Consultation Document

Octamethylcyclotetrasiloxane
(D4)

Chemical Abstracts Service Registry Number
556-67-2

Environment Canada

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1 Introduction

1.1 Purpose and Scope of the Consultation

The substance Octamethylcyclotetrasiloxane, Chemical Abstract Service Registry Number (CAS RN) 556-67-2, referred to throughout this document as "D4", was included in Batch 2 of the Challenge initiative under the Chemicals Management Plan.

The final screening assessment report concluded that D4 is entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, but is not entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. Therefore, it was concluded that D4 met the criteria in paragraph 64 (a) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The Proposed Order to add D4 to Schedule 1 of CEPA 1999 was published on May 16, 2009.

The proposed environmental objective for D4 is to prevent or minimize releases of D4 to the aquatic environment (EC & HC 2009). In order to achieve the lowest level of release of D4 to water that is technically and economically feasible, the Government of Canada is considering:

- Limiting the quantity or concentration of D4 that may be contained in certain categories of personal care products with the potential to result in releases to water, and
- Establishing a maximum D4 concentration in final industrial effluent and requiring the implementation of a substance management plan to ensure that best practices are adopted at facilities where D4 is used.

The consultation paper aims to:

- Inform interested stakeholders of the proposed risk management instruments for D4;
- Give interested and affected parties an opportunity to provide input into the risk management measures for certain personal care products and industrial effluents; and
- Allow Environment Canada to consider any questions or concerns from interested stakeholders on the proposed risk management instruments.

Interested stakeholders may include non-government organizations, provincial, territorial and federal government departments, and various companies.

More specifically, for the proposed measures on products, stakeholders include manufacturers, importers and retailers in the cosmetic and toiletry industry.

For the proposed measure on industrial effluents, stakeholders include manufacturers and formulators of soap and cleaning compounds, cosmetic and

toiletry, pharmaceutical and medicine products, paints, coatings and adhesives, plastic and rubber products, and chemical manufacturers and distributers.

1.2 Objectives

The main objective of this consultation is to invite stakeholders to provide their comments and feedback on the proposed risk management instruments for D4.

The specific objectives are to:

- Develop a common understanding among stakeholders of the issue;
- Solicit comments on the proposed maximum concentration limits in certain personal care products and in industrial effluents;
- Solicit comments on sampling and testing methodologies (e.g. detection limits and accuracy) to evaluate and monitor D4 in industrial effluents;
- Discuss proposed administrative requirements, such as reporting and record keeping;
- Solicit comments on the proposed requirement to develop a Substance Management Plan;
- Discuss feasibility and timelines for the implementation of the proposed regulatory requirements;
- Identify systems to control, mitigate or eliminate the release of D4 to water (e.g. control and capture technologies, chemical alternatives, better handling practices, closed loop system, etc.); and
- Obtain further information with respect to the economics associated with the proposed risk management instruments.

2 Background

2.1 Final Screening Assessment Report

A notice summarizing the scientific considerations of the final screening assessment report for D4 was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, on January 31, 2009, under subsection 77(6) of CEPA 1999. The approach taken in this ecological screening assessment was to examine available scientific information and develop conclusions based on a weight-of-evidence approach and using a precautionary approach, as required under section 76.1 of CEPA 1999.

The final screening assessment report (EC & HC 2008) concluded that D4 is entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, but is not entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. Therefore, it was concluded that D4 met the criteria in paragraph 64 (a) of CEPA 1999.

The report also determined that the Predicted No-Effect Concentration (PNEC) for D4 is 0.0002 mg/L for the aquatic environment.

2.2 Proposed Risk Management Approach

The proposed Risk Management Approach for D4 was made public in January 2009 (EC & HC 2009). It identified potential risk management actions to achieve the lowest level of release of D4 to water that is technically and economically feasible.

In order to address the environmental risks associated with D4, two regulations were proposed:

- to limit the quantity or concentration of D4 in certain personal care products and, where appropriate, in other consumer products that are manufactured in and imported into Canada; and
- to establish a maximum concentration of D4 in industrial effluents and require the implementation of a management system to ensure environmentally sound management practices are adopted at facilities where D4 is manufactured, transformed, or reformulated.

Based on analysis of D4 data related to consumer products received under the Challenge, it was determined that consumer use of cosmetics and toiletries has the most significant impact on the aquatic environment and there was no evidence of releases of D4 to water resulting from the use of other consumer products. For this reason, the Risk Management Approach for Products was modified to focus on concentration limits in certain personal care products.

The proposed requirements of both regulations are discussed further in Section 5 of this document.

2.3 Environmental Monitoring

As part of the Chemical Management Plan Monitoring, Surveillance and Research Program, work is ongoing to collect information on levels of D4 in the following media: wastewater effluent and influent; surface water; sediment; fish; soils following sludge application and air. The data collected will provide information on levels of D4 in the ambient environment as well as an indication of the fate of D4 in wastewater systems. As they become available, the results from this work will be used to inform the development of risk management measures and to later evaluate the performance of these measures.

3 Uses of D4

3.1 Current Uses and Industrial Sectors

A section 71 notice was published under CEPA 1999 to gather information on D4. It was reported that in 2006, D4 was not manufactured in Canada at quantities equal to or greater than the reporting threshold of 100 kg and that between 1 000 000 kg and 10 000 000 kg of D4 was imported into Canada (EC & HC 2008).

