Summary of Public Comments Received on the Challenge substance D4 Siloxane (CAS No. 556-67-2) Proposed Risk Management Approach Document for Batch 2.

Comments on the proposed risk management approach document for **D4 Siloxane** to be addressed as part of the Chemicals Management Plan Challenge were provided by Johnson & Johnson Inc., the Canadian Society for Chemistry, the Personal Care Products Council, the Canadian Environmental Law Association, Chemical Sensitivities Manitoba, Dow Corning Corporation, Proctor & Gamble Inc., the Canadian Cosmetic, Toiletry and Fragrance Association, the Silicones Environmental Health and Safety Council, Dow Chemical Canada, the STORM Coalition, Amway Canada Corporation and the Japan Cosmetic Industry Association.

On July 22, 2010, the Minister announced that a Board of Review will be established to inquire into the nature and extent of the danger posed by D5. As such, responses to comments that were received regarding all three siloxanes that were assessed (D4, D5, and D6) are limited to D4. In addition, comments were received regarding the risk assessment conclusions for the three siloxanes. Responses to these comments will be published at a later date.

A summary of comments and responses is included below, organized by topic:

TOPIC	COMMENT	RESPONSE
Risk management objectives	No specific hazards have been identified in the risk assessment that would need to be addressed in the risk management stage.	The assessment report conclusions were based on an evaluation of possible releases to surface water from municipal wastewater treatment facilities which receive inputs from consumer uses of products containing D4 as well as industrial inputs. The proposed risk management approach addresses both consumer use of products and industrial releases.
	The stated risk management objective to "reduce releases to that which is technically and economically feasible" is of concern.	The intent of risk management is to reduce releases of these substances to levels that would be considered protective of the environment. Technical and economic issues related to attaining this goal are considered during development of risk management measures.

	There should be exemptions in cases where products are deemed "essential" and where there are no safe substitutions for D4 available.	The continued availability of essential products was considered when identifying product categories for risk management.
	Environment Canada and Health Canada should be pursuing prohibition of D4 due to the potential persistent, bioaccumulative and inherently toxic properties of this substance.	The final Screening Assessment Report concluded that D4 meets the criteria set out in paragraph 64(a) of CEPA 1999. It is also concluded that D4 meets the criteria for persistence as set out in the *Persistence and Bioaccumulation Regulations;* however, it was not possible to conclude at this time that D4 meets the criterion for bioaccumulation As a result, D4 is not subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize their release into the environment.
	Environment Canada should compare the proposed risk management approach to results of the United Kingdom Environment Agency/European Chemical Bureau's assessment of D4.	United Kingdom risk assessments indicated potential for releases of D4 during several lifecycle stages including personal care and household product use and personal care product manufacturing. The Environment Canada risk management approach also considers investigating and addressing these potential sources.
	Environment Canada should consider risk management that addresses an identified (actual) risk based on monitoring results and not on modeling results.	Development of risk management measures will consider all available information concerning environmental concentrations of D4 in surface water including appropriate mass-flow modeling and results of environmental monitoring for this substance as they become available. A limited number of samples at wastewater treatment systems and surface water in the vicinity of wastewater treatment system effluents were recently analyzed and the results of this sampling are being considered during development of risk management measures. Further monitoring of D4 in wastewater treatment system influents,

		effluents and biosolids, surface water and landfill leachate is planned.
	Which products would be the focus of risk management measures and the justification for this decision? Any proposed risk management should focus on those products with the potential to result in release of D4 to water.	The focus of risk management measures is on those products and processes that result in releases of D4 to water. Work to collect information on these products and processes has been conducted and the results were presented during consultations on proposed measures. Concentration limits for a range of personal care products have been proposed to reduce potential releases to water. A list of these products and their proposed concentration limits are available in the Consultation Document – Octamethylcyclotetrasiloxane (D4) available on the CEPA Environmental Registry at: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=D259C573-1. Following consultation, further information has been sought from stakeholders to refine product categories being considered.
	No public education campaign or labelling requirements were identified in the RM Approach.	Labelling requirements that protect the health and safety of Canadians are set out in the *Food and Drugs Act*, the *Cosmetic Regulations* and the *Consumer Packaging and Labelling Act and Regulations*. To comply with these requirements, cosmetic labels must supply: • an ingredient list; • the identity of the product, in English and French in terms of common or generic name or function; • a statement of net quantity in metric units of measurement; • the name and address of the manufacturer or distributor; and • directions, warnings or cautions, in English and French where necessary for safe use of the product. Additional elements such as the need for

