

D4 and D5 Record of Environmental Safety:

A Current Analysis of the Canadian Chemical Management Program's Review and Assessment Process

The following is a summary of the most current science relating to the potential environmental behavior of D4 and D5. The data demonstrate how regulatory decisions and actions being considered by the Government of Canada are based on modeled values rather than actual laboratory and field data in the implementation of computer modeling of environmental behavior, and on computer modeling rather than the results of real-world environmental monitoring studies. This review also illustrates why any government review of siloxanes such as D4 and D5 must carefully consider the unique properties of the materials to ensure a complete and thorough review of the science.

Introduction

On January 30, 2009 the Government of Canada announced final screening assessments (“Assessments”) for 16 chemicals in Batch Two of the Chemical Management Program (CMP). Included in Batch Two are Cyclotetrasiloxane, octamethyl- (D4) and Cyclopentasiloxane, decamethyl- (D5), also known as cyclic volatile methyl siloxanes (cVMS).

On May 16, 2009, the Canadian Minister of the Environment proposed an Order to add D4 and D5 to Schedule 1 of the Canadian Environmental Protection Act, 1999.¹ This gives D4 and D5 a designation that permits the agencies to move forward with the risk management phase of the CMP, during which possible environmental regulatory measures are considered.

SEHSC maintains that the Proposed Order to add D4 and D5 to Schedule 1 is based on Assessments that have been conducted in a manner that is not consistent with the current available science. Use of the current 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.”² Currently, the approach used in the final screening assessments over-predicts D4

¹ Canada Gazette Vol. 143, No. 20 — May 16, 2009

² See note 1, above.

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 other governmental agencies³ and Industry that have reported relatively low levels of the materials in the water compartment. In addition important new data relevant to Environment Canada's (EC) 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 measured data⁴. 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, an aquatic toxicity study with D5 shows that the substance is not inherently toxic to small fish following an extended exposure. Further, results from a recently completed long-term fish toxicity study further demonstrated the lack of toxicity of 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 EC staff has exhibited during this proceeding. SEHSC understands that the CMP Advisory Panel considered D4 only in their review conducted in April/May of 2008 and not D5⁵. 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.⁶

³ See p. A-14 and following of the Addendum

⁴ See p. A-14 and following of the Addendum.

⁵ Chemicals Management Plan - Challenge Advisory Panel Summary Report From the meetings held April 11, 2008 and May 9, 2008.

⁶ 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.”⁷ 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.”⁸ The Ministers concluded that for both D4 and D5 long term environmental exposure “may cause adverse effects to aquatic organisms in certain Canadian environments.”⁹ 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.”

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.

⁷ *Canada Gazette* Part I, Vol. 143 No. 5 (January 31, 2009).

⁸ D4 Screening Assessment, p. ii; D5 Screening Assessment, p. iii.

⁹ D4 Screening Assessment, p. iii; D5 Screening Assessment, p. iii.

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.”¹⁰ 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 data is available), which resulted in the development of unreasonable exposure scenarios.¹¹ 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 fish¹² and a long-term toxicity study in fish demonstrates a lack of toxicity up to the limit of D5’s solubility in water.¹³ 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.”¹⁴

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

¹⁰ <http://www.regulation.gc.ca/directive/directive01-eng.asp>

¹¹ See section II, below.

¹² Dow Corning Internal Study 2009-I0000-60763 - Decamethylcyclopentasiloxane (D5): Prolonged (45 days) Toxicity to the Rainbow Trout (*Oncorhynchus mykiss*) Under Flow -Through Test Conditions.

¹³ Lee, M. 2009. Decamethylcyclopentasiloxane (D5) – Early Life-Stage Toxicity Test with Rainbow Trout (*Oncorhynchus mykiss*) Following OECD Guideline #210 and OPPTS Draft Guideline 850.1400. Study No. 13937.6105.

¹⁴ <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 D6.¹⁵

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.¹⁶ The results of modeling conducted with actual measured data as inputs are markedly different and demonstrate that potential quantities of D4 and D5 in the water compartment are significantly lower (*i.e.*, 3 to 4 times lower) than those predicted in the Assessments.¹⁷

¹⁵ 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.

¹⁶ 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.

¹⁷ *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), and David Powell (Dow Corning) are collaborating on a paper, which was presented at The Society of Environmental Toxicology and Chemistry (SETAC) Annual Meeting this November, that addresses the modeling challenges posed by the materials. The paper examined 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 included a comparison of results for D4 and D5 under differing input scenarios with those obtained from actual field measurements. 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.¹⁸

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 recently completed studies regarding the toxicity of D5.

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.

¹⁸ See p. A-14 and following of the Addendum.

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.”¹⁹ 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 study of juvenile rainbow trout exposed for 45 days to D5 under flow-through test conditions shows D5 is not toxic at concentrations up to its solubility limit (LC₅₀ value > 17 µg/L).²⁰ 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.²¹ An additional chronic fish early life stage study was recently completed which significantly adds to the knowledge concerning the substance’s potential effects.²² Results from this latest study demonstrate no toxicity up to D5’s limit of water solubility (the maximum achievable water concentration).

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

¹⁹ See p. 30, *Screening Assessment for the Challenge Decamethylcyclopentasiloxane (D5)*, Environment Canada, Health Canada, November 2008.

²⁰ Dow Corning Internal Study 2009-10000-60763 - Decamethylcyclopentasiloxane (D5): Prolonged (45 days) Toxicity to the Rainbow Trout (*Oncorhynchus mykiss*) Under Flow -Through Test Conditions.

²¹ These results also highlight that a simple read-across from D4 toxicity data is not scientifically appropriate for D5.

²² Early Life-Stage Toxicity Test with Rainbow Trout (*Oncorhynchus mykiss*) Following OECD Guideline #210 and OPPTS Draft Guideline 850.140. Study No. 13937.6105

²³ Early Life-Stage Toxicity Test with Rainbow Trout (*Oncorhynchus mykiss*) Following OECD Guideline #210 and OPPTS Draft Guideline 850.140. Study No. 13937.6105

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.

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. The accuracy and completeness of the Assessments would be greatly enhanced by the incorporation of the two D5 fish toxicity studies which directly address Environment Canada’s questions and concerns.

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 availability of key aquatic toxicity data and 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.

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

Enclosures

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