The most significant Canadian use of D4 is for the manufacture of silicone polymers and copolymers. D4 is also used in personal care products, such as hair and skin care products and antiperspirants. It was also reported for use as a defoamer (pulp and paper, food, petrochemical, petroleum, chemical manufacture and water treatment) (EC & HC 2008).

Silicone polymers that contain D4 have been approved as active and non-active ingredients in pharmaceuticals in Canada, the most common use being in antiflatulance drugs. Other uses of silicones polymers include:

- as a formulation component of personal care products for hair and skin care (i.e. moisturizers, aftershaves, make-up, shampoos, conditioners, hair styling products, etc.);
- antiperspirants and deodorants;
- biomedical uses;
- defoamers for use as processing aids and in household products;
- surfactants and mould release agents;
- lubricants;
- polishes and coatings on a range of substrates including textile, carpeting and paper;
- sealants and architectural coatings; and
- mechanical heat transfer and dielectric fluids and reprography.

Silicone polymers that contain D4 are also used in the production of elastomers that are used in biomedical applications, sealants and adhesives, moulded silicone rubber, film and fabric coating and encapsulation.

3.2 Characterization of Releases into Canadian Water

D4 is not reported to occur naturally in the environment. It is released to the environment in a dispersive manner due to its widespread use. The release of D4 is mainly to air, due to its high volatility, and to water (via effluents from wastewater treatment systems) during personal care product use; however, D4 may also be released to the environment during its use in industrial processes. When D4 is released to wastewater and water, it is expected that a portion would be adsorbed by the suspended solids, such as sewage sludge and sediments (EC & HC 2009).

3.3 Reducing D4 Releases to Canadian Waters

3.3.1 Possible Alternatives

While no information on potential substitutes for D4 was submitted by industry under the Challenge, proprietary information obtained through interviews with industry has revealed the existence of at least a few potential substances that could be useful in alternative formulations. Information available on supplier websites and the existence of certain personal care products that do not contain D4 also indicate the existence of potential alternatives.

It may also be possible that D5 (decamethylcyclopentasiloxane) and D6 (dodecamethylcyclohexasiloxane) may be useful in reformulations, based on their International Nomenclature of Cosmetic Ingredients (INCI) function, physical and chemical similarities to D4.

The use of any alternatives may trigger application of other Canadian regulations, such as the *New Substances Notification Regulations*. The CEPA Environmental Registry should be consulted for more information on the *Canadian Environmental Protection Act, 1999* and its requirements (http://www.ec.gc.ca/CEPARegistry/).

3.3.2 Control and Capture Technology

No information on potential control and capture technologies for D4 was submitted under the Challenge.

According to three wastewater treatment models (ASTreat 1.0, SimpleTreat 3.0 and STP Model 1.5), wastewater treatment plants are efficient in removing D4. A conservative model estimates a D4 removal rate of approximately 95% from secondary treatment plants and approximately 55% from primary treatment plants. For more information on the three models, see Annex 3.

In order to validate the predicted removal rates, a sampling program is planned at different wastewater treatment plants across Canada during 2010.

4 Existing Risk Management Actions

4.1 Information Gathering Activities

Canada

In May and June 2010, a voluntary questionnaire was sent to certain facilities that reported using or releasing D4 and D5 under the Challenge. The purpose of this questionnaire was to help Environment Canada gain a better knowledge of practices used in the industry. The questionnaire is included in Annex 2.

United States

On March 17, 2010, the US Environmental Protection Agency announced that it is preparing an action plan for siloxanes. The action plan is expected to summarize uses, substitutes, human health hazards, environmental hazards, fate and exposure characterization, domestic and international regulatory reviews, and next steps with regards to siloxanes.

4.2 Risk Management Activities

Canada

Pest Control Products Act - D4 is currently classified as a List 2 formulant. List 2 formulants are considered potentially toxic, based on structural similarity to List 1 formulants (defined as having significant concern with respect to their potential adverse effects on health and the environment) or on data suggestive of toxicity. Formulants may be reassessed when new information is received (PMRA 2007).

Transportation of Dangerous Goods Regulations - D4 is a Class 3 substance (Flammable liquid). These regulations establish safety requirements for the transportation of dangerous goods, including means of containment, training, emergency response assistance plans, and accidental release and imminent accidental release report requirements (EC & HC 2009).

Europe

As of May 26, 2010, the chemical priority database of the Swedish Chemicals Inspectorate (PRIO 2006) identifies D4 as a priority risk-reduction substance because it meets the criteria for “Environmentally hazardous, potential long term effects.”

The European Commission Health Working Group agreed that D4 should be classified as a Repr Cat 3, R62, R53 (IHCP 2004). A substance classified as R53 “may cause long-term adverse effects in the aquatic environment.” A substance classified as R62 indicates a “possible risk of impaired fertility”. The Reproduction Category 3 signifies the chemical produces or increases the incidence of non-heritable effects in progeny and/or impairment in reproductive functions or capacity (HSE 2010).

Council Directive 2003/15/EEC states that a *"substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) and found acceptable for use in cosmetic products*."

No conclusion has been made by the SCCNFP to date on D4. However, industry has submitted data indicating products do not use more than 1% D4 (SCCP 2005).

