account the background leading up to the establishment of the Board, and the views of parties, the Board has concluded that the scope of its review should focus on the nature and extent of the danger posed by siloxane D5 to the environment or its biological diversity.

13. The Board was established following the Minister's consideration of the Notice of Objection filed by the Silicones Council. The Notice of Objection indicated that new data and information related to the effects of siloxane D5 on the environment or its biological diversity were available to cast into doubt the conclusion reached by the government in the screening assessments.

14. While the Board recognizes the potentially broad scope of its mandate, at this point, it does not believe that issues related to human health should be the subject of this review. In reaching this decision, the Board took note of the preamble referred to above in the Notice dated August 21, 2010 where it stated that, according to the screening assessment, siloxane D5 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. There is no mention in the Notice to issues related to human health.

15. The Board also notes that even though the CEPA provides that a board of review may be established by the Minister of the Environment alone or in conjunction with the Minister of Health, the Notice states that the Minister of the Environment alone has established this Board.

16. Further, the Board has been advised by parties that the new data and information available following the issuance of the government's screening assessment relates only to environmental or biological diversity issues.

17. In coming to this decision, the Board has carefully considered the points that the Coalition raised in its submission where it proposed a broader scope of review. No doubt, some of the points they raise will be discussed during this process, including the precautionary principle. But other points, including the cumulative impact of siloxanes D4, D5 and D6 on human health, and their impact on vulnerable populations, as well as the human health issues they urge the Board to consider are not supported by new information and, in the Board's view, are beyond the mandate of this Board in this review.

18. While the Board will focus on issues related to the environment or its biodiversity, it reserves the discretion to revisit the scope of its inquiry following its review of the post-screening assessment data and information. Should these data and information indicate that matters related to human health should also be considered, the Board will inform the parties and provide them with an opportunity to address these issues.

DATED this 16th day of November, 2010

"John Giesy"

John P. Giesy
Ph.D., FRSC
Chair, Siloxane D5 Board of Review

"Keith Solomon"

Keith R. Solomon
Ph.D., Fellow ATS
Member, Siloxane D5 Board of Review

"Sam Kacew"

Sam Kacew
Ph.D., Fellow ATS
Member, Siloxane D5 Board of Review