
De: Karluss Thomas [kthomas@sehsc.com]
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À: Existing Substances Existantes [NCR]
Objet: Board of Review Request
Pièces jointes: Final boardofReviewRequest 10 July 09.pdf; Addendum.pdf; D5 Prolonged Tox Abstract.pdf; Environmental Monitoring Studies [Compatibility Mode].pdf

To: The Honorable Jim Prentice, P.C., M.P.
Minister of the Environment

c/o: The Executive Director
Program Development and Engagement Division
Department of the Environment
Gatineau, Quebec K1A 0H3

Dear Minister Prentice:

Please find attached a formal request from the Silicones Environmental, Health, and Safety Council of North America (SEHSC) for a Board of Review
in response to the Proposed Order to add Cyclotetrasiloxane, octamethyl- (D4) and Cyclopentasiloxane, decamethyl- (D5) to Schedule 1 of the
Canadian Environmental Protection Act, 1999; Canada Gazette Vol. 143, No. 20 — May 16, 2009. Attached to this note is the formal Board of Review
request along with accompanying support documents. Don't hesitate to contact me directly if you have any questions.

Best Regards,

Karluss

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July 10, 2009

The Honourable Jim Prentice, P.C., M.P.
Minister of the Environment
c/o The Executive Director
Program Development and Engagement Division
Department of the Environment
Gatineau, Quebec K1A 0H3

Re: Notice of Objection and Request for Board of Review in relation to the Proposed Order to add Cyclotetrasiloxane, octamethyl- (D4) and Cyclopentasiloxane, decamethyl- (D5) to Schedule 1 to the Canadian Environmental Protection Act, 1999; Canada Gazette Vol. 143, No. 20 — May 16, 2009

Dear Minister:

This submission responds to the May 16, 2009, Gazette Notice ("Notice") in which the Governor in Council, on the recommendation of the Minister of the Environment ("Minister"), proposed an Order to add Cyclotetrasiloxane, octamethyl- (D4) and Cyclopentasiloxane, decamethyl- (D5) to Schedule 1 of the Canadian Environmental Protection Act, 1999 ("CEPA") (hereafter referred to as "Proposed Order").[1] As provided for by section 332(2) of CEPA, the Silicones Environmental, Health and Safety Council of North America ("SEHSC")[2] is filing this Notice of Objection and respectfully requests that a Board of Review be established pursuant to section 333 of CEPA "to inquire into the nature and extent of danger"[3] posed by D4 and D5.

SEHSC maintains that a Board of Review is warranted as the Proposed Order to add D4 and D5 to Schedule 1 is based on final screening assessments ("Assessments") that have been conducted in a manner that is not consistent with the best available science. Use of the best available science would not have resulted in the conclusion that D4 and D5 "may cause adverse effects to aquatic organisms in certain Canadian environments" and "have the potential to cause ecological harm."[4] Regrettably, the

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[1] See Canada Gazette Vol. 143, No. 20 (May 16, 2009).
[2] SEHSC is a not-for-profit trade association comprised of North American silicone chemical producers and importers.
[3] CEPA § 333(1)(b).
[4] See note 1, above.

approach used in the final screening assessments over predicts D4 and D5 concentrations in Canadian surface water bodies, and predicts a larger proportion of these substances will reside in the water compartment relative to the other environmental compartments. This is inconsistent with environmental monitoring conducted by Industry and other governmental agencies[5] that have reported relatively low levels of the materials in the water compartment. In addition important new data relevant to EC's environmental assessment of D5 have become available that challenge Environment Canada's inherently toxic designation of D5.

In particular, and as discussed more fully below, instead of incorporating available, actual measured physical property data, unrealistic estimates for key inputs were used in modeling designed to predict where D4 and D5 will be found in the environment. Predicted environmental concentrations relied upon in the Assessments are an order of magnitude higher than both those observed in actual field monitoring studies and those predicted by the models based on these data[6]. Moreover, dilution factors used in predicting potential concentrations of the substances in Canadian waters were capped at low levels that may differ significantly from actual conditions.

Since the release of the Assessments, a recently completed aquatic toxicity study with D5 shows preliminarily that the substance is not inherently toxic to small fish following an extended exposure. Further, results from an on-going long-term fish toxicity study will soon be available that we expect will further demonstrate the lack of toxicity for D5 in the aquatic environment.

SEHSC recognizes the significant efforts on the part of Environment Canada staff in preparing the screening assessments for the chemicals that have been selected for review as a part of the Chemicals Management Program. We also acknowledge the high level of responsiveness Environment Canada staff has exhibited during this proceeding. SEHSC is also of the understanding that the CMP Advisory Panel considered D4 only in their review conducted in April/May of 2008 and not D5[7]. Given that addition to Schedule 1 has the potential to result in significant socioeconomic impacts, including severe global market impacts to Canadian companies importing, processing, and using these substances (regardless of how limited or narrowly focused control measures, if any, imposed through the pending risk management process turn out to be), a Board of Review should be convened to prevent a premature, inadequately supported Schedule 1 listing.[8]

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[5] See p. A-14 and following of the Addendum

[6] See p. A-14 and following of the Addendum.

[7] Chemicals Management Plan - Challenge Advisory Panel Summary Report From the meetings held April 11, 2008 and May 9, 2008.

[8] A listing on Schedule 1 by itself can result in product de-selection and other irreparable impacts even if only limited or narrowly-focused risk management measures are the eventual outcome of the risk management process.

Background

Underlying the Proposed Order is a finding by the Minister of the Environment that D4 and D5 meet the CEPA section 64 definition of "toxic." Under section 64 of CEPA, a substance is "toxic" if:

> it is entering or may enter 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; or
> - constitute or may constitute a danger to the environment on which life depends; or
> - constitute or may constitute a danger in Canada to human life or health.

Pursuant to section 74 of CEPA, the Ministers of Environment and Health prepared Assessments for D4 and D5, and the conclusions of these Assessments form the basis of the Proposed Order. With respect to potential human health impacts, the Ministers concluded that neither D4 nor D5 are "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."[9] Thus, neither substance was deemed to meet the CEPA section 64 definition of toxic based on human health concerns.

With respect to environmental concerns, the Ministers identified the substances as meeting the persistence criteria established in the *Persistence and Bioaccumulation Regulations* in certain environmental compartments. No conclusions were reached regarding bioaccumulation potential due to "conflicting evidence from laboratory studies and predictive models."[10] The Ministers concluded that for both D4 and D5 long term environmental exposure "may cause adverse effects to aquatic organisms in certain Canadian environments."[11] The substances were deemed to satisfy the CEPA section 64 definition of toxic based on an assertion that they are "entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity."

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[9] *Canada Gazette* Part I, Vol. 143 No. 5 (January 31, 2009).

[10] D4 Screening Assessment, p. ii; D5 Screening Assessment, p. iii.

[11] D4 Screening Assessment, p. iii; D5 Screening Assessment, p. iii.

SEHSC believes the conclusions regarding environmental concerns and the resulting Proposed Order are not consistent with the best available science. Further information concerning the basis for SEHSC's Objection and request for a Board of Review follows.

I. The Proposed Order is Inconsistent with the *Cabinet Directive on Streamlining Regulations* as It is Not Based on the Best Available Science

The *Cabinet Directive on Streamlining Regulations* specifies that the Government shall make decisions on "the best available knowledge and science in Canada and worldwide."[12] In this case, the Assessments prepared by Environment Canada are not based on the best available data and scientific knowledge regarding the environmental properties of D4 and D5.

Instead, the assessors relied upon conservative assumptions and modeling which is inconsistent with measured data and recognized scientific principles (*ie*., calibration of a model when actual field is available), which resulted in the development of unreasonable exposure scenarios.[13] In addition, new preliminary aquatic toxicity data have become available which address uncertainties identified in the D5 Assessment. These new data show D5 is not inherently toxic to small fish.[14] Furthermore, numerous additional environmental monitoring studies addressing the question whether D4 and D5 have the capability of biomagnifying in the environment (addressing the "B" Criterion) are currently underway and will be completed at the end of 2009.

In light of these considerations, moving forward on a Proposed Order that is based on overly precautionary assumptions and modeling using estimated input parameters as compared to the best and most current science would be inconsistent with the Government's own *Framework for the Application of Precaution in Science-based Decision Making About Risk* which mandates that "[s]ound scientific information and its evaluation must be the basis for applying precaution."[15]

II. The Underlying Assessments Rely Upon *Estimated* Physical Property Inputs and Overly Conservative Model Assumptions to Predict the Fate and Behavior of D4 and D5

To accurately evaluate the potential ecological impacts of D4 and D5, an understanding of whether D4 and D5 will actually be present in the environment and in

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[12] http://www.regulation.gc.ca/directive/directive01-eng.asp

[13] See section II, below.

[14] See section IV below.

[15] http://www.pco-bcp.gc.ca/index.asp?lang=eng&page=information&sub=publications&doc=precaution/precaution-eng.htm

which compartments (*e.g.*, air, water, soil) and at what levels is required. The Regulatory Impact Analysis Statement included with the Proposed Order states --

> Long-term environmental exposure to D4 and D5 may cause adverse effects to aquatic organisms in certain Canadian environments. Based on this evidence, it is concluded that D4 and D5 have the potential to cause ecological harm.

Implicit to this conclusion, which serves as the basis for the Proposed Order, is that the presence and behavior of D4 and D5 in environmental media is accurately characterized. A comprehensive discussion of this is provided in the Addendum – Detailed Comments on Environment Canada's Final Assessments for D4, D5, and D6 (hereinafter referred to as "Addendum") that SEHSC submitted to Environment Canada with its April 1, 2009 Comments on the Proposed Risk Management Approach Document for D4, D5 and D6.[16]

As described in the Addendum, the distribution of D4 and D5 in the environment that was reported in the Assessments could not be reproduced when the actual measured physical property data was used. The Assessments significantly overestimate the amount of the substances that will partition to the water compartment upon release.[17] The results of modeling conducted with actual measured data as inputs are markedly different and demonstrate that potential masses of D4 and D5 in the water compartment are significantly lower (*i.e.*, 3 to 4 times lower) than those predicted in the Assessments.[18]

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[16] A copy of this document is attached for your reference. As important technical details concerning the modeling conducted by Environment Canada did not become evident until publication of the Final Assessment, SEHSC was precluded from providing detailed comments on the analysis until we submitted comments on the Risk Management Approach document.

[17] Notably, the substances were inappropriately treated as non-volatile chemicals with estimated Type-2 partition coefficients. This treatment is inconsistent with their known properties. See pages A-3 and following of the Addendum for a detailed discussion of the problems with this approach and a comparison of the results utilized in the Assessments with those obtained using more scientifically-valid model inputs.

[18] Id. We note that in recognition of the challenges associated with modeling the cyclic siloxane materials, Don Mackay, Director Emeritus of the Canadian Centre for Environmental Modelling and Chemistry and Professor Emeritus Trent University (the leading Canadian expert on environmental modeling), Mark Bonnell (Environment Canada – who oversaw the modeling in the Assessments), and David Powell (Dow Corning) are collaborating on a paper, which has been accepted for presentation at The Society of Environmental Toxicology and Chemistry (SETAC) Annual Meeting this November, that addresses the modeling challenges posed by the materials. The paper will examine the use of the Equilibrium Criterion multimedia model (*i.e.*, the model used by Environment Canada in the Assessments) with cyclic siloxanes under various input scenarios (*e.g.*, assuming Type 1 versus Type 2 properties). It will include a comparison of results for D4 and D5 under differing input scenarios with those obtained from actual field measurements. Initial results suggest that the model needs to be updated to appropriately handle such substances.

The Assessments not only rely upon estimated model inputs to predict where the substances would end up if released into the environment (*i.e.*, partitioning to air, water, soil, sediment), but overly conservative dilution factors are also used to estimate the concentration of D4 and D5 potentially present in the water compartment. Given that water was identified as the compartment of concern, the impact of this unrealistically conservative approach is significant (assuming lower dilution rates yield higher predicted concentrations, while greater dilution rates result in lower predicted concentrations). We note that despite the fact that nearly 90 percent of the release scenarios considered in the Assessment would result in dilution factors of greater than 10, Environment Canada assigned 10 as the maximum factor it would consider in its modeling. In fact, the predicted environmental concentrations relied upon in the Assessments are an order of magnitude higher than both those observed in actual field monitoring studies and those predicted by the models based on these data[19].

