# ENGO Consolidated Report on

# Public Consultation Meeting on Proposed Risk Management Measures for Octamethylcyclotetrasiloxane (D4)

## August 10, 11 2010 Toronto Ontario

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## September 13, 2010

# ENGO Report

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## A. Introduction

This report is submitted by the five Environmental Non-Governmental Organization (ENGO) delegates selected by the Canadian Environmental Network (RCEN) to attend an Environment Canada (EC) public consultation meeting on proposed regulatory measures for octamethylcyclotetrasiloxane (D4) to limit releases to the aquatic environment.[1] We welcome the Government of Canada's initiative to enact such regulations and thank EC for making our participation possible.

The ENGO delegates support a regulatory approach for D4. However, we find that there are limitations to the proposed regulations that may result in inadequate protection for the environment. We will outline these in the report. We will also outline significant factors not addressed in the proposal that impact on the risk management strategy, including the need to consider D5 at the same time as D4; the indecision on the determination of bioaccumulation for D4; and insufficient consideration for potential adverse health effects, in particular, for vulnerable populations.

***Overall, we support a risk management strategy that would phase out the use of D4 in products and industrial processes, and commit to preparing safer substitution plans. The objective of this strategy should be to achieve a reduction in D4 use by 90% within 18 months of regulations coming into force and elimination within another 2 years.***

## B. Background-Siloxanes in Batch 2 of the Chemical Management Plan

Three siloxane substances, Octamethylcyclotetrasiloxane, Decamethylcyclopentasiloxane, and Dodecamethylcyclohexasiloxane CAS Nos. 556-67-2, 541-02-6, 540-97-6, referred to as D4, D5 and D6 respectively, were included in Batch 2 of the Challenge initiative under the Chemicals Management Plan. During categorization, all of these substances were identified as high priorities for assessment of ecological risk as they were found to be persistent, bioaccumulative and inherently toxic to aquatic organisms. D4 was also prioritized for human health risk.

Although the categorization exercise did not prioritize D5 or D6 for risks to human health, human health assessments were conducted for them as well, due to structure and use patterns similar to D4, and the increased use of D6 as an alternative to D4.

The final screening assessments for D4 and D5 concluded that they are entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, but do not constitute a danger in Canada to human life or health. Thus they met the criteria for being designated toxic under section 64

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[1] Environment Canada, *Consultation Document: Octamethylcyclotetrasiloxane (D4) Chemical Abstracts Service Registry Number 556-67-2*, July 2010. http://www.ec.gc.ca/lcpe-cepa/documents/consultations/octa_d4/consultation_document_octa_d4-eng.pdf

(a) of the *Canadian Environmental Protection Act 1999* (CEPA 1999) and it was proposed that they be added to the List of Toxic Substances, Schedule 1, CEPA 1999. D6 was not determined to be CEPA-toxic.

While D4 and D5 were concluded to meet the criteria for persistence in accordance with the *Persistence and Bioaccumulation Regulations*, the assessments indicated that a determination on bioaccumulation was not possible at the time the assessments were published due to "conflicting evidence from laboratory studies and predictive models".

The consultation dealt with proposed regulatory measures only for D4. Risk management measures for D5 are not being dealt with at this time, despite its toxicity finding, because the Minister of Environment has established a Board of Review to inquire into the nature and extent of the danger posed by D5, in response to a Notice of Objection submitted by the Silicones Environmental, Health, and Safety Council of North America on July 10, 2009. The Board is to present its recommendations to the Minister by March 2011.[2]

