Summary of Public Comments received on the Challenge substance Hydrazine (CAS 302-01-2) Draft Screening Assessment Report for Batch 10

Comments on the draft screening assessment report for hydrazine to be addressed as part of the Chemicals Management Plan Challenge were provided by the Canadian Electricity Association, Dow Chemical Canada ULC, CSM, International Institute of Concern for Public Health (IICPH)& Crooked Creek Conservancy Society of Athabasca (CCCSA), Inuit Tapiriit Kanatami (ITK), NB Power Corporation, Arkema & Charkitt Chemical, Bruce Power, Ontario Power Generation, Manitoba Hydro, JGRChem Inc., Hydro-Québec, and Nova Scotia Power Inc.

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

- Physical-chemical properties
- Bioaccumulation
- Persistence
- Proposed risk management
- Risk management scope
- Data gaps and deficiencies
- Uses
- Exposure
- Risk assessment conclusion

TOPIC	COMMENT	RESPONSE
Physical-chemical properties	The DSAR fails to discuss the fundamental property of hydrazine decomposition that occurs at temperatures reaching ≥250 °C. In thermal power generation, these temperatures are easily achieved and exceeded. Based on this understanding, the estimated 10% discharge of hydrazine is not reflective of thermal generation discharge rates.	Information has been added in the final SAR regarding decomposition of hydrazine at high temperature The open literature suggests some variance in the temperature at which appreciable decomposition occurs. There is evidence that hydrazine is found in the final effluents of power generating stations in Canada. For instance, measured concentrations of hydrazine in the final effluents of nuclear power plants of Ontario are reported in the final SAR.
Bioaccumulation	Hydrazine is not persistent, bioaccumulative, and	A substance may be determined to be harmful to the environment under Section 64(a) or (b) of CEPA 1999 without necessarily meeting the criteria of the *Persistence &*

	inherently toxic (PBiT). The risk quotients (RQ) in the Characterization of Ecological Risk exceed one, however the scenarios used were conservative. Why then is hydrazine considered to have a negative impact on an ecosystem?	*Bioaccumulation Regulations*. The exposure scenarios on which the RQ analyses are based were deemed realistic though information gaps have been filled using protective assumptions. These scenarios indicate that concentrations of hydrazine in surface water near nuclear and fossil-fuel power generating plants across Canada are higher than or close to the levels causing harm to aquatic organisms.
	There was limited data for bioaccumulation in the SAR. There is a need for the consideration of more scientific data in order to justify the bioaccumulation decision made by the government.	It is considered that there is enough scientific evidence to conclude that hydrazine does not meet the bioaccumulation criteria of *Persistence and Bioaccumulation Regulations*. It has been well demonstrated experimentally that hydrazine can be degraded by micro-organisms and metabolized by mammals.
Persistence	Hydrazine will persist in aquatic ecosystems where, under the 'reasonable worst case conditions' it may have a half-life exceeding 125 days. However, the draft assessment concluded that hydrazine is not persistent under the Persistence and Bioaccumulation Regulations.	The half-life values for degradation of hydrazine in water are not ≥182 days, which is the criterion for persistence as set out in the *Persistence and Bioaccumulation Regulations*.
	With uncertainty in the determination of the Predicted Environmental Concentrations (PEC) and the fact that releases of hydrazine have more than tripled from 2006 to 2008 (NPRI data), the government should apply a more	Certain of the assumptions used to calculate the PEC values (e.g. loss to wastewater, sewage treatment plant removal rate) are deemed conservative. According to NPRI, releases of hydrazine and it s salts to water have decreased from 6400 kg in 2008 to 697 kg in 2009. The Government of Canada is proposing to develop an instrument to prevent or minimize hydrazine releases to water, which would reduce the risks posed by hydrazine in the aquatic environment.