		public awareness on D4 and labelling requirements were considered during the risk management development phase. Additional labelling requirements being considered as part of the proposed regulations concerning D4 in certain personal care products would require the container to include information on the date of manufacture or a code representing that date.
	Product categories that distinguish those products that release to water and/or that can be reformulated more easily than others should be developed.	The focus of risk management measures will be on those products that have the potential to result in releases of D4 to surface water. Consideration will also be given to issues concerning reformulation as well as to any exemptions that may be required on the basis of product use (i.e., essential therapeutic products).
	A need exists to address wastewater as a source of D4 including providing information on treatment levels in wastewater treatment plants and application of sludge to landfills and agricultural lands. Pollutants released to wastewater should be prevented at the source.	Releases of D4 from municipal wastewater are considered to be the largest source of these substances in surface water. As such, information related to the removal of these substances in various wastewater treatment processes will be considered during development of release estimates. Land application of sewage sludge containing D4 is not considered to result in significant releases of this substance to water. The proposed risk management measures will result in a reduction in releases of D4 by reducing quantities used in personal care products and quantities released from industrial effluents rather than requiring treatment at municipal wastewater facilities. These actions will also ultimately reduce the amount of D4 released to soil due to land application of sewage sludge.
	Disposal of products containing D4 was not addressed in the RM Approach.	Release of D4 from landfills was not estimated in the screening assessment; however, monitoring of this potential source has indicated that high levels of D4 are present in landfill gas. Future monitoring of landfill leachate will

		provide further information on the significance of release of D4 from this source.
	Environment Canada should consider developing Pollution Prevention Plans to work towards elimination of residual D4 in polymers and copolymers.	The contribution of residual D4 in polymers and copolymers to release of D4 to surface water was considered during development of risk management measures. Instruments targeting the elimination of residual D4 in polymers and copolymers are not the focus of the risk management objective, which is to reduce D4 releases to water through methods that are technically and economically feasible.
Release estimates	Environment Canada should consider using National Pollutant Release Inventory (NPRI) to collect data on industrial releases. A rigorous quality control program for sampling and analysis of D4 is recommended.	Environment Canada will consider proposing the addition of substances found to meet the criteria of section 64 of CEPA 1999 to the NPRI's substances list. Substances declared toxic under the CEPA 1999 in particular are given high priority in NPRI consultations. It should be noted that any party (person, government or organization) in Canada may submit a proposal to Environment Canada for changes to the NPRI program. Changes to the substance list result from the NPRI Consultations process and may include the addition, modification or removal of substances as well as changes in the thresholds at which they must be reported. There are challenges associated with sampling and analysis of D4. Sampling and analytical methodology has been developed by Environment Canada and will be available upon request.
	Environment Canada should investigate the possible role of cyclomethicone and polydimethylsiloxane (PDMS) as undocumented sources of D4.	Releases of D4 from all sources, including cyclomethicone and PDMS, have been considered in the proposed risk management measures for D4.
	A mass-balance analysis should be conducted to confirm the quantity of D4	Work has been undertaken to identify those products and processes with the potential to result in releases of D4 to

	released to water. Consideration should be given to newly available information, industry comments and role of the export of products.	surface water. Information on the types of products containing D4, quantities present in Canada and the role of export of products were considered during development of the proposed product concentration limits. For industrial releases, sampling at industrial facilities and wastewater treatment systems is underway to verify assumptions related to the quantity and concentration of D4 released from these facilities and also characterize the effluent concentration at associated wastewater treatment systems. Results of this work will be considered in the development of the final risk management instrument.
Risk management instruments	Can you clarify the exemptions for therapeutic products?	Any specific exemptions for products subject to risk management measures will be identified during development of the measures. There will be opportunities for public comment.
	The proposed action to address pest control products was "weak" and should indicate a higher priority for reassessment of D4. There is a need to assess alternatives as part of this process and for the process to be transparent.	Pesticides are stringently regulated in Canada to ensure they pose minimal risk to human health and the environment under the Pest Control Products Act (PCPA). Before pest control products are registered for use in Canada, Health Canada thoroughly assesses the health and environmental risks of pesticides. Since the use of D4 have already been assessed under the PCPA, the Risk Management approach for D4, based on the Chemicals Management Plan exercise, was that D4 was reclassified to a List 2 formulant. This will make them a higher priority for reassessment by the Pest Management Regulatory Agency (PMRA).
	The regulatory nature of the proposed RM measures to address reductions of D4 is of concern. Other options should still be considered.	Regulations were initially proposed as the risk management measures to address releases due to product use and industrial processes. Because limited data exists on the current concentration of D4 in industrial effluents, the current risk management proposal is a P2 Planning Notice. The proposed P2 Planning