III. A Conclusion that D4 and D5 meet the CEPA Section 64 Definition of "Toxic" is Premature Pending a Board of Review of all the available science on D4 and D5.

Environment Canada appears to base its conclusion that D4 and D5 qualify as "toxic" under CEPA section 64 on the alleged persistence and toxicity of the substances to aquatic organisms. We note, for instance, that in determining that D4 and D5 are persistent in certain water and sediment environments, the Assessments rely upon data obtained at standard study temperature and pH conditions and then extrapolated to more extreme conditions and compared to persistence criteria. As documented in the attached Addendum, this approach is problematic and not consistent with the latest guidance from scientific experts.

Also as discussed in section IV, below, new data are available that address the aquatic toxicity concerns with D5. In the Assessments, Environment Canada specifically cited the conflicting evidence from laboratory studies and predictive models with respect to the bioaccumulation potential of D4 and D5 and reasonably chose to refrain from making a decision on whether the substances meet the bioaccumulation criteria established in the *Persistence and Bioaccumulation Regulations* until it had an opportunity to review the new information from the on-going environmental studies. We believe the same prudential decision is warranted with respect to on-going studies regarding the toxicity of D5.

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[19] See p. A-14 and following of the Addendum.

IV. New Aquatic Toxicity Data Address Uncertainties Identified in the D5 Assessment and Refute An Overly-Precautionary Assertion that the Substance Poses a Hazard to Aquatic Organisms.

According to the D5 Assessment, "[t]he empirical data suggest that D5 does not exhibit adverse effects on fish and Daphnia at concentrations at or below its solubility limit (0.017 mg/L); however, "caution should be exercised in relation to these results" due to concerns about test duration, whether tissue concentrations achieved steady-state, and life-stage of the fish."[20] The Assessment goes on to conclude that D5 may potentially cause adverse effects to aquatic organisms and meets the CEPA section 64 toxicity criteria based on a determination 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."

New aquatic toxicity data are now available that demonstrate that D5 is not inherently toxic to fish. In particular, a recently completed study of the prolonged toxicity of D5 to juvenile rainbow trout during 45-day exposure under flow-through test conditions shows D5 is not toxic at concentrations up to its solubility limit (LC_{50} value > 17 µg/L).[21] These results are significant as they address the concerns raised in the D5 Assessment and further underscore that adopting an overly precautionary approach and finding that D5 may pose risks to fish is inconsistent with best available science.[22]

An additional chronic fish early life stage study is currently underway which will add to the knowledge concerning the substance's potential effects.[23] Preliminary results from this latest study are expected to be available this September.

We note that Section 4.4 of the Government's *Framework for the Application of Precaution in Science-based Decision Making About Risk* specifically provides that a re-evaluation of a risk decision may be triggered by the emergence of new scientific information. We believe the new toxicity data described above in combination with the detailed concerns documented in the attached Addendum regarding the modeling methods employed by Environment Canada in preparing the Assessments, qualify as information that demand such consideration. Accordingly, consistent with the *Framework*, we believe the Minister has a duty to grant a Board of Review to provide for a considered examination of the true nature and extent of danger, if any, posed by D4 and D5.

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[20] See p. 30, *Screening Assessment for the Challenge Decamethylcyclopentasiloxane (D5)*, Environment Canada, Health Canada, November 2008.

[21] Dow Corning Internal Study 2009-I0000-60763 - Decamethylcyclopentasiloxane (D5): Prolonged (45 days) Toxicity to the Rainbow Trout (*Oncorhynchus mykiss*) Under Flow -Through Test Conditions.

[22] These results also highlight that a simple read-across from D4 toxicity data is not scientifically appropriate for D5.

[23] Early Life-Stage Toxicity Test with Rainbow Trout (Oncorhynchus mykiss) Following OECD Guideline #210 and OPPTS Draft Guideline 850.1400

V. A Considered Risk Assessment Based on Robust Modeling and Actual Monitoring Data Demonstrates that Insufficient Evidence Has Been Provided that D4 and D5 Satisfy the CEPA Section 64 Definition of Toxic.

Under CEPA section 64, a substance may be deemed "toxic" if it has actual or potential exposure to the environment in quantities sufficient to have an immediate or long term harmful effect on the environment. As noted above, we believe that Environment Canada's finding that D4 and D5 meet this definition is based on inappropriate modeling analyses that overstate the substances' potential exposure and risk to the environment. Environment Canada's Assessments do not appear to incorporate the results of actual monitoring data or the most accurate information on how the substances behave in the environment.

In addition to providing a detailed critique of Environment Canada's Assessments, the attached Addendum includes an ecological risk assessment for D4 and D5 that is based on actual measured concentrations of the substances in water (from publicly available data), not on modeled values.[24] The results of this assessment show a low potential for risk to the aquatic environment for D4 and D5. Given the disparity between these results and those relied upon by Environment Canada, a thorough review of the basis for the Proposed Order is warranted.

The *Framework for the Application of Precaution in Science-based Decision Making About Risk's* mandate that a "credible scientific basis" must inform the Government's application of precaution to decision making. Given the divergence in findings between the risk assessment provided in the Addendum and those reported in the Assessments and in light of the fundamental scientific questions with the Assessments underlying the Proposed Order, and the emergence of new scientific data, a Board of Review is warranted to ensure the scientific credibility and validity of the D4 and D5 assessment process.

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[24] See p. A-14 and following of the Addendum.

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For the foregoing reasons, SEHSC objects to the Proposed Order and requests that a Board of Review be convened.

Sincerely,

Karluss V. Thomas

Karluss Thomas
Executive Director, SEHSC

Enclosures

1. Addendum
2. Fish Study Abstract
3. Table of Environmental Monitoring Studies

Addendum to SEHSC's Comments on the Risk Management Approach Document

Octamethylcyclotetrasiloxane (D4, CAS No. 556-67-2) and Decamethylcyclopentasiloxane (D5, CAS No. 541-02-6)

Comments on the Final Screening Assessments for

Octamethylcyclotetrasiloxane (D4, CAS No. 556-67-2),
Decamethylcyclopentasiloxane (D5, CAS No. 541-02-6) and
Dodecamethylcyclohexasiloxane (D6, CAS No. 540-97-6)

Addendum – Detailed Comments on Environment Canada's Final Assessments for D4, D5 and D6

Summary

SEHSC appreciates Environment's Canada's careful consideration of the available data for the cyclic siloxanes. Environment Canada indicates that the approach taken in this ecological screening assessment was to examine various supporting information and develop conclusions based on a weight-of-evidence approach and using precaution as required under subsection 76.1 of CEPA 1999. However, the conclusions presented in the Final Assessments for D4 and D5 are not consistent with the principles elucidated in the "Cabinet Directive on Regulation" and ignore the doctrine laid out the framework for the "Application of Precaution in Science-based Decision Making About Risk." Similarly, the conclusions found in the Final Assessment don't appear to apply the WoE approach required by section 76.1 of CEPA. All three of these directives provide clear guidance with regard to the use of precaution in science-based regulatory decisions and state that balance is required. In their final assessments, the Minister of the Environment appears to have used the principle in a manner that would not be supported by its original intent – to act as a bridge in the absence of scientific certainty where there is sufficient evidence to allow a conclusion to be "reasonable" as outlined in the "Application of Precaution in Science-based Decision Making About Risk." Instead, we believe the assessments conclusions are based on environmental exposure scenarios that fail to recognize that D4 and D5 behave in the environment differently than what can be identified by the standard default models and laboratory screening studies.

The ecological risk predicted by Environment Canada is predicated on inaccurately modeled estimates. SEHSC requests that the modeling approach used by Environment Canada for predicting environmental concentrations of D4 and D5 be reassessed, as this will impact the risk quotients (RQs) upon which the need for RM measures is based. In addition, it is important that actual measured environmental monitoring data be used to calibrate the modeling approach for understanding true environmental concentrations.

Environment Canada's assessments of D4 and D5 do not identify a measurable existing environmental hazard posed by these materials. In addition, the modeling approach used to determine environmental exposure inappropriately overestimates environmental concentrations.

While the final screening assessments did consider the scientific data provided by SEHSC, it does not specifically identify any environmental hazard that would be reduced or eliminated by risk management options. In the assessments, the approach taken was to perform a quantitative risk quotient evaluation of exposure and of ecological effects. Environment Canada examined field measurements of the D4 and D5 in water, but then used predicted environmental concentrations (PECs) of aquatic exposure for approximately 1000 municipal discharge sites for comparison to the predicted no effect concentrations (PNEC) to calculate risk quotients values for each compound. Environment Canada calculated predicted environmental concentrations (PECs) for the water compartment based on the use quantities identified from the section 71 survey submissions and estimates of releases from individual industrial sites and from consumers. The assessment conclusions are based on environmental exposure scenarios that fail to recognize that D4 and D5 behave in the environment differently than what can be identified by the standard default models and derived parameters and are overestimated for the aquatic environment. SEHSC recently (March 27, 2009) consulted with Don MacKay (Director Emeritus of the Canadian Centre for Environmental Modelling and Chemistry and Professor Emeritus Trent University) to assess the appropriate approach for modeling cVMS. The guidance provided was that given the chemical-physical properties of these materials a Type-1 or Type-3 chemical assignment was more appropriate than a Type-2 assignment. **SEHSC therefore requests that the modeling approach used by Environment Canada for predicting environmental concentrations of D4 and D5 be reassessed.**

SEHSC also requests that Environment Canada consider the actual exposure of the aquatic environment to D4 and D5, utilizing the monitoring data already available as well as the data that will become available prior to the end of 2009. The results of these environmental monitoring programs, reflecting actual measures rather than predicted values can be used to calibrate the environmental modeling approach used to predict behavior of these materials. A risk assessment using this approach is provided below.

Releases to the Environment and Environmental Fate

Air releases of cVMS substances were also mentioned in the Risk Assessments. SEHSC agrees with Environment Canada that these types of releases do not significantly contribute to the environmental exposure of cVMS substances as greater than 98 percent of the cVMS evaporate very quickly. Once in the atmosphere, the cVMS do not create or destroy ozone. They bind to particles, and may be transported long distances, but are degraded by hydroxyl radicals in the air and do not back-deposit. Monitoring data and published environmental studies, some of which were cited in the assessments, indicate that air concentrations at locations remote from point sources are very low to non-detectable.

Assessment documents provided by Environment Canada provide tabular summaries of results from the EQC (ver 2.02) Level III fugacity modeling for D4 (Table 4, page 11) and D5 (Table 4, page 13). The documents state that the fugacity modeling was based on the input parameters listed in Appendix 5, but does not specify if the materials were modeled as Type-1, -2, or -3 chemicals. Our understanding is that siloxane materials should be modeled as Type-1 chemicals (i.e., chemicals that partition into all environmental media) or as Type-3 chemicals (i.e., chemicals that partition into air, biota, and solid phases such as soil and sediment, but are essentially insoluble in water) if the Type-3 partition coefficients are available. However, we are only able to reproduce the values in the results tables when modelling D4 and D5 as Type-2 chemicals using the Type-2 partition coefficients listed in Appendix 5.

We were informed that Environment Canada modeled D4 and D5 as Type-2 chemicals based on the recommendations from Dr. Don Mackay at the Canadian Environmental

Modeling Centre at Trent University (CEMC). We have discussed this with Dr. Mackay and he was not aware of any discussions that he or anyone in CEMC may have had with Environment Canada concerning the siloxane materials. Moreover, he indicated that if he were asked for a recommendation that he would not have assigned D4 and D5 as a Type-2 chemicals since Type-2 substances have zero (or very low) vapor pressures such that air-to-water partition coefficients (Kaw; also known as the non-dimensional Henry's Law constant) can not be determined. Clearly, D4 and D5 do not fit the description or category of a Type-2 substance. As reported in Appendix 5 of the Screening Assessment Documents, D4 and D5 have relatively high vapor pressures and measured Kaw values are available for both materials. It is unclear as to why Environment Canada would have assigned and modeled D4 and D5 as Type-2 chemicals.