5 Proposed Regulations

These regulatory proposals aim at preventing or reducing releases to the environment from industrial effluents and from the use of certain consumer products containing D4.

The proposed regulations would be made under section 93 of CEPA 1999. Section 93 provides the authority to develop regulations with respect to a substance specified on the List of Toxic Substances in Schedule 1, including regulations regarding concentration limits, and requirements for sampling, analyses, record keeping, administration, and information submissions.

5.1 Products Regulations

5.1.1 Determination of Product Categories

Based on data received from industry, approximately 87% of D4 was used both in final products for the cosmetic and toiletry industry and in the manufacture of silicone polymers destined for the cosmetic and toiletry industry. The second most significant use of D4 at 11% was in the manufacture of silicone polymers for the coatings, sealants, and adhesives industry. The remaining 2% of D4 use was in final products from sectors including automotive, pharmaceuticals, paints, coatings, cleaning and rubber.

Analysis of the data indicates that the most significant releases to the *aquatic environment* were related to the use of cosmetics and toiletries. While there are numerous types of personal care products containing D4, the focus of this risk management activity is on those with the potential to result in releases to the aquatic environment. Therefore, personal care product categories were classified into three groups:

(i) those with high potential for direct release to water,
(ii) those with moderate potential for release to water, and
(iii) those that are unlikely to result in releases to water.

Factors that were considered when classifying a product into one of the three groups were the volatility rate of D4 as a pure substance, 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. A conservative factor of two was applied to the

published volatility rates (Berthiaume 1999) of 100% volatilization in approximately 30 minutes for D4 as a pure substance. The factor was applied because published information regarding the volatility rate of D4 in finished products is not available at this time. Preliminary indications from laboratory testing performed by Environment Canada are consistent with this assumption.

The proposed products regulations would establish concentration limits on personal care products that are considered to have a high potential for direct releases to water, and those with moderate potential for release to water.

The consultation will discuss the feasibility of the regulatory proposal, described in detail below, which has been developed with requirements that are generally consistent with other existing consumer product regulations under CEPA 1999.

5.1.2 Interpretation and Definitions

5.1.2.1 Definitions

Terms used in the cosmetic industry for various products will not be defined unless otherwise specified in the Table under Section 5.1.3 of this document, where it is necessary to clarify category groupings.

5.1.2.2 Application

The proposed concentration limits would apply to any person who manufactures, imports, sells or offers for sale products for use in Canada as outlined in the Table in Section 5.1.3. Products that are manufactured or imported for export only would be proposed to be exempt from this regulation.

5.1.2.3 Prohibition

No person would be allowed to manufacture, import, sell or offer for sale products outlined in Section 5.1.3 that are for use in Canada if the concentration of D4 exceeds the limit stipulated in the Table in Section 5.1.3.

5.1.3 Proposed Concentration Limits

Concentration limits to be proposed for D4 are included in the table below. An explanation of how these limits were derived is included in Section 5.1.3.1.

A product that may fall into multiple product categories must meet the most restrictive D4 concentration limit, as applicable.

Table 1: Concentration limit by product category

Product Category		**Proposed D4 Concentration Limit (weight %)**
HIGH POTENTIAL FOR DIRECT RELEASE TO WATER		
BATH PREPARATION	Includes bath and body oils, salts used in the tub	0.65
GENITAL LUBRICANT		0.01

Product Category		**Proposed D4 Concentration Limit (weight %)**
HAIR CONDITIONER	Straightening, volumizing, hydrating, thickening, normalizing, curl reviving, colour protector, fortifying, intensive, etc - used in shower and intended to be washed out under normal use	0.02
HAIR DYE	Product which chemically alters colour of hair (i.e. does not include sprays that colour hair surface)	0.01
HAIR MASKS	Deep conditioning treatment left in hair for extended period of time (i.e. more than 5 min), but intended to be washed out	0.01
HAIR SHAMPOO	Straightening, volumizing, hydrating, thickening, normalizing, curl reviving, colour protector, fortifying, intensive, etc - used in the shower and intended to be washed out under normal use	0.01
HAIR WAVING PREPARATION	Perm solutions, neutralizers, hair straightening solutions.	0.05
SHAVING GELS, FOAMS, ETC	Shaving creams, gels, soaps used in sink or tub, depilatories, epilatories, wax strips, cream hair removers, etc. (does not include aftershaves or post treatment of skin after hair removal)	0.01
SKIN CLEANSER	Includes body washes and face cleansers as exfoliants, microdermabrasion products, acid cleansers, shower gels, moisturizing body washes/milks	0.01
MODERATE POTENTIAL FOR RELEASE TO WATER		
DEODORANTS and ANTIPERSPIRANTS	Roll-on, stick, gel, spray, etc	0.01
FACE MASKS AND PEELS		0.08
FACE AND LIP MOISTURIZERS/LOTIONS	Includes serums, gels, creams, moisturizers, balms, etc.	0.2
HAIR GROOMING	Includes shiners, smoothers, protectors, fixatives, defrizzers, etc. in formats such as creams, gels, sprays, pomades, serums, etc. that are intended to style or set hair and be left on	0.65
HAND, NAIL, AND BODY LOTIONS	Includes milks, moisturizers, butters, mousses, etc.	0.55
MAKE UP REMOVER	For eyes or face in liquid, cream, oil, etc.	1.35
MASSAGE OIL		0.01
SUNSCREENS		0.07

5.1.3.1 Determination of Concentration Limits

This section describes the methodology used to determine the proposed concentrations limits that are listed in Table 1.