	precautionary approach for hydrazine than just reduction of use.	
	Additional sources of hydrazine to the environment include accidental discharges (e.g. hydrazine fuel used in aircraft, disposal of hydrazine in landfills, application of pesticides containing hydrazine, etc.). These additional sources of hydrazine exposure should be included in exposure estimates.	The 'build up' of environmental concentrations of hydrazine resulting from multiple anthropogenic sources affecting a common receiving environment appears unlikely because the substance is not persistent in the environment, including soils, and because most of these sources are modest in size and are probably spatially scattered. Overall, NPRI data for 2006 indicates that nearly all the emissions to air, water and soil were associated with the operation of nuclear power plants. In addition, more than 90% of these emissions were to water. Only a very small proportion of total hydrazine released to the environment was to soil.
	The SAR mentions that the facilities included in the report represent 29% of the facilities likely discharging hydrazine to aquatic environments in Canada. It is mentioned that this is a representative sample, however the evidence for this claim is very weak.	The number of plants included in the assessment actually represents 21% of the total number of power generating plants using or potentially using hydrazine in Canada. Those plants are the ones that are steam-based and hence that may use hydrazine as a corrosion inhibitor in their system (unless these plants reported not using hydrazine).
Proposed Risk Management	Proposed RM actions are inadequate to address the risks posed by the non-threshold carcinogen hydrazine. RM actions should address: the impact of releases to air; the effects on communities near the sites that use the substance; exposure via consumer products, pesticides and	As exposures of the Canadian public to hydrazine are considered to be low under current use conditions, the proposed human health risk management objective for hydrazine is to prevent increases in exposure. Current Canadian risk management on hydrazine is considered to minimize human exposure to the extent practicable. No reports of detectable levels of hydrazine in Canadian ambient air were identified in a review of the literature. Nearly all the emissions to air, water and soil reported to the NPRI in 2006 were associated with the operation of nuclear power plants, and more than 90% of these emissions were to water. The Government will continue their review of NPRI submissions in order to monitor changes in release media. Based on the absence of detectable levels in, and limited releases to, the Canadian environment, as well as the reactive nature of hydrazine, it is unlikely that Canadians are exposed to significant concentrations of hydrazine from the environment, both near and

	pharmaceuticals; broadening the scope of industrial facilities that use and release hydrazine; the potential impact of the storage of hydrazine at military installations. It is also recommended that the RM strategy includes Pollution prevention measures and an investigation into the use of safer alternatives.	far from industrial releases. Hydrazine is an industrial chemical not intended to be present in consumer products. Although unwanted impurities in the final products caused by the manufacturing and chemical processes can be present, no existing consumer goods containing hydrazine as an ingredient were identified above current available detection limits. Based on publicly available information and the S.71 submissions, the majority of all on-site releases are made by facilities in the power generating sector. The small quantities of hydrazine used by allies at Canadian Forces Bases are stored in secure facilities with limited access. Once international training exercises are complete, the hydrazine is returned to the allied country. The power generating industry s has identified several replacement chemicals for hydrazine in their boiler systems. None of these chemicals are considered adequate replacements for hydrazine in nuclear facilities; however, some are used in fossil-fuel powered facilities. The Government of Canada plans to develop an instrument to prevent or minimize releases of hydrazine to water from facilities in Canada using boilers to produce steam or electricity where hydrazine is used as a corrosion inhibitor. Specifically, a notice requiring the preparation and implementation of pollution prevention plans with respect to thermal and nuclear power generating facilities using hydrazine is being proposed.
Risk Management Scope	Risk management strategies should follow the Swedish Chemicals Agency's example, where hydrazine is listed as a phase-out chemical. The risk management scope fails to include measures to protect human health from existing uses of hydrazine.	Hydrazine is an industrial chemical not intended to be present in consumer products. Although unwanted impurities in the final products caused by the manufacturing and chemical processes can occur, no existing consumer goods containing hydrazine as an ingredient were identified above current available detection limits. The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to hydrazine. This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.
	Some power generating facilities have already reduced releases of hydrazine into the water through various release reduction initiatives. They should be exempt from any proposed risk management	This factor will be taken into account when developing the risk management instrument to prevent or minimize releases of hydrazine to the environment.