If D4 and D5 are modeled as Type-1 chemicals using the Type-1 properties in Appendix 5 (vapor pressure adjusted so that Kaw is equal to the measured value reported in Appendix 5), substantially different results are obtained. The results in the tables below show that modeling of D4 and D5 using Type-2 partition coefficients, relative to Type-1 properties, overestimates the amounts that will partition to the water compartment and underestimates the amounts that will partition to the soil and sediment compartments.

EQC results for D4 modeled as a Type-2 and Type-1 chemical (Vp = 232 Pa)

Compartment of emission	Percentage of substance partitioning into each compartment							
	Air		Water		Soil		Sediment	
	Type-2	Type-1	Type-2	Type-1	Type-2	Type-1	Type-2	Type-1
Air (100%)	100.0	99.7	0.0	0.0	0.0	0.3	0.0	0.0
Water (100%)	13.7	1.1	72.2	16.6	0.0	0.0	14.2	82.3
Soil (100%)	88.5	11.2	0.0	0.0	11.5	88.8	0.0	0.0

EQC results for D5 modeled as a Type-2 and Type-1 chemical (Vp = 154 Pa)

Compartment of emission	Percentage of substance partitioning into each compartment							
	Air		Water		Soil		Sediment	
	Type-2	Type-1	Type-2	Type-1	Type-2	Type-1	Type-2	Type-1
Air (100%)	100.0	99.7	0.0	0.0	0.0	0.3	0.0	0.0
Water (100%)	5.5	0.0	38.9	12.1	0.0	0.0	64.7	87.8
Soil (100%)	71.2	0.9	0.0	0.0	28.7	99.1	0.0	0.0

If the chemical partitioning properties are in thermodynamic balance with the physical-chemical properties, output from the EQC model should be the same regardless if Type-1, Type-2, or Type-3 chemical properties are used. We are not aware of any measured Type-2 partition coefficients that are available for D4 and D5, so we can only assume that the values identified in Appendix 5 of the screening assessment documents represent estimated values. However, it is not identified in the documents how the Type-2 partition coefficients were obtained. If we use the EQC model to estimate the Type-2 partition coefficients from measured Type-1 properties, the values differ by 2-3 orders of magnitude, as shown in the tables below. This indicates that the Type-2 partition coefficients listed in Appendix 5 of the screening assessment documents are not in thermodynamic balance with the measured Type-1 properties listed in the Appendix. This also leads to the conclusion that the fugacity modeling should have been based on Type-1 properties rather than Type-2 partition coefficients.

D4 Type-2 partition coefficients used by Canada compared to Type-2 partition coefficients estimated from the EQC model using measured Type-1 properties. Values are expressed in Log units.

Partition coefficient	Type-2 properties (Canada)	Type-2 Properties (EQC Model)
Air-water (dimensionless)	2.69	2.69
Soil-water (L/kg)	2.52	4.40
Sediment-water (L/kg)	2.82	4.70
Suspended particles-water (L/kg)	3.52	5.40
Fish-water (L/kg)	4.13	5.19
Aerosol-water (dimensionless)	2.00	4.41

D5 Type-2 partition coefficients used by Canada compared to Type-2 partition coefficients estimated from the EQC model using measured Type-1 properties. Values are expressed in Log units.

Partition coefficient	Type-2 properties (Canada)	Type-2 Properties (EQC Model)
Air-water (dimensionless)	3.13	3.13
Soil-water (L/kg)	3.47	5.94
Sediment-water (L/kg)	3.77	6.25
Suspended particles-water (L/kg)	4.47	6.94
Fish-water (L/kg)	4.12	6.73
Aerosol-water (dimensionless)	2.00	4.59

Characterization of Ecological Risk

In Environment Canada's assessments of D4 and D5, the approach taken was to perform a quantitative risk quotient evaluation of exposure and of ecological effects (or potential hazard). Environment Canada examined field measurements of the D4 and D5 in water, but then used predicted environmental concentrations (PECs) of aquatic exposure for approximately 1000 municipal discharge sites for comparison to the predicted no effect concentrations (PNEC) to calculate risk quotients values for each compound.

Environment Canada calculated a predicted environmental concentration (PEC) for the water compartment based on the use quantities identified from the section 71 survey submissions and estimates of releases from individual industrial sites and from consumers. In addition, Environment Canada used Type-2 chemical partitioning properties to evaluate the environmental fate of D4 and D5 after this release. It is not known why Canada did not use Type-1 or Type-3 chemical partitioning properties for the evaluation, which would be more appropriate for this class of materials. Measured Type-2 chemical partitioning properties for D4 and D5 do not exist. When D4 and D5 were modeled using **measured** Type-1 chemical partitioning properties, the results are significantly different from the results Environment Canada obtained using **estimated** Type-2 chemical partitioning properties. Canada appears to overestimate the amounts of D4 and D5 that partition to the water compartment. The net result is that the predicted environmental concentrations (PECs) are overestimated for the aquatic environment.

In the Aquatic Risk Distribution Environment Canada have their dilution factor capped at 10. It is unclear why Environment Canada took this very conservative approach. Using data that was used to develop the model being used there are 585 records which include the population served, flow, and type of treatment. Using Environment Canada's factor of 3 to account for low flow compared to average flow which is what is available, then about 522 of the 585 or about 89% have dilution factors > 10. How was a cap in the dilution factor of 10 determined because the data on actual STP releases and river flows from Canadian Water and Wastewater Association suggest that this is highly conservative?

It is also not clear what removals Environment Canada is using for the various types of STP. We would assume that the stabilization ponds, secondary and tertiary treatments would be similar to the ASTREAT predictions for activated sludge of 44% to sludge, 53% to air and 3% to effluent.

Environment Canada also acknowledges uncertainty particularly concerning the assessment of D5. They indicate that "although a risk quotient analysis was conducted for D5, the empirical ecotoxicity evidence suggests that the threshold at which adverse effects in pelagic biota is expected to occur has not been observed in available toxicity tests. Therefore the risk quotients calculated in the above scenario are essentially "unbounded" and **may not represent "real" observable effects expected at the above sites."**

In our analysis of ecological risk for D4 and D5, we focused on producing an aquatic risk distribution as well, but our intent was a risk distribution or probability based on **measured** concentrations of each chemical in water, not PECs, and a subsequent comparison to EC's projected PNEC values to examine risk. Fundamentally, a probabilistic assessment of what is the likelihood of an adverse effect occurring from the concentrations of D4 and D5 that are actually being found in the environment. Based on this assessment there is a low potential for risk to the aquatic environment for D4 and D5.

SEHSC also believes that ongoing environmental research and monitoring will substantiate this position and that is it crucial to wait for that data before making any final recommendations on risk management for D4 and D5.

SEHSC scientists have developed a cooperative relationship with Environment Canada scientists to share technical knowledge of sample collection and analytical methods for cVMS. Workshops, presentations at scientific meetings, shared sample-collection expeditions, and cooperative technical guidance form a background for gaining a better understanding of the unique properties of silicone materials and the real-world behaviors of D4 and D5. This relationship is a part of SEHSC's on-going environmental monitoring in the US and Canada (in Toronto Harbor, Lake Ontario, Lake Pepin, Lake Opeongo, and other sites). The EC scientists who participated in the 1st Annual Workshop on Siloxanes in the Environment, held March 27 & 28, 2008 in Burlington, ON, agreed on, and had encountered, the same difficulties in working with these materials both in laboratory studies and in the collection, storage, and analysis of environmental samples. The 2nd Annual Workshop on Siloxanes in the Environment is currently scheduled for April 20-21, 2009 in Burlington ON. Scientists from around the world will be participating in this workshop and discussing the challenges of monitoring for cVMS.

SEHSC has already committed to a comprehensive research and environmental monitoring program in consultation and collaboration with scientists from Environment Canada and other regulatory agencies around the world. Collaborative monitoring programs also are on-going with Norway and the Polar Research Institute, Sweden, and the UK. Focused scientific workshops and scientific forums at SETAC and SETAC Europe further the information exchange between the silicone industry scientists and the scientists in regulatory agencies in North America and Europe on key aspects of quality control, sampling, storage, and transport issues, and analytical techniques. As significant effort has already been invested into this program, SEHSC proposes a more formal joint effort between Environment Canada and key stakeholders. This joint agreement could be developed through the Consultation process with all key stakeholders. This would allow utilization of already developed analytical methodologies and inputs from experts around the world. This underscores the need to comprehensively assess how D4 and D5 behave in the environment before any RM approaches are determined and any socio-economic impacts occur.

Persistence and Bioaccumulation Potential

Persistence Potential of D4 and D5

The D4 and D5 Final Screening Assessment assumed a read-across to cooler temperatures from laboratory sediment studies conducted at standard study temperatures. Based on this they concluded that the lack of fast degradation of D4 and D5 under some environmental conditions, especially in colder Canadian environments, will result in a half-life in sediment of $t_{1/2}$ > 365 days. In addition for D5, they suggest D5 is expected to persist for relatively long periods at low temperatures and neutral or slightly acidic water conditions in Canadian waters (pH 6–7, temperature 5–10°C). A recent focus on evaluating persistence of organic compounds in environmental media (air, water, soil, sediment) in terms of their single-medium degradation half-lives was undertaken to provide guidance to reviewers of chemical dossiers for POPs and PBTs proposed for action (SETAC, 2008); some of the workshop findings were presented by Dr. R. Boethling, US EPA, Washington, DC, USA at the 2008 SETAC North America Annual Meeting. Dr. Boethling noted the following:

> *Persistence is determined by a range of transformation processes acting in concert. At the screening level, pH and temperature adjustment does not seem necessary. Further, the question of pH and temperature correction also needs to be addressed in the light of the original intention leading to the selection of the present set of persistence (half-life) criteria. Two intentions seem to have contributed to the selection of the final values. The first was to avoid widespread use of chemicals with properties closely resembling those of "known" POP-type compounds. This approach is often termed the "reference chemical approach". The second was to ensure that levels of a given chemical would significantly decrease within a reasonable timeframe, e.g. within a year, once its emission was reduced or stopped entirely. This approach is also known as the "management approach". It is reasonable to assume that cut-off criteria defined according to the "reference chemical approach" are related to available half-life data for known POPs. Since these half-lives are likely to have been derived under laboratory conditions,* ***these are the conditions for which the comparison should take place****. According to the "reference chemical approach" temperature and pH correction therefore does not seem justified.*

If Environment Canada were to apply the "reference chemical approach" at the screening level as it was originally intended then D4 would not be considered persistent in water or sediment and D5 should not be considered persistent in water or sediment (based on read across as applied by Environment Canada in this assessment). It appears that Environment Canada advanced to the "management approach" when D4 and D5 did not meet the original screening criteria according to the "reference chemical approach" which seems overly precautionary compared to recent expert conclusions.

Dr. Boethling's observations are consistent with the field and laboratory findings on D4 and D5, where studies have shown that most cVMS are eliminated by sewage treatment plants (STP), either by evaporation or by binding to particles in the sludge and Nordic monitoring results indicate that little is present in the effluent waters (e.g., 0.06-0.98 ppb D5). Similarly, data from Lake Pepin, MN and Lake Opeongo in Canada also have cold water climates, but do not show elevated cVMS concentrations in water. Lake Ontario has detectable levels close to wastewater outflows in Toronto Harbor, but do not demonstrate significant levels beyond the immediate outflow areas.

Bioaccumulation Potential of D4 and D5

Environmental exposure of aquatic organisms to lipophilic compounds may occur through the water column, food, and sediment. However, uptake of highly hydrophobic or lipophilic chemicals (*i.e.*, log K_{OW} values greater than ~5) from water is considered to be negligible for most fish, compared to uptake via consumption of contaminated foodstuffs (Bruggeman *et al*., 1984; Muir *et al*., 1985; Thomann, 1989; Nichols *et al*., 2004). A compound is said to 'biomagnify' when lipid-normalized concentrations (or fugacity) of accumulated chemical residues in biological organisms increases with increasing trophic position (Fisk *et al*., 2001; Hu *et al*., 2006). It has been proposed that bioaccumulative substances be defined as substances which biomagnify in the food web - *i.e*., lipid-normalized concentrations (or fugacity) increase with increasing trophic position (Gobas *et al*., 2008). Based on this definition, it was concluded that that the most relevant criterion for assessing chemical bioaccumulation was the Trophic Magnification Factor (TMF), and that the most conclusive evidence to demonstrate that a chemical substance biomagnifies was a TMF > 1 (SETAC, 2008).