Criteria for Reduction:
The concentration limits have been established with the aim of meeting the Predicted No Effect Concentration (PNEC) of 0.0002 mg/L for D4 and having an aquatic Risk Quotient (RQ) of less than one. The RQ is a function of the PNEC. A risk of adverse effects exists for aquatic organisms when the RQ is greater than one.

Step 1 – Determine Average Concentration in Various Personal Care Products
The first step in determining the concentration limits was the use of Health Canada's Cosmetic Notification System database to group products that contain pure D4 into categories, such as hair grooming products, traditional hair conditioners, make-up removers, etc. The midpoint of the concentration range and the number of products for each range was then used to determine the average concentration for a category.

Step 2 – Determine Expected Mass (M_E) of D4 Released to Water through the use of Personal Care Products
The Mass Flow Tool, a modelling tool that tracks the mass of a substance throughout its lifecycle, was then used with data received during the Challenge to determine the potential mass of D4 being released to Canadian waters. The Mass Flow Tool accounts for the various stages of the substance, such as production losses through transfers, to air, to water in cleaning operations, or product use, exports, etc.

It is estimated that approximately 60% of personal care products containing D4 that are manufactured in Canada are exported. Products to be exported are not proposed to be subject to the regulations. This factor was therefore considered in the determination of the expected mass to be released to water.

A release of 10% to water through the use of all personal care products was also used and is based on an assumption made by the United Kingdom (Brooke 2006).

Step 3 – Determine Maximum Mass (M_M)of D4 that may be released to Water while still achieving a Risk Quotient of Less than One
The mass of D4 entering wastewater treatment plants is an input variable in the wastewater treatment plant model called Megaflush. The model contains a database of over 900 wastewater treatment sites in Canada and calculates the Predicted Effluent Concentrations and aquatic Risk Quotient of a chemical in a body of water for each site, given the mass entering Canadian waters. The model

takes into account the population served, influent and effluent flow rates, type of receiving water and removal rates for various wastewater treatment processes. The input mass was adjusted using an iterative process until the effluent concentrations resulted in no aquatic risk, meaning the Risk Quotient is less than one, for 97% of sites across Canada.

A reduction factor was calculated using the following formula:

$$\%\,\text{Reduction} = \frac{M_E - M_M}{M_E} \times 100\,\%$$

Step 4 – Reduce Average Concentration of Personal Care Products by Factor Determined in Step 3

Based on the calculations above, the average concentrations of certain personal care products that have a high or moderate potential for release of D4 to water are proposed to be reduced by 90%.

The D4 concentration limits established for the defined product categories are anticipated to manage the risks associated with the use of D4 in personal care products to a level that is acceptable for discharge at 97% of wastewater treatment sites. Of the remaining sites that did not meet a Risk Quotient of less than one, over 80% are considered to have no treatment.

5.1.4 Permitting

The proposed regulations may allow for application for a permit in situations where there is no technically or economically feasible alternative or substitute for the substance in the product.

The permit would expire two years after the day on which it is issued, unless the applicant submits an application for renewal that meets the specified requirements at least 90 days before the day on which the permit expires. The permit may be extended only once for an additional two years for a given product and the same use.

The permit would require the applicant to provide a description of a plan that identifies the measures to be taken by the applicant to minimize or eliminate any harmful effect of the toxic substance on the environment.

Any information that is submitted to the Minister under the proposed regulation is to be dated and signed by the person to whom the regulation applies or the person authorized to act on their behalf, to certify that the information is accurate and complete.

5.1.5 Labelling

Any person that manufactures, imports, sells or offers for sale products that are subject to the proposed regulations would have to indicate on the container in which the product is to be sold the date on which the product was manufactured

or a code representing that date. If a code is used, the person shall provide an explanation of it to the Minister, on request.

5.1.6 Reporting Requirements

No reporting requirements are proposed.

5.1.7 Record Keeping

Any person that manufactures, imports, sells or offers for sale products that are subject to the proposed regulations would have to maintain records at their place of business in Canada, or at any other place in Canada where they can be inspected, for a period of five years. If the records are kept at any place other than the person's principal place of business, the person must provide the Minister with the civic address of the place where they are kept. Records may be kept in electronic format. The records would contain the following information:

For manufacturers:

- trademark or trade name of the products, quantity of the products manufactured containing D4, the respective concentrations, and date of manufacture;

For importers:

- trademark or trade name of the products, quantity of the products imported containing D4, and date of import;
- port of entry, harmonized commodity description, coding system number, importer number, bill of lading, invoice, all documents submitted to Canada Border Services Agency;
- contact information and address of principal place of business of the sender of the product;

For sales to suppliers, wholesalers, or retailers:

- trademark or trade name of the products sold, quantity of the products sold containing D4, and date of sale;
- delivery date, contact information and address of supplier, wholesaler, and retailer to whom the product was sold.

5.1.8 Coming into Force

The proposed regulation would come into force one year after the day that they are registered for manufacturing and importing and two years for sale and offer for sale, to allow a sell through period.