## Issues/Comments

- Bioaccumulation: The lack of a determination on bioaccumulation is of great concern, not only because it is well recognized that D4 has the potential to bioaccumulate to some extent, but also because a decision on the determination of bioaccumulation would inform the government whether a virtual elimination approach should be pursued. In the meantime, a precautionary approach in the face of uncertainty in this matter requires that the strongest possible measures to manage D4 should be taken, including a commitment to phase out the use of this substance.
- Outcome of D5 Review: We are very concerned about the outcome of the Board of Review's reconsideration of D5 and intend to follow the matter closely. The outcome of the review is expected to have significant implications for the measures being considered for D4, as a finding for D5 will inform the strategy development process. Further to this point, the current review of D5 makes it impossible to consider at this time strategies that could apply to both D4 and D5, and possibly take into consideration cumulative exposures and risks from both of these substances.
- Human Health: While the assessment did not find D4 or D5 to be harmful to human health, we remain concerned about potential effects of cumulative or long-term exposure to D4, D5 and D6 and to siloxanes in polydimethylsiloxanes (PDMS), especially for vulnerable populations. Animal studies carried out by the Danish Environmental Protection Agency showed adverse effects of D4 exposure such as impaired fertility and effects on the liver and other organs, which may indicate potential effects on human health. The US Environmental Protection Agency is examining several issues related to siloxanes, including human health hazards. We believe that the likelihood of adverse human health effects cannot be dismissed and that this matter should be reviewed as new information becomes available.

[2] See Government Notices, Department of the Environment, Canada Gazette Part I (Vol. 144, No. 34 — August 21, 2010). http://www.gazette.gc.ca/rp-pr/p1/2010/2010-08-21/html/notice-avis-eng.html#d102. See also Government of Canada. CEPA Registry. Response by The Honourable Jim Prentice to the Notice of Objection, dated July 20, 2010. https://www.ec.gc.ca/CEPARegistry/documents/objections/Min_Resp_NO_Siloxanes.cfm.

## C. Uses and Releases of D4

### Uses

According to information received from the Section 71 Survey, D4 was not currently manufactured by any company in Canada above the 100 kg reporting threshold in 2006. Quantities of D4 reported imported into Canada ranged between 1,000,000 kg and 10,000,000 kg for that year. The primary use of D4 is in the manufacturing of silicone polymers and copolymers. D4 is also used in personal care products, e.g. deodorants, hair and skin care products, sunscreen, and antiperspirants.[3]

Based on 2006 data, approximately 87% of D4 use in Canada is in the cosmetic and toiletry industry, both in final products as well as polymers for that industry. The second most significant use (11%) is in the manufacture of silicone polymers for the coatings, sealants, and adhesives industry. The remaining 2% of D4 use is in final products from sectors including automotive, pharmaceuticals, paints, coatings, cleaning and rubber. The concentration of D4 in defoamers is very low and is not considered a significant release source. Facilities using over 100 kg of D4 per year tend to be located around large urban centers.

According to the screening assessments, D4 is found in nearly 100 cosmetic products in Canada. In comparison, D5 is found in nearly 3,000 cosmetic products and D6 in about 530. In addition, about 6,000 cosmetics containing cyclomethicone (polydimethylcyclosiloxane (PDMS)) contain these siloxanes.[4]

### Releases

D4, a highly volatile organic chemical, is not a naturally occurring substance. It is released to the environment mainly through consumer product use and disposal, and also during its use in industrial processes. Most of D4 that is released goes to air, due to its high volatility. Smaller amounts are released to water via effluents from wastewater treatment systems. When released to wastewater and water, a portion is expected to be adsorbed by sewage sludge and sediments. Based on model results, EC has estimated that 18 000 kg would be released to water from personal product use and 23 000 kg from effluents.

D4 has been detected at sewage treatment plants, landfills and near industrial plants as well as in indoor and ambient air far away from industrial activity. Some of D4 ending up in wastewater sludge may then be sent to landfills, incinerated or applied to agricultural soils as fertilizer.

## D. Proposed Risk Management Instruments

### Overview

The proposed environmental objective is to prevent or minimize releases of D4 to the aquatic environment. The risk management objective is to achieve the lowest level of release of D4 to water that is technically and economically feasible. The following regulatory measures have been proposed towards achieving these objectives:

- **Products:** Limit the quantity or concentration of D4 that may be contained in certain personal care products through regulation that are manufactured in and imported into Canada; and

[3] Consultation Document for D4.
[4] Cyclomethicone is a mixture of siloxanes bearing CAS RN 69430-24-6.

- **Industrial use**: Establish a maximum D4 concentration in industrial effluents and require the implementation of a Substance Management Plan (SMP) to ensure that environmentally sound management practices are adopted at facilities where D4 is manufactured, transformed, or reformulated.