TMFs are derived from the slope of the regression of log lipid-normalized concentrations of the chemical in organisms from a food web versus their trophic level. As such, a TMF represents the trophic level increase of a chemical substance that is averaged across the food web rather than a single predator-prey relationship. Consequently, TMFs are preferable to single predator-prey relationships for comparing biomagnification between ecosystems and are particularly useful for comparing bioaccumulation of individual chemicals within a well-defined food web. In addition, TMFs may be broadly applied across systems that differ considerably in their location and characteristics (Houde *et al.*, 2008).

Biomagnification of cyclic volatile methylsiloxane (cVMS) materials, specifically, D4, D5, and D6, was determined in Lake Pepin, Minnesota, a natural flood-plain lake on the Mississippi River located approximately 80 km downstream from the Twin Cities of Minneapolis and Saint Paul, Minnesota USA (Powell and Woodburn, 2009). TMFs for the three cVMS materials were determined for a benthic invertebrate-to-fish food web using the stable isotopes of nitrogen ($\delta^{15}N$) and carbon ($\delta^{13}C$) to estimate trophic positions and carbon flow to consumers (Post, 2002; Jardine *et al*., 2006). Several key points should be noted from the Lake Pepin cVMS field results (Powell and Woodburn, 2009):

- In the Lake Pepin food web, lipid-adjusted concentrations of D4, D5, and D6 all declined with increasing trophic level. This indicates that bioaccumulation of these cVMS compounds is <u>not</u> due to simple water-to-lipid partitioning, *i.e*., bioconcentration via the gills. If bioconcentration was the dominant process for bioaccumulation, the lipid-normalized cVMS concentrations should be approximately equal across the various organisms of the food web. The Lake Pepin data show that simple water-to-lipid partitioning was <u>not</u> the key process for accumulation, thereby demonstrating that the bioconcentration process was not highly pertinent to uptake of D4, D5, and D6 into aquatic organisms. Hence, bioaccumulation of D4, D5, and D6 in the Lake Pepin food web occurred predominately via dietary biomagnification processes controlled by food uptake and associated mitigation processes such as metabolism, growth dilution, low uptake and assimilation efficiencies, and reduced bioavailability due to chemical sorption in the water/sediment phase(s). Collectively these mechanisms led to TMF values of 0.30, 0.16, and 0.14 for D4, D5, and D6, respectively. The results from Lake Pepin showed that cVMS materials undergo trophic dilution in aquatic food webs, *i.e*., TMFs < 1 are indicative of materials that do not biomagnify and are considered to be non-bioaccumulative (SETAC, 2008). In conclusion, the Lake Pepin field data demonstrate that laboratory BCF values for the three cVMS materials are not appropriate measures for regulation of the 'B' potential of these chemicals, as dietary uptake predominates. As noted by Environment Canada (EC), the laboratory BMF values for D4 and D5 are <1, and the Lake Pepin TMF field data <1 confirm that the laboratory BMFs are more appropriate and suitable measures of the ‘B’ trophic dilution processes observed for the cVMS materials.

- The hierarchical ranking of ‘B’ with (1) TMF, (2) BMF, and then (3) BCF measures for cVMS materials was reinforced by findings from a recent SETAC workshop on bioaccumulation processes (SETAC, 2008); some of the workshop findings were presented by Dr. Frank Gobas of Simon Frazier University at the 2008 SETAC North America Annual Meeting. Dr. Gobas noted the following:

  “*Despite the lack of a recognized definition for a B substance, we defined a B(ioaccumulative) substance as a substance which biomagnifies in the food-web, i.e. increases in normalized concentration (or fugacity) with increasing trophic position.* ***It was concluded that the most relevant B criterion is the TMF (Trophic Magnification Factor), and that the most conclusive evidence to demonstrate that a chemical substance biomagnifies is a TMF > 1 (emphasis added)****. In absence of data on the TMF, the BMF (i.e., Biomagnification Factor) is an indicator of the chemical’s potential to biomagnify through the food chain. While the BCF is generally used to characterize B substances, the BCF is not a good surrogate for BMF or TMF in terrestrial food-webs. The BCF is an acceptable surrogate for the BMF or TMF in aquatic food-webs if the route of exposure (water vs. diet) does not affect biotransformation rate of the chemical in the organisms and if bioavailability issues are not introducing significant experimental artifacts”* (Gobas *et al*., 2008).

Dr. Gobas’s observations are consistent with the field and laboratory findings on D4 and D5, where laboratory-measured BMF values <1 were predictive of field behavior (*i.e*., Lake Pepin TMF values <1 for all three materials). This finding correlates with research from the scientific literature, which indicates that uptake of highly hydrophobic chemicals (log K_{OW} >5) from water (*i.e*., bioconcentration) is considered to be negligible for most aquatic species, compared to uptake via consumption of contaminated foodstuffs (Bruggeman *et al*., 1984; Muir *et al*., 1985; Thomann, 1989; Nichols *et al*., 2004).

- An in-depth modeling analysis of the TMF data from Lake Pepin, MN (USA) has been performed by HydroQual (2009), on behalf of the Silicone Health Environment and Safety Council; this report is attached. The field data were modeled using the Thomann-Farley bioaccumulation/foodchain model (Thomann *et al*., 1992), available through Manhattan College (http://mciwpc.org/); this model is functionally similar to other foodchain models (Arnot and Gobas, 2004). A necessary modification made to the model was to exclude the standard relationship used to estimate chemical assimilation efficiency based on log K_{ow}, as this equation significantly overestimated the uptake efficiency for the cVMS materials; the modeled efficiency used to successfully fit the Lake Pepin field data for D4, D5, and D6 was 10%. In addition, the modeled gill uptake efficiency varied between 50% for D4, 15% for D5, and 1.5% for D6. A composite cumulative loss (metabolism + elimination) rate constant (k_{loss}) was set at approximately 0.01 (day^{-1}) for D4 and D5, and zero for D6. In brief, the model was able to successfully describe the field data, illustrating that the primary route of exposure was through the diet (>50% for D4 and >90% for D5 and D6), and not bioconcentration via the water column. In addition, the model predicts cVMS concentrations in fish decline over time, due to growth and elimination rates that are faster than the rates of accumulation from diet and water exposures; this effect is largely due to poor dietary assimilation. The paper concludes by examining the unique physico-chemical properties of cVMS compounds that may play a part in their limited uptake rate across membrane interfaces and suggests that a combination of high hydrogen bonding basicity (*i.e.*, high Abraham hydrogen bond B values) and high log K_{ow} values (>5) is consistent with limited gut uptake rates (Lipinski *et al*., 1997).

Fish Metabolism rates for D5

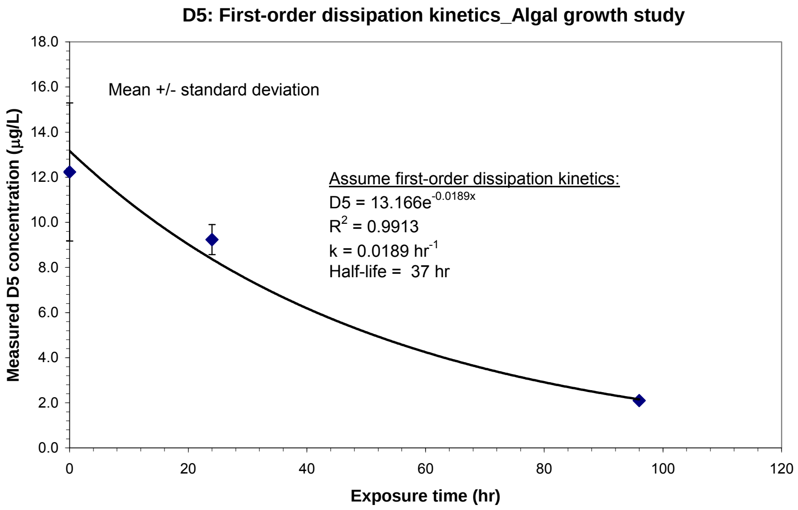
There appears to be some confusion regarding the fish metabolism of D5 and, given the complexity of the information submitted to EC, this is understandable. In the work of Springer et al. (2007) and Domoradzki et al. (2007), ^{14}C-D5 was administered to adult rainbow trout (~1 kg) in a bolus dose via oral gavage at ~12 µg/g bw and followed via blood and tissue monitoring for 96 hours. Of the recovered ^{14}C activity, 75% was eliminated via the feces and only 25% was absorbed by the fish; of the absorbed ^{14}C activity, 14% was attributed to D5 metabolites collected in the fish (blood, gastrointestinal tract, bile, urine, liver tissue, gonads, and fat). A subsequent examination of the data by Woodburn and Domoradzki (2008) used pharmacokinetic compartmental modeling of the ^{14}C-D5 and metabolite residues to determine explicit elimination and metabolism rate constants (i.e., k_2 and k_m values, respectively) for D5 in trout. This model used the measured ^{14}C measured concentrations of parent D5 and total metabolites in fish blood collected at regular intervals during the 96-hour study. Research has shown previously in work with hydrophobic organic compounds in fish that blood concentrations of such compounds are routinely used to reflect both the magnitude and kinetics of chemical concentrations expressed on a whole-body basis (Barron et al., 1991; Barron et al., 1993; Nichols et al., 2004). In summary, Woodburn and Domoradzki (2008) calculated a trout metabolism rate constant (k_m) of ~0.007 hr^{-1} (0.17 day^{-1}) for ^{14}C-labeled D5 by using a simple compartmental model and available data on D5 and metabolites in trout blood; this fish metabolism rate constant is consistent with the collected trout blood residue data over 96 hours.

Ecological Effects Assessment

Request for reconsideration of D5 Algal Growth Study:

Acute and chronic studies with D5 on rainbow trout and daphnia were reviewed by EC and deemed acceptable for use in the screening assessment. All of the studies reviewed had no-effect concentrations (NOECs) at the limit of D5 functional water solubility (~15 µg/L or ppb) or at the highest concentration that could be maintained in the test. Sediment acute and chronic studies with chironomids (midges) and *Lumbriculus sp.* were also reviewed and considered valid for use in the screening assessment. The only study for D5 classified as ‘invalid’ by EC was a 96-hr algal growth study with the freshwater green algae, *Pseudokirchneriella subcapitata* (Springborn, 2001). It is unclear, however, why that is the case. The study was performed to satisfy both US EPA and OECD guidelines, by measuring both cell density and growth rate (OECD, 2006). Performance and acceptance criteria for the control organisms were met, as required per guidelines. Media concentrations of D5 were measured and reported. At test initiation, the nominal D5 concentration was 20 µg/L and the measured was 12 µg/L. It is not uncommon for a difficult-to-test, highly volatile compound such as D5 to have an initial measured concentration in water lower than the nominal dose, and the dose level will often decline in a first-order manner over the period of static exposure. In order to maintain concentrations throughout the test, the study was run in a closed, minimal headspace system. This is particularly unique for an algal study as the organisms need a source of carbon to continue to grow and reproduce adequately. As a result, sodium bicarbonate ($NaHCO_3$) was added to all treatment and control vessels in order to ensure a healthy supply of carbon for the test system, as recommended by the OECD Guidance Document 23 on difficult-to-test substances (OECD, 2000). The study was run as a limit test, starting above the limit of D5 water solubility (~15 µg/L). As stated, growth in the control vessels met the acceptance criteria (OECD, 2006). The spiked, measured D5 concentration was 12 µg/L on Day 0, 9.2 µg/L on Day 1, and 2.1 µg/L on Day 4; the geometric mean concentration over the 4-day period was 6.2 µg/L. Even though the concentrations by the end of the study were lower than at initiation, the results of the study show that when you put D5 in water, in a worst-case closed system, there are no long-term impacts to algae. In addition, the dissipation of D5 in the algal media appears to strictly follow first-order kinetics (*i.e.*, $C = C_o * e^{-k*time}$), as shown in Text Figure 1, with a measured D5 dissipation half-life of 37 hours; this dissipation of D5 is likely predominately due to volatility losses, which would be consistent with first-order kinetics. In conclusion, we submit that the algal growth study on D5 (geometric mean concentration of 6.2 µg/L over four days) should be considered ‘acceptable’ or ‘acceptable with limitations’ and that the overall conclusion of considering D5 inherently toxic is not supported by the available empirical data for D5 with fish, invertebrates, and algae.