5.2 Industrial Release Regulations

5.2.1 Application and exclusion

These proposed regulations would apply to facilities that manufacture D4 in a quantity equal to or greater than 100 kg per year or to facilities that use, process or transform D4 into a mixture or product, in a quantity of 100 kg or more.

The intent is for the regulations to apply to users and manufacturers of the pure substance, formulated products or mixtures containing the substance. The regulations would not apply to users of products containing the substance. The intent of the proposed regulations is to exclude facilities that do not generate an effluent.

5.2.2 Prohibition of release

The proposed regulations would prohibit the release into the environment of a final effluent with a concentration exceeding the release limits.

The proposed release limits would need to be met within one year of the coming into force of the regulations.

5.2.3 Determination of the proposed release limits from final industrial effluents

The proposed regulations would limit the release of D4 from final industrial effluents to a maximum concentration. In order to determine the proposed release limits for D4, Environment Canada has considered the factors identified in Table 2 :

Table 2: Factors considered in the calculations of the release limits for D4

Parameters	**D4**
Predicted No-Effect Concentration (PNEC) (ug/L)	0.2
Partitioning Factor (%) (Water + sediments)	86.4
Maximum dilution in the environment	10
Estimated removal rate of an average WWTP (%)	55.4

One of the proposed release limits is calculated as follows:

Equation 1:

$$RL = \frac{PNEC * DF}{PF * (100\% - \%Removal_{WWTP})}$$

Where:

- RL: Release limit
- PNEC: Predicted No-Effect Concentration
- DF: Dilution Factor
- PF: Partitioning Factor
- % $Removal_{WWTP}$: % Removal from Off-Site Wastewater Treatment Plant

Modeling applied in the screening assessment accounted for dilution of wastewater treatment plant effluents discharged into surface receiving waters. Dilution factors were limited to a maximum value of 10 to be protective of aquatic organisms living in proximity to discharge points. The limiting dilution factor of 10 applies to about 75% of surface waters that receive effluent from industrial facilities, with lower dilution factors applying in the balance of cases.

Based on the Screening Assessment Report (EC & HC 2008), D4 may partition in significant quantities to air, water and sediment when released into water. Therefore, Equation 1 takes into account that a portion of D4 released to water partitions to air.

As indicated in section 3.3.2, wastewater treatment plants can remove a certain portion of D4. Equation 1 takes into account these removal efficiencies. However, as secondary treatment removal rates may vary greatly (depending on the capacity and the type of treatment system) and to provide an environmental protection factor, only the removal rates of primary wastewater treatment plants were used in the calculations.

If the industrial effluent is discharged to an off-site wastewater treatment plant, the proposed D4 release limit is 5.2 ug/L and if the industrial effluent is discharged to surface water bodies, the proposed release limit is 2.3 ug/L.

5.2.4 Substance Management Plan

The proposed regulations would require facilities that are subject to these regulations to develop, implement and maintain a Substance Management Plan (SMP). The purpose of the SMP is to ensure that best management practices are adopted at facilities where D4 is used, to minimize releases to the environment .

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 the effluent

is above the Method Detection Limit (MDL). The facility will then have one year to develop an SMP, and two years to implement it.

The SMP would include the following elements:

a. A list of factors that could increase releases of D4 in the industrial effluent.
   - Examples of factors include type of technology, human error, accidental release, manufacturing process, type of equipment, etc.

b. Procedures to reduce the risk of release by addressing factors identified in (a). Procedures would include method to minimize human error (such as training and standard operating procedures), inspection of critical equipment identified in (a), etc.

c. An inspection protocol to verify that the procedures in (b) control the risks efficiently.
   - The inspection protocol would include:
     i. A list of the items to be inspected (equipment, procedure, operation, etc.);
     ii. Frequency of the inspection. At least one inspection per calendar year would be required;
     iii. Qualifications required from the person performing the inspection.

Facilities that would be required to develop an SMP would also be required to prepare an inspection report. The inspection report would include the date of the inspection, the name and qualifications of the inspector and the observations (result of the inspection).

When the inspection report reveals that a procedure in (b) does not prevent or minimize the risk associated to the factor identified in (a), a corrective action plan would need to be developed. The corrective action plan would include a description of measures taken to remedy, reduce or mitigate the risk and a timeline to implement these measures.

The regulations would require that the SMP be reviewed and, if necessary, updated at least once per calendar year.

5.2.5 Sampling Requirements

It is proposed that samples be taken at least four times per year, and at least 70 days apart. The samples should be undiluted and representative of the facility industrial effluent and representative of normal operating conditions.

In order to reduce administrative burden, it is also proposed that if a facility obtain four consecutive analytical results under the method detection limit, the facility

would be allowed to reduce the sampling and testing frequency to two times per year at least 120 days apart.

5.2.6 Laboratory Analysis

The proposed regulations would require that analysis of the samples be performed by a laboratory that is accredited by a Canadian accrediting body under the International Organization for Standardization standard ISO/IEC 17025: 2005 entitled *General requirements for the competence of testing and calibration laboratories*, as amended from time to time.

The regulations would not specify the method to be used for analyzing samples. However, the method used would need to meet specified analytical requirements of detection limit, precision and accuracy. This would provide flexibility in conducting analysis for laboratories, expedite the use of new analytical techniques and result in less costly approaches to conducting required testing.