	measures.	
	The government should add hydrazine to the *Environmental Emergency Regulations* for all facilities that release, use, dispose, sell or import this chemical, regardless of the threshold for use or release of hydrazine.	Hydrazine has been listed in the Environmental Emergency Regulations since they came into force in 2003. Facilities with the equivalent of at least 6.8 tonnes of pure hydrazine on site, that is in a concentration of 10% or greater, and with a hydrazine container size of at least 6.8 tonnes are required to prepare and implement an environmental emergency plan. In addition, the Government of Canada is proposing to lower the regulated threshold for hydrazine in these regulations.
Data gaps and deficiencies	No attempt was made to determine whether there could be higher than calculated concentrations in some water bodies as the result of several facilities emitting hydrazine into the same receiving waters.	Exposures from multiple facilities were not considered because no data was available to estimate PECs from combined sources. However, given the rapid decay rate of the substance in water, it is expected that elevated concentrations are likely limited to the vicinity of the discharge, thus, site specific analyses are considered appropriate for the estimation of PECs.
	NPRI data for 2008 are the first to record releases of hydrazine to land, in the amount of 296 kg. Non-aquatic toxicity data should be taken into account.	Releases to land should not be of concern because there is solid published evidence to the effect that hydrazine is rapidly degraded in soils by auto-oxidation and microorganisms – these studies have been described in the assessment report. Also, the mass of hydrazine released to land is small.
	Because there is a lack of empirical data for hydrazine releases from the facilities using the substance as a corrosion inhibitor or other uses, there is a need to collect additional release	Releases were estimated based on best available data and knowledge and considered appropriate, though conservative, for use in the exposure assessment. Nevertheless, in addition and where relevant, research and monitoring may support verification of assumptions used during the screening assessment and, where appropriate, the performance of potential control measures identified during the risk management phase.

	data through mandatory surveys in order to reduce the uncertainty factors in the assessment.	
	Release data for multiple years would reduce or eliminate potential bias in the assessment.	All the assessments of substances conducted as part of the Challenge are based principally on data obtained via section 71 of CEPA for the calendar year 2006. The data for hydrazine can be assumed to be representative of the mid-decade 2000, as suggested by the relatively constant releases of hydrazine to the environment reported by the NPRI for the years 2004 to 2007.
	All releases of hydrazine should be reported through the NPRI. Based on the potential to do harm to the aquatic environment and its carcinogenicity, there should be no reporting threshold.	Companies that meet reporting requirements for the National Pollutant Release Inventory (NPRI) are already required to report their releases of Hydrazine (and its salts) to NPRI.
	The uncertainty of modelled estimates to hydrazine exposure is not discussed in the assessment.	Upper-bounding estimates were determined using environmental modelling software when recent, Canadian data was unavailable. The uncertainties associated with the use of modelled estimates rather than empirical data are documented in the assessment.
	New information provided could better inform the government as to the changes that are considered essential in the risk management regimes for this substance.	The Government of Canada will continue to consider all comments and additional information received on risk management scope documents. All comments are carefully considered and are helpful in improving risk management strategies. The public comment period is extremely helpful in assisting the Government to develop strong and effective risk management actions.
	Reports to NPRI and the Challenge for releases of hydrazine to the environment are conservative estimates and that actual releases are much less than reported.	The Challenge screening assessments are based on considerations of the available data. The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. Thus the process being used for Challenge substances is not to wait until data gaps are filled, but to act on what we know now. New information can be received through several mechanisms, some of which are defined under specific sections of CEPA 1999. Examples of such mechanisms include mandatory industry submissions,

		international decisions, and emerging science and monitoring. All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted.
	There are major data gaps and uncertainties in ecological and human health factors.	The Challenge screening assessments are based on considerations of the available data. The Government of Canada has stated that the absence of new information will not preclude the Ministers from issuing a decision that safeguards human health and the environment. New information can be received through several mechanisms, some of which are defined under specific sections of CEPA 1999. Examples of such mechanisms include mandatory industry submissions, international decisions, and emerging science and monitoring. All substances that have undergone assessment remain subject to future evaluation if new, substantive information is identified that indicates that further consideration is warranted.
Uses	Hydrazine use is critical in the operation of nuclear generating units. The listing of hydrazine on Schedule 1 of CEPA and/or the reduction of the use of hydrazine in generating stations will impose significant challenges on operators of nuclear power generating plants since the consequences of inadequate nuclear steam cycle chemistry control include decreased safety margin and more frequent and extensive repairs, resulting in increased worker radiological exposure and generation of active waste.	The risk management proposed for hydrazine is an instrument to prevent or minimize releases of hydrazine to water from facilities in Canada using boilers to produce steam or electricity. A prohibition on the use of the substance or mandatory restrictions on use volumes in Canada is not currently under consideration.
	The draft screening assessment report estimates	Based on new information received, a value of 7.56% is now used for loss of hydrazine to wastewater in nuclear power plants. For those fossil-fuel power plants for which no