Text Figure 1: D5 dissipation curve from algal growth study


D5: First-order dissipation kinetics_Algal growth study
Mean +/- standard deviation
Assume first-order dissipation kinetics:
D5 = 13.166e$^{-0.0189x}$
R^2 = 0.9913
k = 0.0189 hr^{-1}
Half-life = 37 hr
Measured D5 concentration (µg/L)
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
0
20
40
60
80
100
120
Exposure time (hr)

Critical Body Burdens of D4, D5, and D6

The accumulated tissue residue or "burden" of a chemical in aquatic biota has been proposed to be a more appropriate indicator of adverse effects in aquatic organisms than water concentrations, as the overall tissue residue is considered to represent a more toxicologically relevant "dose" (McCarty and Mackay, 1993; Barron et al., 2002); this approach is commonly referred to as the "critical body residue" or CBR method. A CBR of 0.2 to 0.8 mmol/kg has been calculated for fathead minnows for observation of sublethal effects due to a narcosis mode of action by nonpolar chemicals (McCarty and Mackay, 1993). Examination of accumulated body residue levels for aquatic vertebrates collected with the Lake Pepin, MN field study produces the following table (Text Table 1) of body residue levels for D4, D5, and D6:

Text Table 1. Body burden values for D4, D5, and D6 from Lake Pepin fish.

Statistical measure	D4 (mmol/kg)	D5 (mmol/kg)	D6 (mmol/kg)
Mean	2.3×10^{-5}	1.9×10^{-4}	8.3×10^{-6}
Minimum	1.7×10^{-6}	1.3×10^{-5}	5.0×10^{-7}
Maximum	2.0×10^{-4}	1.2×10^{-3}	6.0×10^{-5}

A body burden "safety factor' may be calculated for D4, D5, and D6 by comparing the mean accumulated residues to the lower level sublethal effects (narcosis, nonpolar organic chemicals) CBR of 0.2 mmol/kg (McCarty and Mackay, 1993). For D4, D5, and D6, the body burden safety factors for the accumulated residues from Lake Pepin, MN aquatic vertebrates, when compared to a CBR for sublethal effects due to narcosis effects from nonpolar chemicals, are approximately 8500, 1000, and 24000, respectively. In conclusion, these data indicate that if Lake Pepin accumulated residues are taken as representative of urban environmental systems, that safety factors of at least 1000-fold exist between accumulated cVMS residues and sublethal effect levels based on narcosis effects from nonpolar chemicals.

Silicone Industry's Risk Assessment on D4, D5, and D6:

Octamethylcyclotetrasiloxane (D4; CAS No. 556-67-2)
Decamethylcyclopentasiloxane (D5; CAS No. 541-02-6)
Dodecamethylcyclohexasiloxane (D6; CAS No. 540-97-6)

(A) Ecological Risk Assessment of D4, D5, D6 - Water:

In their screening assessments of D4, D5, and D6, EC examined both field measurements of the cVMS materials in water, but also used predicted environmental concentrations (PECs) of aquatic exposure for approximately 1000 municipal discharge sites for comparison to calculate risk quotients from PNEC values for each compound. The use of a PEC database of approximately 1000 sites produced an aquatic risk distribution for each chemical, based on this method. In our analysis of ecological risk for each cVMS material, we focused on producing an aquatic risk distribution as well, but our intent was a risk distribution or probability based on measured concentrations of each chemical in water, not

PECs, and a subsequent comparison to EC's projected PNEC values to examine risk probability. Fundamentally, a probabilistic assessment frames risk in the proper context, *i.e.*, what is the likelihood of an adverse effect occurring (Woodburn, 2000)?

D4:

For D4, the water residues examined in a probabilistic approach were taken from Norden (2005) and NILU (2007), as these data represent the most recent, publicly-available information on this chemical. Sewage treatment plant (STP) influents and landfill runoff water samples were excluded from analysis, as such water does not represent aquatic ecosystems supporting organisms and populations; STP effluent samples were included in the analysis, and zero dilution was assumed, representing a worst-case situation for aquatic populations. Figure 1 presents the D4 aquatic field data as a cumulative probability distribution, with a comparison to the D4 PNEC value of 0.2 µg/L; non-detectable residues of D4 were presumed to be present at 50% of the detection limit. In an available dataset of N=37 samples, no exceedence of the PNEC value was observed, indicating a less than 3% probability (1/(N+1)) of D4 water concentrations exceeding this residue level in field situations, including STP effluent discharges. In conclusion, the available field measurement data on D4 in aquatic systems indicate that the probability of real world, aquatic ecosystem concentrations of this material exceeding the proposed PNEC value of 0.2 µg/L is quite small, less than 3%.

D5:

For D5, the water residues examined in a probabilistic approach were taken from Norden (2005), NILU (2007), Boehmer and Gerhards (2003), and Sparham (2008), as these data represent the most recent, publicly-available information on this chemical. STP influents and landfill runoff water samples were again excluded from analysis, as such waters do not represent aquatic ecosystems supporting organisms and populations; silicone manufacturing STP effluent samples were included in the analysis (Boehmer and Gerhards, 2003), and zero dilution was assumed, representing a worst-case situation for aquatic populations. Figure 2 presents the D5 aquatic field data in a cumulative probability distribution, with a comparison to the D5 PNEC value of 15 µg/L; non-detectable residues of D5 were presumed to be present at 50% of the detection limit. In an available dataset of N=94 samples, only two samples in exceedence of the PNEC value were observed, and both were present in STP effluent from a silicone-producing facility in Germany (Boehmer and Gerhards, 2003). These data indicate there is a less than 3% probability of D5 water concentrations exceeding this residue level in field situations, including STP effluent discharges (2/(N+1)). In conclusion, the available field measurement data on D5 in aquatic systems indicate that the probability of real world, aquatic ecosystem concentrations of this material exceeding the proposed PNEC value of 15 µg/L is quite small, less than 3%, and that such exceedences would most likely occur in effluent from silicone-producing STPs.

D6:

For D6, the water residues examined in a probabilistic approach were taken from Norden (2005) and NILU (2007), as these data represent the most recent, publicly-available information on this chemical. STP influents and landfill runoff samples were excluded from analysis, as such waters do not represent aquatic ecosystems supporting organisms and populations; silicone manufacturing STP effluent samples were included in the analysis (Boehmer and Gerhards, 2003), and zero dilution was assumed, representing a worst-case situation for aquatic populations. Figure 3 presents the D6 aquatic field data in a cumulative probability distribution, with a comparison to the D6 PNEC value of 4.6 µg/L; non-detectable residues of D6 were presumed to be present at 50% of the detection limit. In an available dataset of N=37 samples, no exceedence of the PNEC value was observed, indicating a less than 3% probability (1/(N+1)) of D6 water concentrations exceeding this residue level in field situations, including STP effluent discharges. In conclusion, the available field measurement data on D6 in aquatic systems indicate that the probability of real world, aquatic ecosystem concentrations of this material exceeding the proposed PNEC value of 4.6 µg/L is quite small, less than 3%.

(B) Ecological Risk Assessment of D4, D5, D6 - Sediment:

The lipophilic nature of the cVMS materials suggests that sediment adsorption is a likely removal mechanism of these compounds from water and empirical evidence supports this concept (Norden, 2005; NILU 2007). Risk quotients for sediment were not explicitly examined in the EC screening assessments of D4, D5, and D6, but probabilistic comparisons of measured cVMS sediment residues to sediment NOEC values may still be made for each material.

D4:

For D4, the sediment residues examined in a probabilistic approach were taken from Norden (2005), NILU (2007), and Powell and Kozerski (2007), as these data represent the most recent, publicly-available information on this chemical. Figure 4 presents the D4 sediment field data in a cumulative probability distribution, with a comparison to the D4 NOEC value of 44 µg/g dw (measured) from a prolonged (28 d) midge toxicity study (Krueger et al., 2008a); non-detectable residues of D4 were presumed to be present at 50% of the detection limit. In the available dataset of N=33 samples, none of the sediment residues were in exceedence of the NOEC value and there is an approximate ≥500-fold safety factor between the D4/midge chronic NOEC and the 95th centile sediment concentration, *i.e.*, the concentration that encompasses 95% of the available sediment field data on D4 or 95% of available sediment concentrations are at or less than 0.08 µg-D4/g dw. Collectively, these data indicate that there is less than a 1% probability of D4 sediment levels achieving or exceeding the sediment NOEC for this material and a minimum 700-fold safety factor exists between the NOEC and ≥95% of the available sediment field data on this chemical. In conclusion, the available sediment field data on D4 indicate that the likelihood of sediment concentrations of this material achieving levels within a factor of 700 of the chronic sediment NOEC value is quite small, less than 5%, and the probability of achieving or exceeding the NOEC is less than 1%, indicating little risk to benthic species.

D5:

For D5, the sediment residues examined in a probabilistic approach were taken from Norden (2005), NILU (2007), Boehmer and Gerhards (2003), and Powell and Kozerski (2007), as these data represent the most recent, publicly-available information on this chemical. Figure 5 presents the D5 sediment field data in a cumulative probability distribution, with a comparison to the lowest available D5 NOEC values of 69-70 µg/g dw from a full life-cycle midge toxicity study (Springborn Smithers, 2003; Krueger et al., 2008b); non-detectable residues of D5 were presumed to be present at 50% of the detection limit. In the available dataset of N=53 samples, none of the sediment residues were in exceedence of the NOEC value and there is an approximate ≥100-fold safety factor between the D5/midge chronic NOEC and the 95th centile sediment concentration, *i.e.*, 95% of available field sediment concentrations are at or less than 0.6 µg-D5/g dw. Collectively, these data indicate that there is less than a 1% probability of D5 sediment levels achieving or exceeding the sediment NOEC for this material and a minimum 100-fold safety factor exists between the full life-cycle D5 sediment NOEC and ≥95% of the available sediment field data on this chemical. In conclusion, the available sediment field data on D5 indicate that the likelihood of real sediment concentrations of this material achieving levels within a factor of ~100 of the full-life cycle sediment NOEC value is quite small, less than 5%, and the probability of achieving or exceeding the NOEC is less than 1%, indicating little risk to benthic species, and any such exceedences would most likely occur in areas adjacent to effluent from silicone-producing STPs (Boehmer and Gerhards, 2003).

D6:

For D6, the sediment residues examined in a probabilistic approach were taken from Norden (2005), NILU (2007), and Powell and Kozerski (2007), as these data represent the most recent, publicly-available information on this chemical. Figure 6 presents the D6 sediment field data in a cumulative probability distribution, with a comparison to the lowest available NOEC value of 69-70 µg/g dw from a full life-cycle midge toxicity study on D5 (Springborn Smithers, 2003; Krueger et al., 2008b); non-detectable residues of D6 were presumed to be present at 50% of the detection limit. In the available dataset of N=33 samples, none of the sediment residues were in exceedence of the NOEC value and there is an approximate ≥250-fold safety factor between the D6/midge chronic NOEC and the 95th centile sediment concentration, *i.e.*, 95% of available field sediment concentrations are at or less than 0.3 µg-D6/g dw. Collectively, these data indicate that there is less than a 1% probability of D6 sediment levels achieving or exceeding the sediment NOEC for this material and a minimum 250-fold safety factor exists between the full life-cycle D6 sediment NOEC and ≥95% of the available sediment field data on this chemical. In conclusion, the available sediment field data on D6 indicate that the likelihood of real sediment concentrations of this material achieving levels within a factor of ~250 of the full-life cycle sediment NOEC value is quite small, less than 5%, and the probability of achieving or exceeding the NOEC is less than 1%, indicating little risk to benthic species from this compound.