The analytical methods would be required to meet a detection limit of 0.25 ug/L with an accuracy of 30% and a precision of 30%.

5.2.7 Record Keeping

It is proposed that the owner or operator of a facility would need to keep all the documents listed below at the facility to which these regulations apply or, on notification of the Minister, at any other place in Canada where they can be inspected for a period of at least five years beginning the date of their creation.

- Plan with the location of the final effluents
- Analytical results (dates, method, laboratory)
- Justification for the date of the sampling and analysis
- Substance Management Plan and information used to develop, implement and maintain the SMP
- Inspection report
- Corrective action plan
- Annual report and information used to prepare the report
- Other information required by these regulations

5.2.8 Annual Reporting

Facilities would be required to submit an annual report to the Minister that would contain the following:

- The name of the facility, the street and physical address of the facility (if different), and the telephone number and e-mail address (if applicable) of the person submitting the report;
- The quantity of the substance manufactured and/or used in the calendar year and the method used to determine this quantity;
- The estimated quantity of the substance released in the effluent during the calendar year and the method used to determine this quantity;

- The effluent flow rate and the method used to determine it.
- The dates, method and results of sampling and analysis.

The quantity of the substance released could be calculated using the measured concentration of the substance in the effluent and the effluent flow rate. The concentration of the substance in the effluent would be determined by the sampling and analysis requirements described in sections 5.2.5 and 5.2.6. To determine the effluent flow rate, three options can be considered: installation of a flow meter, instantaneous measurement of the effluent flow rate or estimation of the effluent flow rate based on the available information.

5.2.9 Reporting Accidental Release into the Environment

Where there occurs or is a likelihood of a release into the environment of a substance in contravention of a regulation, paragraph 95(1)(a) of CEPA 1999 requires that a written report be submitted to an enforcement officer.

The proposed regulations would require that the following information be contained in the written report:

(a) the name, civic address and telephone number of the person submitting the report;
(b) the civic address of the facility where the release occurred or is likely to occur;
(c) in the case of a release, the date, time, duration and exact location of the release;
(d) in the case of the likelihood of a release, the date, time and location where the release is likely to occur;
(e) the estimated quantity of D4 that was released or may have been released;
(f) a description of the circumstances leading to the release or likely release, including identification of its cause, if known, and any corrective action taken;
(g) a description of measures taken to remedy, reduce or mitigate any danger from the release; and
(h) the identification of all persons and agencies notified as a result of the release.

This proposed content of this report is consistent with other regulations made under CEPA 1999.

Also, in case of non-compliance with the release limits and when a written report must be submitted under section 95 of CEPA 1999, it is proposed that samples be collected and analyzed each week until the concentration of D4 in the effluent is below or equal to the proposed release limits. When the results of three consecutive analyses determine that the concentration in the effluent is below or equal to the proposed release limits, the frequency of the sampling and analyzing

would be required at the frequency indicated in section 5.2.5, i.e. at least four times per year, and at least 70 days apart.

5.2.10 Certification of information to be submitted

Any information submitted to the Minister under the proposed regulation is to be dated and signed by a person authorized to do so, to certify that the information is accurate and complete.

5.2.11 Coming into Force

The proposed regulations would come into force on the day they are registered.

The proposed release limits would need to be met within one year of the coming into force of the regulations.

It is proposed that a facilities would be required to develop an SMP, when one result of an analysis of the final effluent determines that the concentration in the effluent is above the Method Detection Limit (MDL). The facility will then have one year to develop an SMP, and one additional year to implement it.

6 Performance Measurement of Proposed Regulations

For the products regulations, random test sampling of the relevant personal care products may be used to assess the success of the proposed products regulations.

For the industrial release regulations, the frequency of occurrence of releases above the regulatory limit reported each year and random site inspections may be used to evaluate the success of the proposed industrial release regulations.

Results of environmental monitoring would be used as indicators to assess the performance of both the proposed regulations in achieving their environmental objective.

7 Next Steps

The consultation will be followed by a comment period. Comments received during this period may be taken into consideration while drafting the proposed regulations. Please submit comments in writing no later than September 3, 2010.

Environment Canada welcomes the distribution of this consultation document to any interested and affected parties. A copy of this consultation document will be available on the CEPA 1999 Environmental Registry [www.ec.gc.ca/ceparegistry].

Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the

information a request that it be treated as confidential. Comments on these two regulatory proposals should be submitted to the addresses provided below. Please ensure that comments are addressed to the appropriate person:

	Industrial release Regulations	**Products Regulations**
By Mail	Director Chemical Production Division Environment Canada Place Vincent Massey, 19th Floor 351 St-Joseph Blvd. Gatineau QC K1A 0H3	Director Products Division Environment Canada Place Vincent Massey, 18th Floor 351 St-Joseph Blvd. Gatineau QC K1A 0H3
By Email	pgpc-cmp.dppc-cpd@ec.gc.ca Please type "Consultation on D4 industrial effluent regulations" in the subject line of your message.	Products.Produits@ec.gc.ca Please type "Consultation on D4 product regulations" in the subject line of your message.
By Fax	819-994-5030	819-953-3132

It is the intent of the Government of Canada to publish a proposed risk management instrument for certain products in the *Canada Gazette*, Part I, in Spring 2011. The final instrument would be published in Winter 2012.