	that approximately 10% of hydrazine used in power generation is discharged in effluent flows. However, the technical basis for this assumption is not clearly defined.	information was received, a value of 10% is used based on the value provided for a nuclear power plant and assuming that losses of hydrazine in fossil-fuel and nuclear power plants are similar.
	The data that Bruce Power reports to the NPRI are typically based on engineered calculations that are overly conservative. Hydrazine release estimates based on typical measured and limiting concentrations in discharge pathways indicate that the total amount and average concentrations of hydrazine released to the environment are a small fraction of the values indicated by the NPRI data.	The values used in the exposure scenario for the Bruce power plant are based on measured effluent concentrations as well as modelled concentrations. The latter do not use NPRI data in the calculations.
	Significant presence and exposure to hydrazine may result from drug and/or food applications. This exposure should be considered in any decisions (risk assessment or management) but should not impair the safe usage of drugs or key activities such as the delivery of a safe food supply.	In Canada, hydrazine has been identified as a residual impurity in one component of a coating for one laminated film used to package a variety of foods. Since hydrazine is used as a starting ingredient and due to its reactive nature, it is not expected that it would be in the final product at a significant level. Hydrazine is an industrial chemical not intended to be present in consumer products. No consumer products containing hydrazine as an ingredient were identified. When used as a raw material or an intermediate in the formulation of consumer products, hydrazine may be found in final products as an unintended residual. Hydrazine is not permitted to be used in any food additive applications, nor is there any data that suggests it is used directly in food packaging.
	Possible uses of hydrazine in metal plating and textile production are not discussed	Hydrazine use in metal plating and textile production was not identified in Canada.

	in any detail in the screening assessment.	
	Information has been provided on a hydrazine-substitute for use as a corrosion inhibitor in boilers at power generating stations.	The Government of Canada will continue to consider all comments and additional information received regarding new alternative technologies and techniques, as well as alternative chemicals and substitutes for hydrazine. Available information on alternatives and the risks of the alternatives is considered during the risk management process. The Government of Canada welcomes input from stakeholders on alternatives for hydrazine.
Exposure	To date, the levels of hydrazine have not been measured in the receiving water into which Canadian power plant effluents flow. The literature indicates that, where numerous measurements were taken in Japan, hydrazine was not detected in surface waters.	Insufficient information was provided to enable a clear interpretation of hydrazine concentrations in Japanese receiving waters. It is not possible at this time to interpret the measured occurrence of hydrazine downstream of point sources because of the paucity of monitoring data for this substance.
	Environmental fate of hydrazine is highly dependent on ambient conditions. This inserts a high degree of uncertainty in the risk assessment which has not been fully characterized.	Uncertainty associated with hydrazine exposure due to variable environmental conditions was addressed in the assessment by the use of conservative estimates of exposure to hydrazine from environmental media.
	The conclusions drawn in the assessment would be more robust had long-term monitoring data been utilized.	The Challenge screening assessments are based on considerations of the available data. Data gaps and uncertainties in the exposure assessment, including the very limited information on hydrazine and hydrazine hydrate in environmental media and food, are documented in the screening assessment.