In conclusion, risk assessment calculations on D4, D5, and D6 in water and sediment were conducted using probabilistic techniques. These methods are useful in framing risk in the proper context, *i.e.*, what is the likelihood of an adverse effect occurring? Results of the risk calculations clearly indicate that both in water and sediment environments, the likelihood of any adverse ecological result occurring as a result of chemical exposure to a cVMS material is quite small, less than 3% at worst and generally less than 1%. The most likely environment for an ecologically significant exposure appears to be at the outfalls of industrial STP systems, where exposure residues are, of course, maximized. Given the lipophilic nature of cVMS materials, benthic organisms in sediments systems would appear to have a greater exposure opportunity than pelagic organisms. However, given the low toxicity of cVMS materials to benthic species, comparison of NOEC levels to measured field exposure concentrations show that the 95% concentrations are 100- to 500-fold lower than the long-term NOEC levels for tested benthic species, such as worms and midges.

Figure 1. D4 aquatic field data, expressed as a cumulative probability distribution, compared to Environment Canada PNEC of 0.2 µg/L.

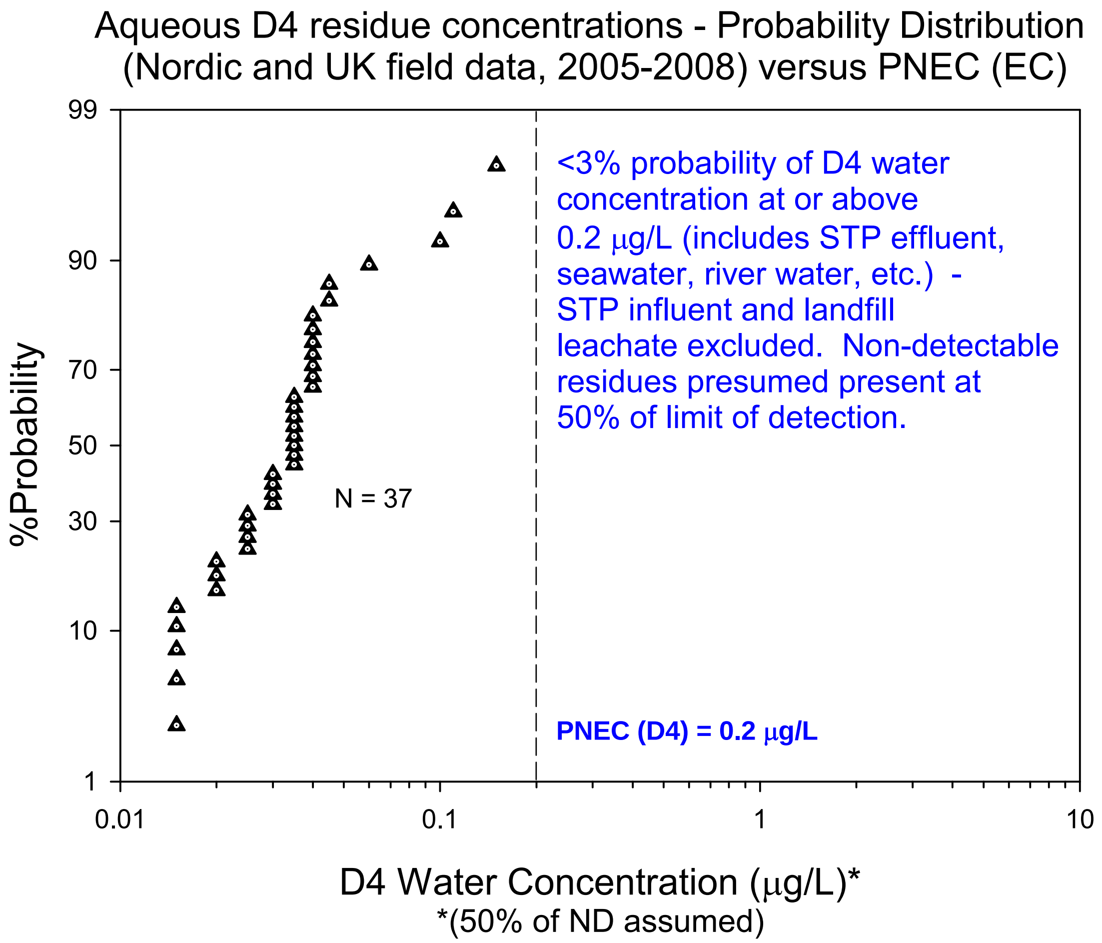


Figure 2. D5 aquatic field data, expressed as a cumulative probability distribution, compared to Environment Canada PNEC of 15 μg/L.

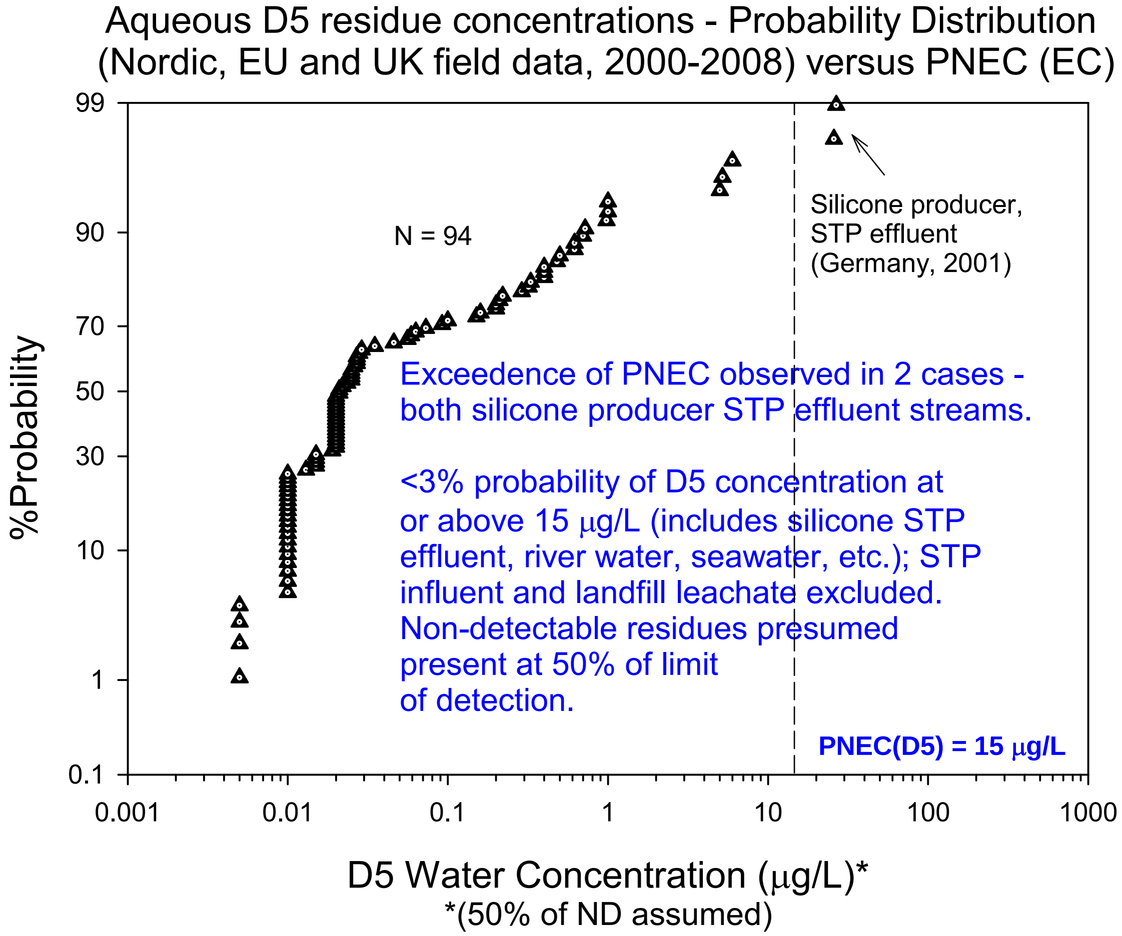


Figure 3. D6 aquatic field data, expressed as a cumulative probability distribution, compared to Environment Canada PNEC of 4.6 µg/L.

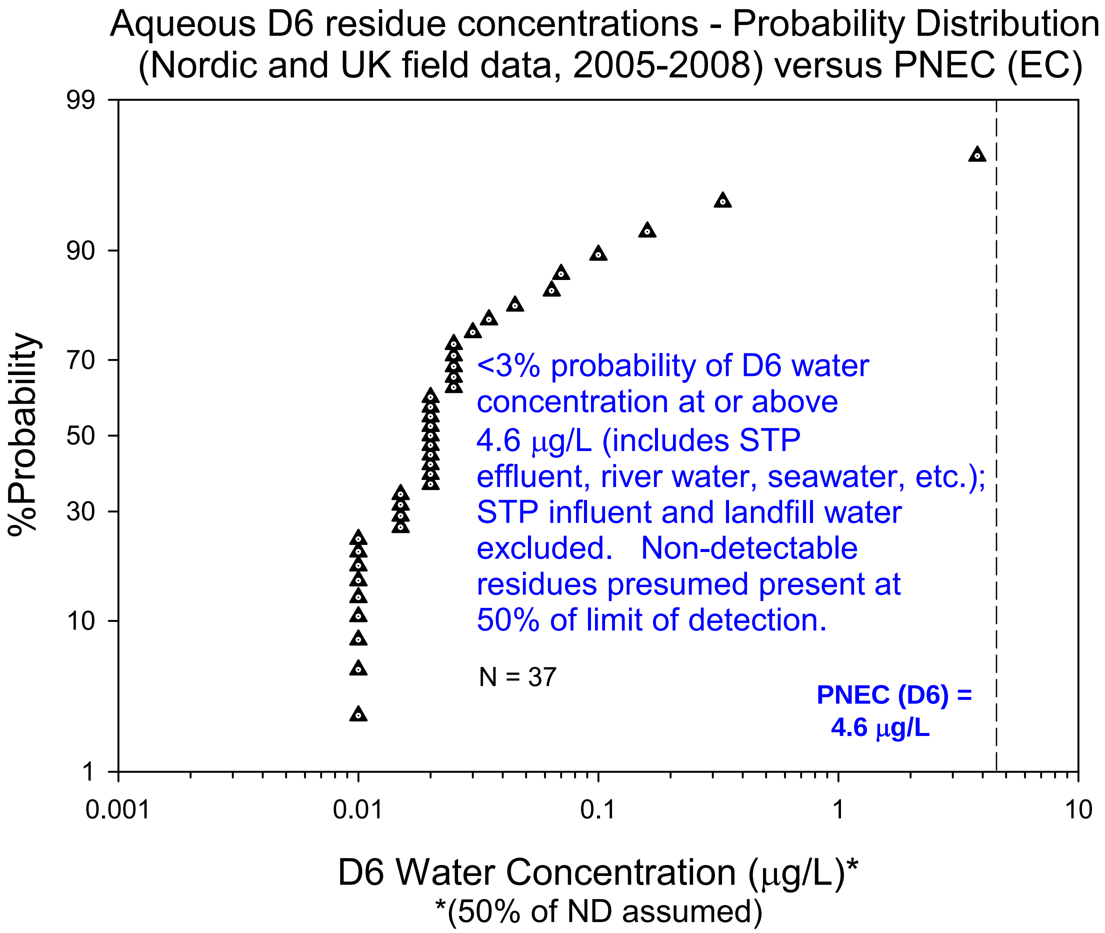


Figure 4. D4 sediment field data, expressed as a cumulative probability distribution, compared to sediment NOEC of 44 µg/g dw.