The approach is based on "lifecycle management" (i.e. not a virtual elimination approach). It proposes to establish certain concentration limits for D4 in personal care products, which would cover D4 whether it is intentionally added as an ingredient or present as an impurity (or present unintentionally), and in industrial effluents. Exemptions could be provided for therapeutic products assessed on a case by case basis.

Both proposed regulatory measures are based on the Predicted No Effect Concentration (PNEC), and use different approaches to achieve the stated risk management objective.

As a component of the Chemicals Management Plan Monitoring, Surveillance and Research Program, a sampling program focused on municipal waste water treatment plants is being designed to provide information on levels of D4 in the ambient environment and an indication of the fate of D4 in wastewater systems. [5] Industrial waste treatment could be included in a second phase. Leachates from landfill may also be considered.

Environment Canada indicated that additional data would be useful in the following areas: usage trends; capture and control technology; and alternatives, including their technical and economic impact. The use of alternatives for substitution for D4 may trigger the application of other Canadian regulations, such as the *New Substances Notification Regulations,* and re-assessment processes under the Chemicals Management Plan.

## Issues/Comments

- Confidentiality: There is a large degree of uncertainty in the range of D4 imported (i.e. between 1,000,000 - 10,000,000 kg of D4 was imported in 2006). As well, data gathered about usage trends contain confidential business information and has been reported as a range.
- Data gaps: Data gaps continue to exist on the types of products these chemicals are used in and how these chemicals are used. Voluntary mechanisms to collect use data, such as surveys, are not appropriate or effective in filling data gaps. Furthermore, specific information from these surveys is not publicly available.
- Alternatives and Substitutes: Substitution for D4 with safer alternatives should be integrated within the risk management approach. Assessments of alternatives should be hazard-based rather than risk-based to ensure that the most precautionary approach is followed so that the alternatives identified do not adversely impact human health and the environment. The assessments should be published or recorded publicly for stakeholder review.
- Exposure via air: The most significant route of Canadian intake is via indoor air as noted in the assessment report. No attention is paid to this exposure in combination with other chemicals at the same time, both in terms of total load and synergistic effects.
- Vulnerable populations: While EC indicated that they did consider vulnerable populations in the assessment, this consideration was limited. It did not include chronic exposure or incorporate consideration of a broad range of vulnerable populations (for example, pregnant women,

[5] Ibid p. 4

aboriginal peoples, people with Multiple Chemical Sensitivities, asthmatics, workers, communities in the vicinity of industries using and disposing of D4, etc.).

- Exemptions: Exemptions for therapeutic products on a case by case basis is not supported unless there are extraordinary essential use situations which can be justified.
- Focus of Regulations: The proposed regulatory measures do not provide reduction targets for levels of D4 in the environment. Mechanisms for reducing the use of D4 need to be employed so that they would result in a quantifiable and meaningful reduction of D4 in the environment.
- Emission reduction targets: The establishment of reduction targets for D4 in industrial effluent should trigger/encourage facilities to invest in and explore pollution prevention measures, particularly in finding alternatives to D4.Without such reduction targets, the focus of control measures will be primarily on ensuring that D4 is captured or diluted to permissible levels before its release to the environment.
- Long-Range Transport: Insufficient consideration has been given to the impact of long-range transport. In particular, the assessment for D4 estimated it to have the longest range of travel compared to D5 and D6, and is most likely to contaminate the Arctic. Though there is no Canadian monitoring data, Norwegian studies show that the chemicals bioaccumulate in fish livers and other marine life. The tendency of siloxanes to travel north and their ability to bioaccumulate in wildlife make them of particular concern for First Nations, Inuit and Métis populations and the environment that they depend upon for sustenance.
- Public oversight: As has been noted, the absence of public transparency in so many aspects of the process is a serious problem. Industry is being relied on to supply information, but much of it is confidential. In this circumstance, there are no means for public interest organizations to challenge the information, or lack thereof. Publicly available information as to levels of D4 in products and which products do not contain D4 would be useful for consumers.
- Reporting releases to National Pollutant Release Inventory (NPRI): The risk management strategy does not propose to add D4 to the NPRI. Since D4 has been found CEPA-toxic, it would be appropriate that D4 be added for reporting to NPRI with no volume threshold for reporting.