		Notice was published in *Canada Gazette*, Part I on January 15, 2011 (http://canadagazette.gc.ca/rp-pr/p1/2011/2011-01-15/pdf/g1-14503.pdf). Public comments on the proposed Notice should be submitted prior to March 16, 2011. The proposed P2 Planning Notice would require facilities manufacturing or using equal to or more than 100 kg of D4 per year and releasing D4 in their effluents to prepare and implement Pollution Prevention Plans. This approach will also allow Environment Canada to collect information to better define industrial releases of D4.
Alternatives	There are currently no available alternatives for all product categories. Issues with reformulation include the unique properties of D4 and lack of safe alternatives.	Significant comment has been received on the lack of alternatives for all product categories. For this reason, the category approach has been identified that will allow for a consideration of available alternatives on a category basis. 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 alternatives. 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.
	Environment Canada should ensure that D4 is not used as replacements for Volatile Organic Compounds (VOCs).	Cyclic, branched or linear completely methylated siloxanes are excluded from the definition of VOC. As an exempt-VOC, D4 may be used as an alternative for VOCs in certain products. Generally, the VOC requirements address releases of volatile substances to air. The risk management for D4 will address potential releases to water.
Socio-economic impacts	The proposed risk management measures would result in a significant	Issues concerning the economic impact of any proposed measure are considered during the risk management development

	negative impact on the Canadian economy, and specifically on those manufacturers whose products are implicated in a competitive international marketplace. Restrictions on the use of D4 in products manufactured in Canada means a competitive disadvantage to Canadian companies in comparison to international companies who may not have similar restrictions.	phase. The international nature of product manufacturing is acknowledged as an important consideration.
	Environment Canada should complete a cost-benefit analysis to determine if there is an overall benefit to reducing the use of D4 in the marketplace.	A cost-benefit analysis is completed on proposed regulatory measures during the risk management development phase. The results of this analysis are presented in a Regulatory Impact Analysis Statement (RIAS) along with the proposed regulatory measures. Information to inform a cost-benefit analysis is gathered with the assistance of industry associations, companies and subject matter experts.
Consultations and timing	Extensive consultation on any proposed measures is needed.	For D4, stakeholders were identified through the Challenge and were invited to participate in the consultation process in August 2010. The meeting was followed by a comment period. Comments resulting from the consultation meeting have been considered in the development of the proposed control measures. Further consultation with stakeholders is anticipated prior to publication of any final instruments.
	The Government should delay timing of risk management to consider studies due at end of 2009.	As indicated in the proposed risk management approach document for D4, a proposed risk management instrument must be published in Canada Gazette within 24 months following the proposal to add these substances to Schedule 1 of the Canadian Environmental Protection Act, 1999 (CEPA 1999). Any information available prior to this date

		may be considered during development of proposed risk management measures.
	Industry is willing to work with Environment Canada to provide information concerning use patterns and releases of D4 in Canada.	Environment Canada has worked with several companies and industry associations to ensure that the information on which risk management measures are based is representative of current practices.
Monitoring	The use of monitoring information to evaluate progress toward elimination of D4 is recommended.	Monitoring for D4 in the air and wastewater has been planned as part of the overall monitoring program established under the Chemical Management Plan (CMP). Results of this monitoring work will be available to both inform the development of risk management measures and evaluate the progress in achieving the risk management objective.
	Environment Canada should monitor D4 in remote areas of Canada in the winter months to determine potential long-range transport concerns.	As indicated in the assessment report, D4 has the potential for long-range transport, but a very low potential for deposition. This transport mechanism was not a significant factor in the assessment conclusions. Future monitoring work under the CMP Monitoring and Surveillance Program may provide additional information on levels of D4 in remote areas of Canada.