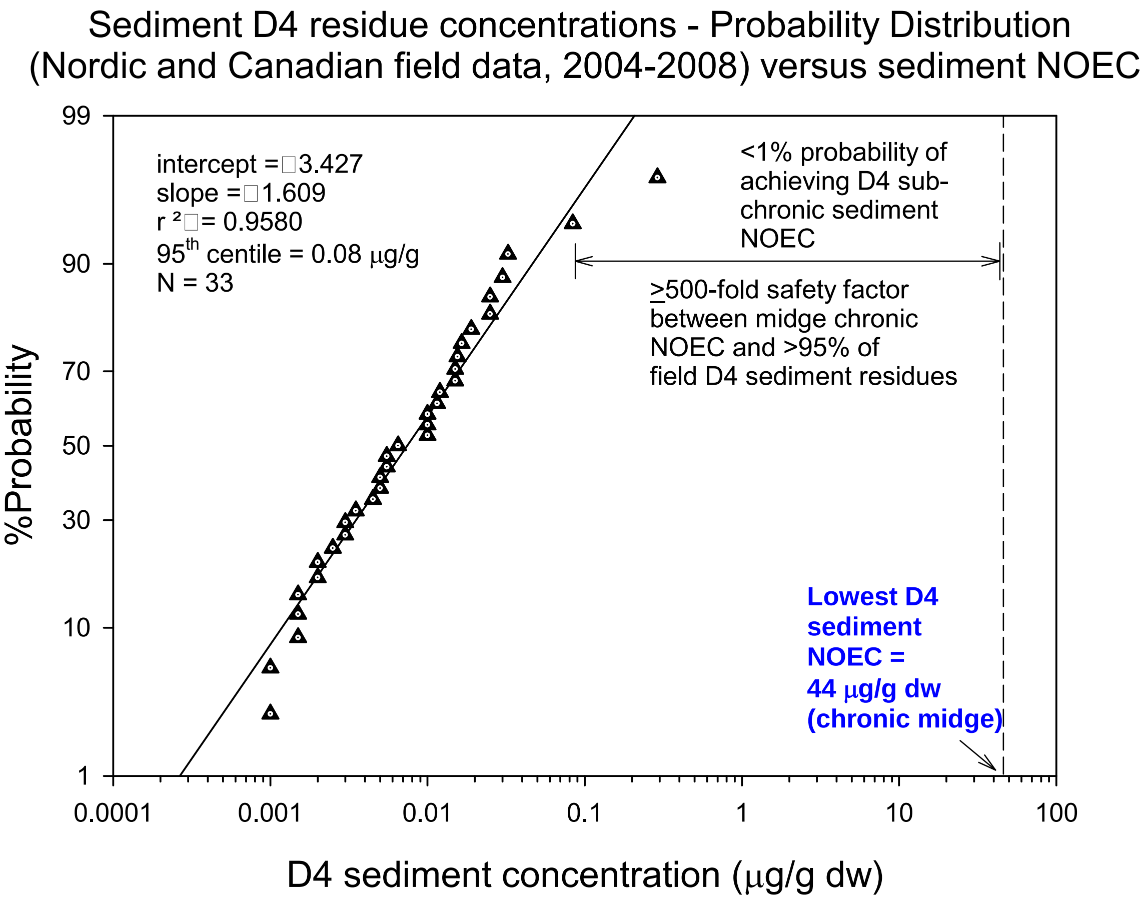


Figure 5. D5 sediment field data, expressed as a cumulative probability distribution, compared to sediment NOEC of 69 µg/g dw.

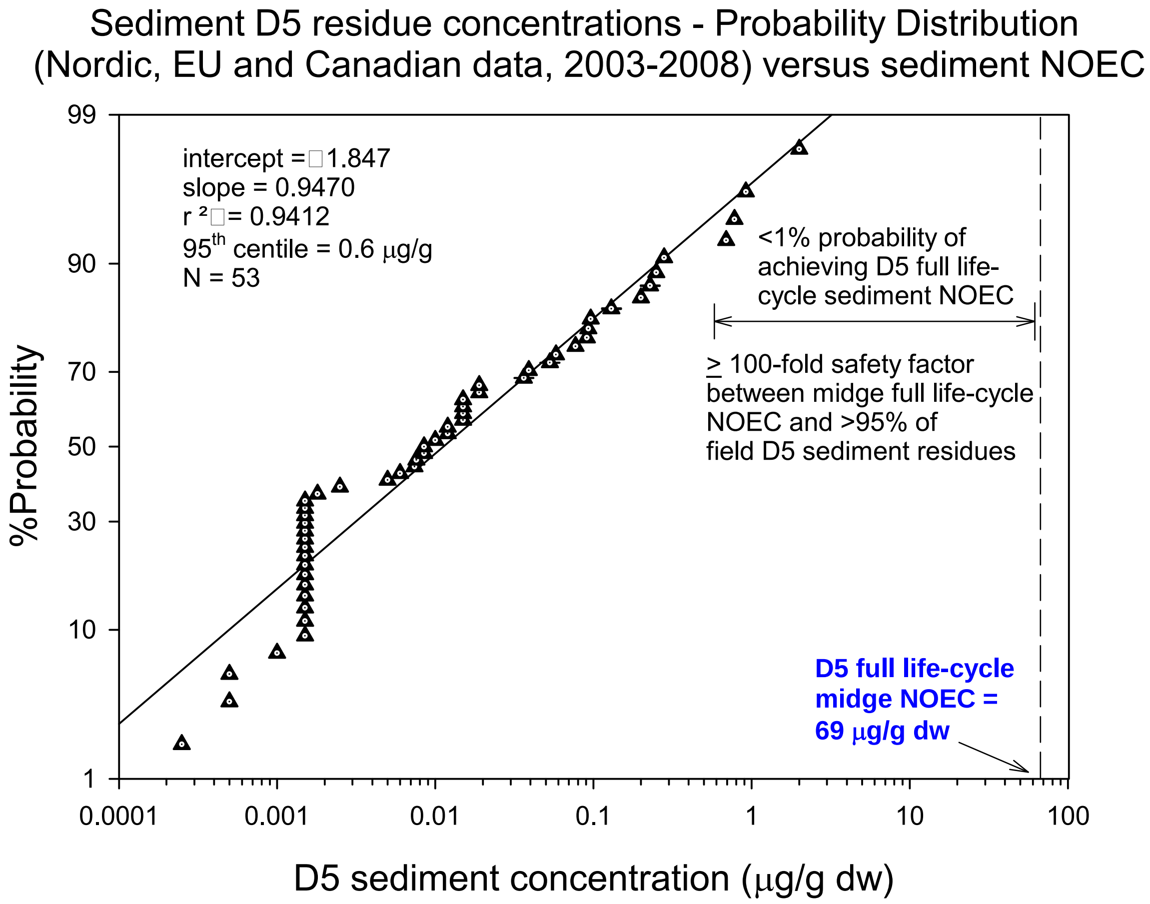
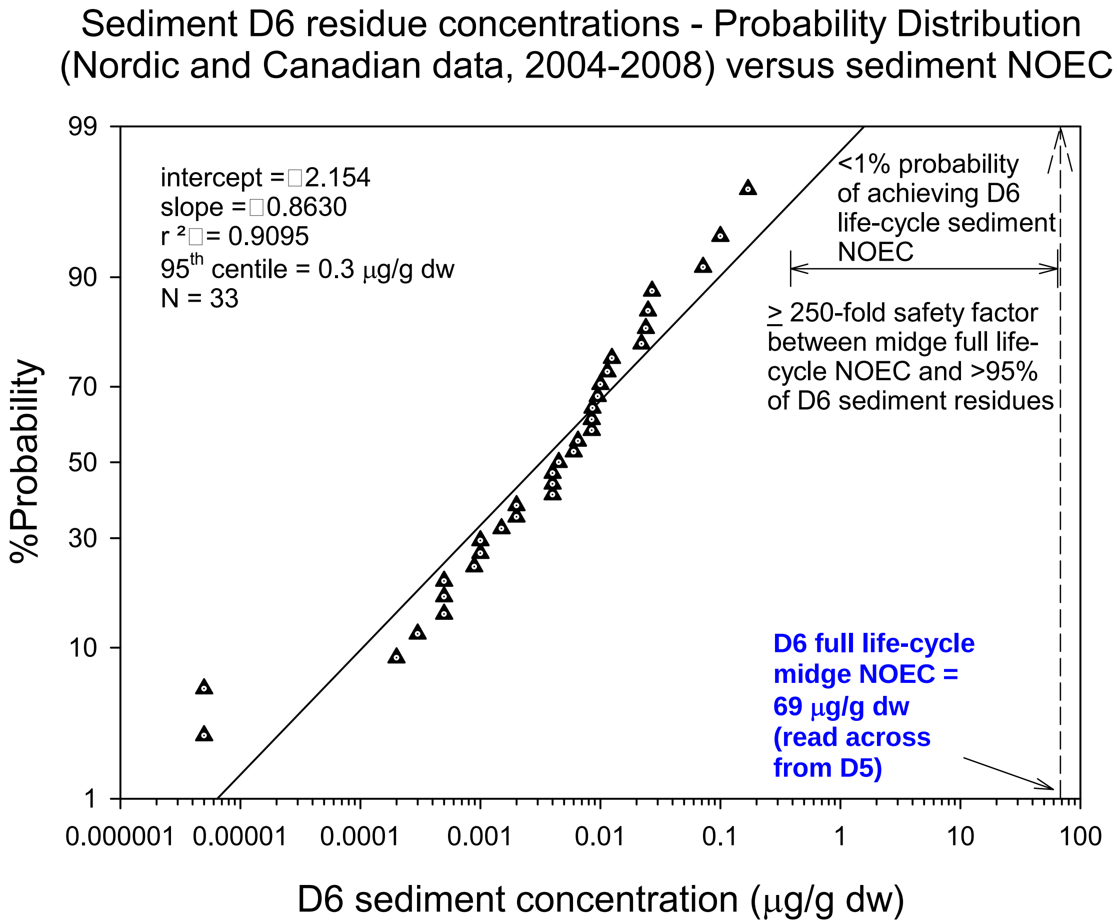


Figure 6. D6 sediment field data, expressed as a cumulative probability distribution, compared to sediment NOEC of 69 µg/g dw.



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Title : **Decamethylcyclopentasiloxane (D5): Prolonged Toxicity to the Rainbow Trout) Oncorhynchus mykiss) Under Flow-Through Test Conditions**

Author : **Drotter, Durt R., Woodburn, Kent B.**

ABSTRACT

The purpose of this study was to determine the prolonged toxicity of decamethylcyclopentasiloxane (D5) to the rainbow trout (*Oncorhynchus mykiss*) during a 45-day exposure under flow-through test conditions. The test was performed based on procedures in OECD Guideline 204, Fish, Prolonged Toxicity Test: 14-day Study. The results of the study were based on nominal test concentrations. The in-life phase of the test was performed from March 16, 2009 to April 30, 2009.

Juvenile rainbow trout (average total length 27 mm) were exposed to five test concentrations, a negative (dilution water) control and a solvent control (0.1 mL dimethylformamide/L). Ten rainbow trout were exposed in each test chamber and two replicates were tested per treatment group for a total of 20 fish per test concentration. Dilution water was dechlorinated municipal water. Each replicate received approximately 7.2 volume additions per day. Nominal test concentrations were 1.1, 2.1, 4.3, 8.5 and 17 µg/L. The highest test concentration chosen was the published water solubility of D5. Analytical determination of test concentrations was not performed during this study.

Visual observations of the test solutions during the test indicated that the solutions were clear and colorless. Three times during the test a stock solution delivery pump stalled. However, due to the prolonged (45 day) exposure, these temporary (≤ 6 hour) interruptions in test substance delivery were not considered to influence the overall exposure.