## Recommendations

- Mandatory mechanisms to collect information to fill data gaps in a timely manner are needed. The government should require information from industries through the development of comprehensive surveys rather than use voluntary methods such as questionnaires which have been shown to be ineffective.
- The current regulatory proposals for D4 should include target level reductions and timelines. It is recommended that a reduction target be set at 90% within 18 months of the measures coming into force with additional reductions towards elimination within another 2 years. Above all, regulatory efforts must be directed toward phasing out the use of D4.
- A Safer Substitution Plan, as an essential component of the risk management approach, should include a requirement to identify safer substitutes for D4. Assessments for safer alternatives should be conducted in a manner more rigorous than what is presently required for existing or new substances under the New Substances Regime and be based on the inherent hazard properties. Test methods in research for safer alternatives should be subject to broad stakeholder input as well as validation.

- Consideration should be given to prevent D4 in leachates from landfill, and prevent potential releases of D4 resulting from other means of disposal (e.g., incineration), and from spreading fertilizers with D4 on lands.
- Monitoring and Sampling: These programs should be expanded to include other siloxanes, including polysiloxanes. Furthermore, sampling should be undertaken in areas where a higher level of use, release or production of D4 is expected (e.g., Great Lakes ecosystem) and in other vulnerable ecosystems, including northern regions, due to the potential for long range transport of D4. It is also recommended that longitudinal studies be carried out in specific regions to allow for trend analyses. The results of these sampling efforts should be released for public review.
- D4 should be added for reporting to NPRI with no volume threshold for reporting.

# E. Product Regulations

### Overview

Given that consumer uses of certain personal care products have the highest potential for release to the aquatic environment, the proposed approach for risk management is to limit the concentration of D4 that may be contained in certain personal care products that are manufactured in, imported into, sold or offered for sale in Canada.

The regulation would apply to any person who manufactures, imports, sells, or offers for sale products for use in Canada as outlined in Table 1 in the Consultation Document. It is proposed that products which are for export only would be exempt. The proposed instrument is expected to be published in the spring of 2011.

There will be provisions that may allow for a permit when there is no technically or economically feasible alternative or substitute for D4. The permit would expire two years after the date on which it was issued, unless the applicant applies for renewal. The permit would be extended only once. Permitting requires the applicant to provide a plan that identifies measures to be taken to minimize or eliminate harmful effects of the substance on the environment. With regard to permitting, EC indicated at the consultation that they would need to consider whether information would be provided to the public on which products do not meet the regulations. EC also stated that given past experience with similar provisions, it expects that only a small number of permits would be requested and granted.

The proposed regulatory measure also includes record keeping and labelling requirements. There would be no reporting or testing requirements for the regulated community, however, random testing of products may be conducted by EC to verify compliance. Compliance testing may target areas where non-compliance is suspected.

It was further stated at the consultation that there are no requirements for industry laboratories to be accredited to ISO 17025 standards, although there may be benefits of being accredited. Laboratory test methods to analyze products at the proposed levels have been developed and will be published by EC in a guidance document.

Health Canada indicated that most cosmetic products sold in Canada originate from the United States and Europe (i.e. approximately 1 % from developing countries) and that the current labelling regulations applying to cosmetics apply to D4 as an intentionally added ingredient. Labelling requirements do not cover impurities.