It is the intent of the Government of Canada to publish a proposed risk management instrument for industrial effluent releases in the *Canada Gazette*, Part I, by January 29, 2011. The final instrument would be published by July 2012.

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ANNEX 1: QUESTIONS FOR DISCUSSION

Environment Canada is seeking to fill data gaps for the development of regulations for D4. Environment Canada is asking stakeholders to prepare for the consultation by reviewing the questions in advance and preparing responses.

Questions in sections A1- 1 to A1- 3 will be focused on at the consultation while sections A1- 4 and Annex 2 list other questions that may come up during the consultation.

Some stakeholders may also have been contacted by Environment Canada before the consultation regarding some of these questions via a voluntary questionnaire (see Annex 2).

A1- 1: COMMON QUESTIONS FOR PRODUCTS AND INDUSTRIAL RELEASE REGULATIONS

1. Trends in the use of D4
2. Are there suitable alternatives available for D4?

A1- 2: PRODUCTS REGULATIONS

1. Are there concerns with the proposed structure of the Products Regulations?
2. Are the product categories selected appropriate?
3. Are there limitations to achieving the proposed concentration limits?

A1- 3: INDUSTRIAL RELEASE REGULATIONS

1. Do you have any concerns regarding how the release limits have been calculated?
2. Are the proposed release limits achievable? Do you think you already meet the release limit?
3. What do you think of the requirement of the Substance Management Plan and the proposed threshold for its application?
4. Do you have any concerns with the proposed sampling and analysis requirements?
5. In your opinion, what would be the best option for the determination of the effluent flow rate (when determining the quantity release in the effluent)?
6. Do you have any concerns with other administrative requirement (annual report, record keeping, etc.)?

A1- 4: OTHER QUESTIONS FOR THE PRODUCT REGULATIONS:

1. What is the approximate cost of substitutes?
2. What is the cost of D4?
3. What is the average cost of formulations (intermediate products used in final products) containing D4?
4. Do the identified substitutes change the efficacy of the product?
5. Are there process/manufacturing equipment changes required to use substitute(s)? If so, what is the estimated cost of upgrading the manufacturing plant to handle the substitute?
6. How long would it take to reformulate a product?
7. What are the costs associated with reformulation of a product?
8. Have reformulation efforts already begun for some products?
9. How long would it take for a company to comply with the proposed product regulation?
10. Are there studies to show that the use of leave-on products, such as hair grooming, deodorants, and moisturizers, is not a potential release to water?
11. How does industry understand the definition of cyclomethicone? (i.e. Is it considered to be the same thing as D4? A polymerized mixture using D4 with residuals of pure D4?)

ANNEX 2: VOLUNTARY QUESTIONNAIRE (2010)

The following questions were sent to certain facilities in May and June 2010. If your facility did not receive this questionnaire and are interested in providing Environment Canada with the information for your facility, answers to these questions should be sent by email to pgpc-cmp.dppc-cpd@ec.gc.ca. Please type "Consultation on D4 - Industrial release regulations – Questionnaire" in the subject line of your message.

1. Quantity, use and cost of the substances:

(a) Can you provide the quantity and use of D4 and D5 for the last 5 years ending with 2009? If yes, please provide them.
(b) What is the trend in use for D4 and D5 in your facility? Do you know the trend in use for D4 and D5 for your industrial sector?
(c) What is the cost of D4 and D5 per unit (please identify unit of measurement) over the last 5 years?

2. Alternatives:

(a) Are D4 and D5 alternatives to each other? In what cases?
(b) Are there alternatives to D4 and D5 that can currently be used to replace them?
(c) Are these alternatives currently available in Canada?
(d) What are the costs per unit (please identify unit of measurement) of these alternatives?
(e) Do you know if or when these alternatives will be available in Canada?
(f) If no alternatives are currently available, are you aware of any on-going research?

3. Industrial Process:

(a) In what kind of processes are D4 and D5 used at your facility? Please briefly describe the process.
(b) Is it a continuous process or a batch process?
(c) Is it a closed-loop system?
(d) Does the process involving D4 and D5 use dedicated lines?
(e) Do you have drains on the floor?
(f) Is there any possibility of D4 or D5 entering these drains? If it goes into the drains, are the liquids collected or treated?
(g) Is there possibility of release of D4 and D5 to waterways during the process or maintenance of the equipment? If yes, where?

4. Shipping and Handling Practices:

(a) In what kind of containers are D4 and D5 delivered to the facility (Drums, tote, road truck, rail)?
(b) Are these containers directly connected to the process lines? If not, how do the substances enter the process?

(c) How are the empty containers handled (Rinsed on site? Shipped back to supplier? Sent to specialized handling/disposal facility?)?
(d) If applicable, what are the costs associated with rinsing, returning back to suppliers or to disposal facilities?

5. Cleaning Practices:

(a) What are the cleaning and rinsing practices at the facility for the process?
(b) Where does the cleaning/rinse water go? Is it recovered and shipped to a specialized handling facility? Re-used in the process? Treated on site?
(c) What are the associated costs to these cleaning practices?