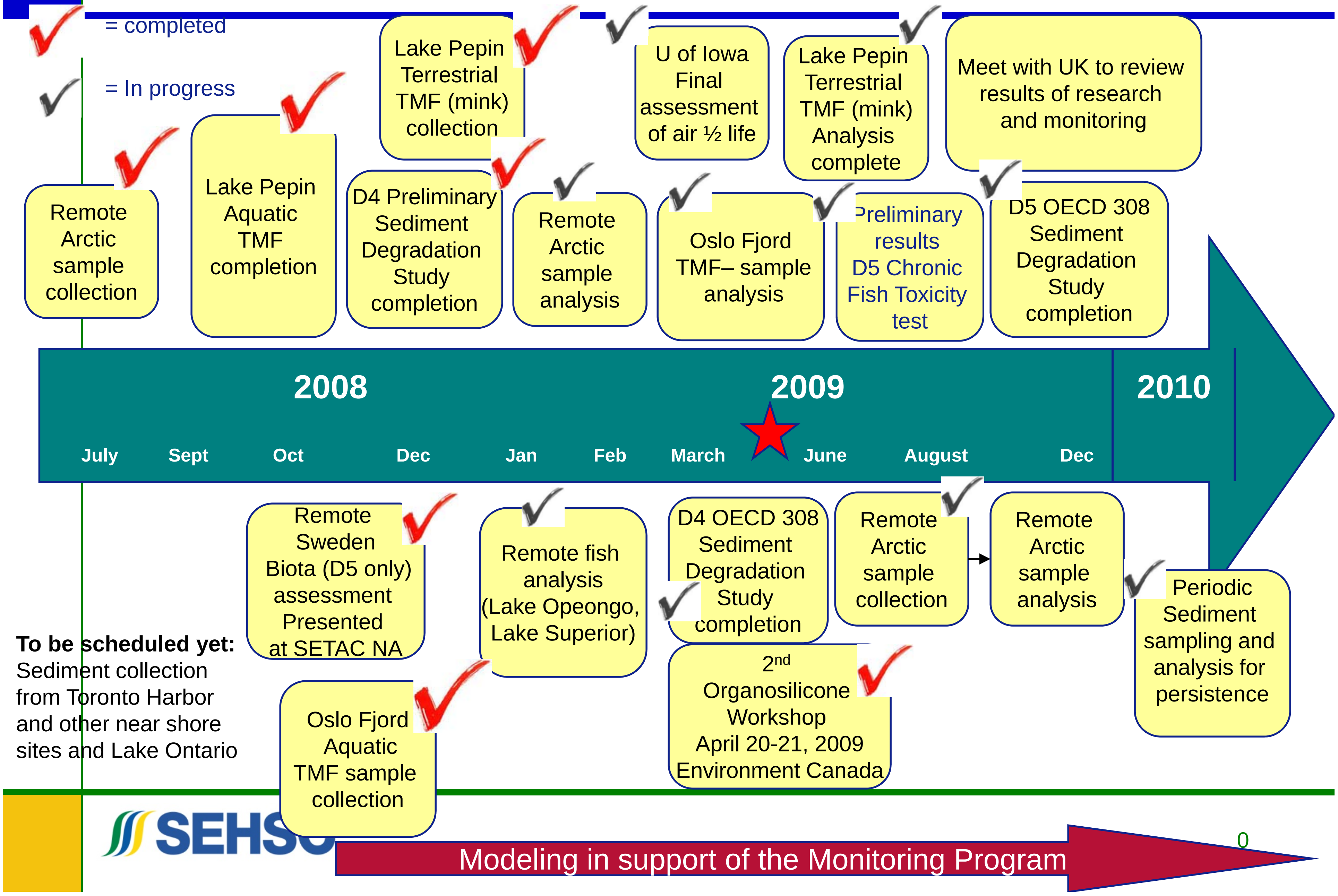
Manual measurements of temperature during the test ranged from 11.4 to 12.4°C. Measurements of dissolved oxygen remained ≥ 8.0 mg/L (76% of saturation) and pH ranged from 7.1 to 7.5. Dilution water characteristics at test initiation were as follows: hardness – 120 mg/L as $CaCO_3$, alkalinity – 64 mg/L as $CaCO_3$ and conductivity – 337 µmhos/cm. Daily measurements of total residual chlorine were <10 µg/L.

For this study, the target exposure period was approximately 80% of steady-state conditions, in order to maximize body burden residues of D5 in the young fish and therefore provide a worst-case assessment of potential toxicity following long-term

exposure. A long-term fish bioconcentration study on D5 has been conducted and the depuration rate constant (k_2) from that work was used to calculate this exposure timeframe; this period was determined to be approximately 45 days, using methods from OECD Guideline 305.

After 45 days of exposure (approximately 80% of steady-state conditions), all surviving rainbow trout appeared normal and healthy. Mortality in the negative control, solvent control, 1.1, 2.1, 4.3, 8.5 and 17 µg/L treatment groups was 5, 5, 0, 5, 25, 20 and 5%, respectively. Fisher's exact test showed that mortality was significantly different in the 4.3 µg/L treatment group in comparison to the pooled controls ($p \leq 0.05$). However, due to the lack of significant mortality in the 8.5 and 17 µg/L treatment groups, this mortality was not considered to be treatment-related. The 45-day LC50 value for rainbow trout (*Oncorhynchus* mykiss) exposed to decamethylcyclopentasiloxane (D5) was determined to be >17 µg/L; the limit of water solubility. There were no statistically significant reductions in mean wet weight or total length of rainbow trout exposed to D5 at concentrations ≤ 17 µg/L in comparison to the pooled controls ($p > 0.05$). Consequently, the NOEC for rainbow trout in a prolonged (45-day) exposure to D5 was 17 µg/L.

Cyclic Siloxanes Environmental Research and Monitoring Timeline (Revised 6-15-09)



✓ = completed

✓ = In progress

Remote Arctic sample collection

Lake Pepin Aquatic TMF completion

Lake Pepin Terrestrial TMF (mink) collection

D4 Preliminary Sediment Degradation Study completion

Remote Arctic sample analysis

U of Iowa Final assessment of air ½ life

Oslo Fjord TMF– sample analysis

Lake Pepin Terrestrial TMF (mink) Analysis complete

Preliminary results D5 Chronic Fish Toxicity test

Meet with UK to review results of research and monitoring

D5 OECD 308 Sediment Degradation Study completion

Remote Sweden Biota (D5 only) assessment Presented at SETAC NA

Oslo Fjord Aquatic TMF sample collection

Remote fish analysis (Lake Opeongo, Lake Superior)

D4 OECD 308 Sediment Degradation Study completion

2nd Organosilicone Workshop April 20-21, 2009 Environment Canada

Remote Arctic sample collection

Remote Arctic sample analysis

Periodic Sediment sampling and analysis for persistence

To be scheduled yet: Sediment collection from Toronto Harbor and other near shore sites and Lake Ontario

Modeling in support of the Monitoring Program

Cyclic Siloxanes - Table of Key Ongoing Studies and Interim Reports (Revised 6-15-09)

Project	PBT Endpoint	Sponsor	Sample Collection/ Processing	Draft Report	Final Report	Status
Lake Pepin: Aquatic food web Monitoring	Biomagnification in aquatic food web	Silicone Industry	DNR - May-2008 of and Dow Corning HES Lab	Oct. 2008 (Completed and sent to Environment Canada and UK)	March 2009	Draft report submitted - Final report complete. Needs to be submitted to EC and UK along with B Modeling report.
Lake Pepin B Modeling	Trophic magnification modeling	Silicone Industry	Dow Corning HES Lab and HydroQual, Inc	March 2009	June 2009	Modeling results mirror those obtained in the food chain monitoring of Lake Pepin (TMF is below 1). A poster was presented at SETAC North America utilizing the AQUAWEB model and ar SETAC EU. A draft report from HydroQual is under review.
Lake Pepin Sediment Monitoring	Fate and Transport	Silicone Industry	Dow Corning HES Lab Evonik Analytical Lab	July 2009	Dec 2009	Initial sediment monitoring was conducted in 2006, 2007, 2008 and will be sampled again in 2009.
Lake Pepin: Terrestrial food web	Biomagnification in terrestrial food web	Silicone Industry	DNR and Dow Corning HES Lab.	June 2009	Sept 2009	Mink have been collected. Analysis should be complete by June 2009.
Lake Pepin QWASI Modeling	Fate and transport prediction with comparison to monitoring data	Silicone Industry	Cranfield University	May 2009	July 2009	First draft report has been circulated for review.
Lake Opeongo: Aquatic monitoring	Bioaccumulation in aquatic biota	Silicone Industry	Environment Canada and Dow Corning HES Lab	March. 2009 (Delayed due to QC issues)	July 2009	Detection limits not sufficient for food web assessment. A draft report should be issued in the next month.

Cyclic Siloxanes Table of Key Ongoing Studies and Interim Reports continued (Revised 6-15-09)

Project	PBT Endpoint	Sponsor	Sample Collection/ Processing	Draft Report	Final Report	Status
Lake Ontario/Toronto Harbor Sediment Monitoring	Fate and transport	Silicone Industry	Environment Canada and Dow Corning HES Lab	Complete	Complete	Complete
Lake Ontario QWASI Modeling	Fate and transport prediction with comparison to monitoring data	Silicone Industry	Cranfield University	May 2009	July 2009	First draft of report has been circulated for review.
Lake Ontario/ Lake Superior Lake Trout	Bioaccumulation in aquatic biota	Silicone Industry	Environment Canada and Dow Corning HES Lab	March 2009 (Delayed due to QC issues)	July. 2009	Additional sampling is being considered.
Inter-lab comparison of Reference biota samples with and without siloxanes	Analytical Method inter lab validation	Silicone Industry and Environment Canada	Environment Canada Norwegian Pollution Control (NILU), Dow Corning HES Lab, Evonik Analytical Lab, Stockholm University	August 2009	Dec. 2009	Samples have been purchased and processed for transfer to laboratories. Whole fish handling and processing will also be incorporated.
Norway inter-lab comparison: Analysis of Cod Livers	Analytical Method inter- lab validation	Silicone Industry	Norwegian Pollution Control Dow Corning HES Lab Evonik Analytical Lab	March. 2009	June 2009	Final report in progress. Final reviews and edits of the data underway.

Cyclic Siloxanes - Table of Key Ongoing Studies and Interim Reports continued (Revised 6-15-09)

Project	PBT Endpoint	Sponsor	Sample Collection/ Processing	Draft Report	Final Report	Status
Remote monitoring	Long-range transport	Silicone Industry	Norwegian Pollution Control Dow Corning HES Lab Evonik Analytical Lab	April 2009	Sept 2009	Samples collected from Norway in November 2008. Analysis complete. Preliminary results presented by CES at SETAC EU Workshop.
Oslo Fjord: Aquatic food web	Bioaccumulation/ Biomagnification in aquatic food web	Silicone Industry	Norwegian Pollution Control Dow Corning HES Lab Evonik Analytical Lab	May 2009	Oct. 2009	Samples collected from the Norway in November. Analysis underway. Draft analysis expected by end of April 2009. This is dependant on outside analysis of lipid and isotopic fractionation.
Oslo Fjord - CoZMO-POP and multi-compartment QWASI-based modelling of Oslo Fjord (= Oslofjord POP Model)	Fate and Transport prediction with comparison to monitoring data	Silicone Industry	Cranfield University	April 2009	Oct 2009	First draft of Oslo Fjord CoZMO-POP and multi-compartment QWASI-based modelling of Oslo Fjord (= Oslofjord POP Model) circulated for review.
Remote Sweden Biota (D5 only)	Bioaccumulation in aquatic biota	Unilever	Stockholm University	Feb 2009 (Poster)	Dec 2009	Poster presented at SETAC North America (Poster provided to EC and UK)
CoZMo-POP Model for Persistent Organic Pollutants: Baltic proper region with the "Coastal Zone	Fate and Transport prediction	Silicone Industry	Cranfield University	May 2009	July 2009	Draft Report in progress

Cyclic Siloxanes - Table of Key Ongoing Studies and Interim Reports continued (Revised 6-15-09)

Project	PBT Endpoint	Sponsor	Sample Collection/ Processing	Draft Report	Final Report	Status
Report on dynamic and temperature dependent modeling of Lake Ontario and Lake Pepin	Fate and Transport	Silicone Industry	Cranfield University	Sept. 2009	Dec.2009	Modeling ongoing
Atmospheric Degradation Study of D4 and D5	P – ½ life in air	Silicone Industry	University of Iowa/Dow Corning	March 2009 (University of Iowa were delayed due to flooding of their labs)	Aug. 2009	Additional work continues to show that that partitioning to aerosol surfaces with reaction on the surface may constitute an important loss pathway for the relatively volatile siloxane species in the environment. 2 reports have been issued by the University of Iowa and the work was presented at the Canadian Workshop. Preliminary DC work was presented at SETAC EU.
Aerobic transformation of D4 in water/sediment systems	P – ½ life in sediment	Silicone Industry	Dow Corning HES Lab	April 2009	July 2009	Preliminary study complete and results submitted to Environment Canada and UK. Definitive study nearing completion.
Aerobic transformation of D5 in water/sediment systems	P – ½ life in sediment	Silicone Industry	Dow Corning HES Lab	Nov 2009	Dec. 2009	Preliminary study nearing completion and definitive study just initiated.

SEHSC