## Issues/Comments

- Exports: Approximately 60% of personal care products containing D4 manufactured in Canada is exported. ENGOs are very concerned that the proposed measures on D4 in products do not require products intended for export to comply with the regulations. While products intended for exports are expected to comply with regulations of the receiving countries, Canada should ensure that these products will not adversely impact human health and the environment. These products should, at the minimum, meet the requirements of Canadian regulations. To exempt such products from regulation is unacceptable. Other countries should not serve as a dumping ground for products that are unacceptable in Canada.
- Permitting: Permitting is essentially granting a reprieve from the regulation even though EC indicated that these provisions are not intended to be used as an exemption mechanism, but rather to provide flexibility. It is not clear as to the extent this permitting provision would be granted, despite EC indicating that they do not expect much use. The absence of alternatives is an inadequate reason to allow permits. There is a lack of public transparency as to which facilities are requesting permits, the conditions under which they are granted, and the plans required for minimizing or eliminating harmful effects.
- Testing: The proposal for product testing is inadequate. There is no routine required testing protocol, only random testing for compliance in cases where non-compliance is suspected. Unless there is mandatory routine testing, it is not clear how non-compliance would be identified. The test method should be subject to broad stakeholder input as well as third party validation.
- It is not clear whether "record-keeping" and labelling requirements apply to products to be exported.
- The proposals for labelling are limiting for public transparency despite the understanding that the Cosmetic Regulations would require the labelling for D4. Currently, labelling requirements do not cover impurities. The current labelling provision would not inform consumer that D4 was found CEPA-toxic. —
- Are the records to be made available to the public?
- Reporting requirements were not proposed. As a result, there was no discussion as to what information would be reported or if such information would be made public. Reporting to the public is an essential component to promote transparency and accountability. At a minimum, annual reporting to demonstrate progress to implement the regulation is supported.
- There is no requirement for a product take-back program. Furthermore, there are no proposed actions to deal with the matter of disposal of products containing D4. This is of significant concern for two reasons: those products that exceed the proposed concentration levels will be destroyed and other toxic chemicals may be released or produced in the process; second, there is the possibility that products that exceed the concentration limit may be exported to other countries that do not have lower regulatory requirements.

## Recommendations

- Labelling requirements should be applied to any products containing D4, whether imported or manufactured in Canada for domestic use or export, and include levels of impurities. Labelling should indicate that D4 is toxic to the environment.

- Exported products should be covered by the regulations.
- Permitting privileges must be severely limited, if granted at all. We support limiting permitting to therapeutic products with a defined essential use.
- A testing protocol should be in place. Random testing will not address the issue of non-compliance.
- Testing results and permitting plans should be publicly available.

## F. Product Categories and Concentration Limits

The focus of the product regulations is on those with the greatest potential to result in releases of D4 to the aquatic environment. At the consultation, EC clarified that the strategy aims to reduce pollution at the source, rather than relying solely on waste water treatment, and that the life cycle approach it uses is intended to take into account new uses or expansions of uses in the market place, should they occur.

Using Health Canada's Cosmetic Notification System database, personal care product categories were classified into three groups: those with high, moderate and unlikely potential for release to water. Factors considered when classifying a product were the volatility rate of pure D4, the average concentration of D4 in the product, the purpose of the product, where and when the product is normally applied to the body, and how long the product is likely to be left on before it is washed off.[6]

The methodology used to determine the proposed concentration limits for products took into account average concentrations of D4 in various products and the expected mass of D4 released to water. EC explained the steps of the methodology and calculations at the consultation meeting, and clarified that it used available data for its calculations, that the volatilization rate used was that of pure D4 times a factor of two and that no adjustments were made for volume of application or dose.

The proposed limits are set in order to meet the predicted no effect concentration **(**PNEC) value of 0.2 µg/L and have a Risk Quotient (RQ) less than one. [7]

EC has noted data gaps and indicated that additional data would be useful to refine the model. EC will also ensure that the methodology used to determine the proposed limit is described in more detail.

### Issues/ Comments

- From a public interest perspective, the adequacy of section 71 notices to provide information, given the number of data gaps identified is highly questionable. While the industry indicated that they provide data on an ongoing basis, the public's access to this information is limited to the information presented in the chemical assessment reports.
- In light of concerns raised by industry, we would be very interested in receiving notification of any reconsideration of categorization of products; the model used to calculate the concentration limits; the modeling used to estimate the Predicted Environmental Concentration (PEC) resulting from the use of personal care products; and the PNEC value derived from the risk assessment exercise.

[6] Consultation Document p. 9.

[7] **Risk quotient (RQ) -** Ratio of *predicted exposure concentration* to *predicted no effect concentration*. A risk of adverse effects exists if the RQ is greater than one. If the value is below one, there should be no risk as a result of the predicted exposure.

- From a public interest perspective, serious consideration must be given to environmental and societal benefits from taking regulatory action on D4 as well as costs to industry to achieve the proposed concentration limits.