6. Industrial Effluent (wastewater):

(a) Does your facility have an effluent? If yes, what kind of effluent (process, cooling water, sanitary, other)?
(b) Is your effluent treated on-site? If yes, what kind of treatment and for which effluent i.e. process effluent, cooling waters, sanitary?
(c) What are the costs associated with the treatment system (initial capital investment and on-going annual operating costs)?
(d) Is your effluent discharged into the municipal wastewater treatment plant (please indicate the type of municipal wastewater treatment, if known: primary, secondary)? To a water body?
(e) Is your effluent likely to contain D4 or D5?
(f) Do you have equipment to measure the effluent flow rate (e.g. flow meter)?
(g) Do you have an estimate of your effluent flow rate (or water consumption – would the water consumption be representative of the effluent flow rate?)?
(h) Is your process effluent separate from the sanitary effluent and cooling effluent?
(i) Would you be able to install equipment to measure your process effluent flow rate? Would you have an estimated cost of installing this equipment?
(j) What would be the associated costs (capital and operating) of this equipment?

7. Facility Shut Down (for maintenance or process upset):

(a) Is there possible release D4 or D5 during facility shut down?
(b) What would be the impact of a shut down on the concentration of siloxanes in the effluent (because of possible lower effluent flow rate)?

8. Technology to control or reduce release of siloxanes:

(a) Are you aware of any existing control technology to control or reduce releases of D4 and D5 in industrial effluent?
(b) Do you have an estimate of removal efficiency for D4 or D5 and of the cost associated with this technology?

9. Sampling and analysis:

(a) Have you ever tested your industrial effluent for D4 or D5? If yes, what were the results of these tests? What were the costs of the analysis?
(b) Do you currently sample and analyze other substances in your effluent? If yes, please provide a list of substances.
(c) Are these analysis done on site or sent to a private laboratory?
(d) What would be the cost associated with sampling and analysis of D4 and D5 in your effluent (analysis, material, shipping, labor)?

10. Management System:

(a) Do you have any management systems in place (ISO, Responsible Care, other)?
(b) What would be the cost associated with developing and implementing such a system?
(c) Are you a member of an industry association? If yes, please provide name of the association.

11. Municipal and provincial regulatory requirements:

(a) Does your facility operate under a permit or certificate issued by the province? If yes, under which regulations?
(b) Does your facility operate under a permit or certificate issued by the municipality? If yes, under which by-law?
(c) Are there any municipal rule or by-law(s) that controls your effluent?

12. Other information:

The following question will only be asked to companies that have previously provided data on release to water

(a) How did you estimate or calculate the reported value in the section 71 notice?
(b) Were these values based on estimates/assumptions? What were they?
(c) Is it possible that there could be some trace of D4 or D5 in an analyzed sample of your effluent?
(d) Would you be willing to collaborate with EC and give us the permission to sample and analyze your effluent?

ANNEX 3: DESCRIPTION OF WASTEWATER TREATMENT MODELS

ASTreat 1.0 refers to a windows based computer model designed by Procter & Gamble (1999) to determine the chemical removal rates within an activated sludge treatment plant. It assumes a process consisting of a primary clarifier, an aeration tank, a secondary clarifier, a digester and dewatering unit. The program does not contain chemical databases and requires the user to input concentration, chemical properties, and operating conditions. (Crechem 2006)

SimpleTreat 3.0 is a spreadsheet-based fate model for organic chemicals in a conventional activated sludge process. It was originally developed by Struijs et al. (1991) at the Netherlands National Institute for Public Health and the Environment (RIVM) as a simple spreadsheet model based on the OECD SimpleBox approach. Version 3.0 is capable of predicting the removal efficiency of slowly biodegradable and hydrophobic chemicals. (Crechem 2006)

STP Model 1.5 is a windows based computer model developed by the Canadian Environmental Modelling Centre at Trent University. It uses a conventional activated sludge treatment plant and assumes a process consisting of a primary clarifier, an activated sludge aeration basin, and a secondary clarifier. It contains 16 chemicals with partition and biodegradation data, but can be expanded through the addition of user-defined substances. The program requires the user to input chemical properties and facility conditions. (Crechem 2006)

All three models are designed for steady-state conditions. (Crechem 2006)

ANNEX 4: LIST OF ACTIVITIES COMPLETED

Date	Activity
May 12, 2007	Release of "Batch 2" of the Challenge and the accompanying technical documents.
September 12, 2007	Deadline for submission of information under the section 71 notice on "Batch 2" substances (if no extension granted).
November 13, 2007	Deadline for submission of additional information by interested stakeholders, including on the extent and nature of the management/stewardship of "Batch 2" substances.
May 17, 2008	Publication in *Canada Gazette* and start of 60-day public comment period on (a) the draft screening assessment, (b) the proposal to pursue one of the measures as specified under subsection 77(2) and (c) the risk management scope documents.
January 31 2009	Publication in *Canada Gazette* of final assessment decision under subsection 77(6), release of proposed risk management approach document, and start of 60-day public comment period on the proposed risk management approach document.
April 1, 2009	End of 60-day public comment period.
May 16, 2009	Publication in *Canada Gazette* of proposed order adding certain batch 2 substances to Schedule 1 of CEPA 1999, and start of 60-day public comment period.
July 15, 2009	End of 60-day public comment period on the proposed order.