	Release data for multiple years would reduce or eliminate potential bias in the assessment.	All the assessments of substances conducted as part of the Challenge are based principally on data obtained via section 71 of CEPA for the calendar year 2006. The data for hydrazine can be assumed to be representative of the mid-decade 2000, as suggested by the relatively constant releases of hydrazine to the environment reported by the NPRI for the years 2004 to 2007.
	It was assumed that hydrazine occurs in the polymer polyvinyl pyrrolidone (PVP) at levels that pose negligible risks.	The risk posed by residual levels (<1 part per million) of hydrazine in PVP is based on the general population's exposure to hydrazine from PVP. This finding is consistent with conclusions of other national and international authorities.
	The Canadian government should include hydrazine in their drinking water guidelines.	Hydrazine is not expected to be found in a large number of drinking water supplies throughout Canada and it is not frequently detected therefore, a drinking water guideline for hydrazine would not be developed.
	It is not clear in the assessment whether hydrazine has been tested for in various environmental media and not detected or if no testing has been done.	The detection limit of hydrazine was reported in the assessment report for each case that hydrazine was tested for.
	Because hydrazine may be harmful at any level of exposure, it is important to create exposure estimates that include as many sources of hydrazine as possible.	The conservative approaches used to characterize exposure to the general population are considered to address any potential exposures from industrial emissions.
	The assessment notes that standard reproductive toxicity tests were not available. How then can it be said that hydrazine is not a reproductive or developmental toxic substance.	Although reproductive toxicity tests were not available on hydrazine, information on reproductive toxicity of the hydrated form of hydrazine was available and was taken into consideration in the assessment.

	The effluent flow rates for power generating stations are underestimated. Actual annual water takings should be used for calculations.	It is agreed that the effluent flow rates that were used for exposure characterizations were underestimated in the draft report. The actual annual water takings reported by the stakeholder for some plants were used to estimate effluent flow for these plants as well as for the other plants included in the assessment. The water takings reported were in line with statistics of water use for electric power generation produced by Statistics Canada.
	Estimating pro-rated flow rates using the ratio of capacity to effluent flow is not an appropriate method since the stations are not running at full capacity all the time.	It is agreed that estimates of daily effluent flows would be more exact if based on power generated during the year rather than based on installed capacity. However, the former estimates are often not available for specific plants while estimates of capacity installed are obtained more easily, for example from the websites of power utility companies. This uncertainty is now flagged in the section on uncertainties.
	The DSAR document should provide references to explain the origin and application of the equation used to estimate the aquatic concentration from industrial releases.	This equation is used for site-specific exposure scenarios for releases to the aquatic environment. It has been adopted by Environment Canada and is used by other jurisdictions internationally.
Risk Assessment Conclusion	The Screening Assessment did not adequately consider exposure to vulnerable populations such as workers.	The Challenge screening assessments are based on considerations of the available data. The various conservative exposure scenarios used are considered to be protective of both the general and vulnerable populations in Canada. However, if information is available which suggests that a specific sub-population would be particularly vulnerable, this information would be considered in the assessment. Hazard information obtained from occupational settings, in particular epidemiological information, is also considered..
	Any future re-evaluation of this assessment should fill current data gaps: Unknown concentrations in Canadian environmental media and food.	In addition and where relevant, research and monitoring will support verification of assumptions used during the screening assessment”.
	The question of release to land from the use of pesticides containing hydrazine should be	In Canada pesticides and their constituents are assessed by the Pest Management Regulatory Agency of Health Canada, and they are regulated under the Pest Control Products Act.

	addressed.	
	The synergistic effects of substances should be considered in risk assessment.	Consideration of aggregate, synergistic and antagonistic effects is not precluded from a screening assessment. However, in order to be considered, sufficient information to undertake such analyses would be needed.
	Information available to the public has not been addressed. At this stage, there is no public knowledge as to amounts of hydrazine used specifically in products, or adequate release information, or education about its harmful effects.	Screening assessments are science-based assessments of the available data. All available data and information was considered in the assessment.
	The determination of carcinogenicity of hydrazine appears to be based solely on its designation as a probable carcinogen rather than the actual risk posed.	Health Canada considers that evidence of carcinogenicity (i.e., classification by one or more international/national agencies), in the absence of a fully explained mode of action analysis, is sufficient to propose a conclusion that there is a probability of harm at any level of exposure and that the criterion in paragraph 64c of CEPA is met. The application of a precautionary approach is applied.
	Full peer review disclosure should be presented.	There are both advantages and limitations of identifying the names of peer reviewers in the screening assessments, and different approaches have been taken with respect to the ecological and human health peer reviewers.