**Recommendations**

- A thorough review and revisions should be undertaken on section 71 surveys issued by the government to ensure that required information is received from industry on such things as amounts and uses of particular chemicals, the products that contain the chemicals, and toxicity information. The onus should be placed on industry to submit the necessary data in the required timeframe. If the data is not available or not submitted, the government should take measures that are in keeping with the precautionary principle.
- Stakeholders should be notified of any reconsideration of categorization of products; the model used to calculate the concentration limits; the modeling used to estimate the Predicted Environmental Concentration (PEC) resulting from the use of personal care products; and the PNEC value derived from the risk assessment exercise.
- More detail on each step of the method used to determine the proposed concentration limit is required in order for stakeholders to better understand the assumptions, rationale and data sources used.
- More serious attention should be paid to environmental and societal benefits from taking regulatory action than has been exhibited to date.

## G. Industrial Release Limit Regulations

The proposed industrial release limit regulations would apply to any facility that manufactures D4 in a quantity of 100 kg or more, and to any facility that uses, processes, or transforms D4 into a mixture or product in a quantity of 100 kg or more. The regulations would not differentiate between D4 that is intentionally used vs. incidental presence. The proposed release limits would need to be met within one year of the regulations coming into force. The proposed instrument is to be published in *Canada Gazette*, Part 1 by January 29, 2011.

Only facilities that have an effluent would be targeted. The proposed regulation would prohibit the release of D4 in excess of a proposed release limit.

The development of a Substance Management Plan (SMP) would be required in cases in which D4 is detected above the detection limit in the effluent, which would be specified in the regulations.

Other requirements include sampling and analysis, annual reporting and reporting of accidents, as well as record keeping. The frequency of occurrence of releases above the regulatory limit reported each year and random site inspections would serve to measure the performance of the regulations, and results of environmental monitoring would serve to assess progress toward achieving the environmental objective.

Reporting provisions would include the quantity of D4 used, and an estimate of how much is discharged, to be calculated from effluent flow rate and results of sampling and analysis. Reporting requirements would not include information on which products or how much product is manufactured. Parameters factored into the calculation of the release limit include the PNEC, the partitioning factor, the percentage of removal expected from off-site wastewater treatment plant as well as dilution.

As points of clarification, EC stated that site specific assessments are not being considered at this point, that no partitioning factor was considered for the closed pipe leaving the site line and that a summary of the regulatee reporting could be made public.

### Sampling and Analysis Requirement and Methodology

### Issues/Comments

- The models and scenarios presented do not adequately address the cumulative input of all siloxanes and siloxane mixtures and the ability of treatment plants to address these inputs.
- According to three wastewater treatment models referred to, a D4 removal rate of approximately 95% is estimated from secondary treatment plants and approximately 55% from primary treatment plants.[8] However, these models are outdated and did not consider tertiary treatment plants.[9] This may impact the calculation of proposed limits.
- What measures are in place in areas where there are no wastewater treatment plants?
- It is not acceptable that the sampling frequency may be lowered below four times per year under any circumstances.
- Public transparency requires that reports on the results of testing for all facilities covered by the regulation be made available to the public in an accessible format.
- The key question is whether the proposed release limits will result in the reduction and even elimination of D4 use as well as drive the development of safer alternatives. At the moment, the absence of reduction and elimination targets makes it difficult to predict the effectiveness of the regulation.

### Recommendations

- EC should review up-to-date information on wastewater treatment facilities and re-consider their determination of removal rates for D4 and impact on the proposed regulated limit.
- Environment Canada needs to develop guidance for facilities impacted by effluent regulations.
- The sampling frequency should be maintained at four times a year, and increased as recommended when a level is greater than the MDL until sufficient testing shows otherwise.
- Reporting on the results of testing for all facilities covered by the regulation should be made available to the public in an accessible and easy format.

## H. Substance Management Plan (SMP)

### Overview

The purpose of the SMP is "to ensure that best management practices are adopted at facilities where D4 is used, manufactured, transformed or processed." It is proposed that a facility will be required to develop an SMP when one result of an analysis of the final effluent determines that the concentration in

[8] Consultation Document for D4 July 2010 p. 6, p. 15 Equation 1.

[9] Canada Wastewater Treatment: www.buyusa.gov/canada/en/wastewatertreatmentequipmentincanada.pdf. Currently, Canada has 3,700 water and wastewater facilities, 21% of which receive tertiary wastewater treatment, 47% secondary and 23% primary. 950 facilities require upgrades to tertiary or secondary treatment. (*Canada Gazette,* March 20 2010).

the effluent is above the Method Detection Limit (MDL). The facility will have one year to develop an SMP, and a second year to implement it. SMPs do not have to be submitted to EC.

The SMP would include a list of factors that could increase releases of D4 in industrial effluent, procedures to reduce the risk of release, and an inspection protocol to verify the procedures are efficient in controlling the risks.

Facilities required to develop an SMP would be required to develop an inspection report. The inspections proposed are internal (i.e., not third party inspections). Companies that already practice this type of inspection could rely on existing practices to meet the requirements. Criteria for the qualifications required for inspectors would not be set by the regulations; it would be up to each facility to determine their requirements.

Most laboratories are accredited to standards (e.g., ISO) to perform certain test methods; the industry can rely on this accreditation to ensure the competency of laboratories used for testing. While there was concern expressed that there are currently no commercial laboratories who conduct D4 testing, the capacity for testing may be in place by the time the regulations are implemented.

**Issues/Comments**

- The proposed regulation "would apply to facilities that manufacture D4 in a quantity equal to or greater than 100 kg/year, or to facilities that use, process or transform D4 into a mixture or product, in a quantity of 100 kg or more." It was unclear from the consultation how many facilities this proposed regulation will affect and how many facilities will not be required to meet the regulations. Facilities that do not meet the volume threshold will be allowed to continue operations with no changes.
- The regulations need to address when the SMP requirements will terminate.
- The benefits of the SMP as a continuous improvement mechanism may not be derived if it is triggered only by having a result above the MDL. This is only an incentive to reduce D4 to the regulated levels but not to replace it with a safe alternative or eliminate it.
- The lack of a requirement to file SMPs with EC and the self-inspection aspect of the SMP do not provide assurance to the public that the appropriate measures are in place for reduction of D4.

# I. Key Recommendations and Conclusions

- The risk management strategy for D4 should include reduction targets to be achieved by the proposed regulations on products and industrial effluents. The objective of the regulations should be the phase out of D4.
- The government should finalize its determination on the bioaccumulation of D4. This will influence the scope of the measures required for D4, which may include a requirement for virtual elimination.
- A process for public engagement should be developed with respect to the findings of the D5 Review and its potential impact for D4.
- The government should require the identification and promote the use of safer alternatives to D4 for both consumer products and industrial processes. Furthermore, assistance should be given for research on alternatives to D4, and to the nature of tests and assessments that would be needed to ascertain the safety of substitutes.

- The proposed regulations should ensure that disposal issues including management of stockpiles of products containing D4 or supplies of D4 are addressed.
- The reporting mechanisms proposed for both product and industrial effluent regulations should be strengthened to ensure full public transparency and accountability.
- The regulations for products intended for export should be no less stringent than those for products offered for sale in Canada.
- Exemptions and permits granted to certain products must be restricted and considered only in cases of a defined essential use.
- The government should review, revise, and expand the scope of the Section 71 survey so that more explicit and timely data that would better inform the government on use patterns and amounts, and relevant toxicity data are provided. All data collection should be mandatory.
- Similarly, the government should reduce the scope of information that can be classified by industry as confidential to improve transparency of process and information to the public.
- Given human toxicity data on D4 and its prevalent use in consumer products, there is potential for adverse human health effects. The government should keep apprised of new and on-going research by international and other agencies (US EPA, Sweden, and the European Commission) on human health effects of siloxanes and ensure that cumulative/synergistic effects and effects on vulnerable populations are considered.
- Labelling requirements should include the presence of D4 as a residue.
- The government should monitor D4 in all environmental media in remote areas in Canada (the far north) during various seasons, including winter.

In conclusion, we are in support of the federal government's proposal to take regulatory measures on D4. We consider federal regulations preferable to provincial or municipal approaches which would lead to piecemeal and inconsistent approaches.

At the same time, we find the scope of the proposed regulations limited and recommend that that they be strengthened, taking into account our concerns and recommendations.

***In line with the comments in our report, we urge the government to pursue a risk management strategy that would phase out the use of D4 in products and industrial processes; include safer substitution plans; and stipulate reduction targets to support a phase out in a timely manner.***

We appreciate the opportunity to having participated in this consultation and look forward to continuing dialogue on this matter.

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