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PROPOSED RISK MANAGEMENT APPROACH

for

Hydrazine

Chemical Abstracts Service Registry Number (CAS RN):
302-01-2

Environment Canada
Health Canada

January 2011

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for hydrazine, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

The Government of Canada plans to take the following actions with respect to hydrazine:

1. implement Significant New Activity provisions under the *Canadian Environmental Protection Act, 1999* to hydrazine;
2. 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; and
3. reduce the regulated threshold for hydrazine under the *Environmental Emergency Regulations.*

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9.1 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Challenge to Industry and Other Interested Stakeholders

The substance hydrazine, Chemical Abstract Service Registry Number (CAS RN)[1] 302-01-2, is included in Batch 10 of the Challenge under the Chemicals Management Plan.The Ministers of the Environment and of Health (the Ministers) have conducted an assessment under section 68 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) to assess whether the substance meets one or more of the criteria as set out in section 64 of CEPA 1999[2].

The substance hydrazine was identified as a high priority for assessment of human health risk because it was considered to present an intermediate potential for exposure and had been classified by other agencies on the basis of carcinogenicity. The Challenge for this substance was published in the Canada Gazette on June 20, 2009 (Environment Canada 2009). A substance profile was released at the same time. The substance profile presented the technical information available prior to December 2005 that formed the basis for categorization of this substance. As a result of the Challenge, submissions of information pertaining to the substance were received.

Although hydrazine was determined to be a high priority for assessment with respect to human health, it did not meet the categorization criteria for persistence or bioaccumulation in the *Persistence and Bioaccumulation Regulations* but it did meet the criteria for toxicity to aquatic organisms.

Information-gathering authority in section 71 of CEPA 1999 is used to gather specific information where it is required. The information that is collected is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

1.2 Final Assessment Report Conclusion for hydrazine

A notice summarizing the scientific considerations of a final assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for hydrazine on December 25, 2010, under paragraphs 68*(b)* and 68*(c)* of CEPA 1999. The final report concluded that hydrazine is, on the basis of the carcinogenicity, for which there may be a probability of harm at any level of exposure, entering or may be entering the environment in a

[1] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society

[2] A determination of whether one or more of the criteria of section 64 are met and whether risk management may be required is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 on the substances in the Chemicals Management Plan (CMP) Challenge Batches 1-12 is not relevant to nor does it preclude an assessment against the hazard criteria specified in the Workplace Hazardous Materials Information System [WHMIS] *Controlled Products Regulations* for products intended for workplace use.

quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The final report also concluded that hydrazine does not meet the criteria for persistence and for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of hydrazine in the environment results primarily from human activity. In some cases, estimated concentrations of hydrazine in surface water across Canada are higher than or close to the estimated no-effect levels. Based on this information, it is concluded that hydrazine is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (Canada 2010).

For further information on the final report conclusion for hydrazine, refer to the final report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-10/index-eng.php.

1.3 Proposed Measure

As a result of an assessment of a substance under section 68 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. In that case, either Minister can provide information and make recommendations respecting any matter in relation to the substance. While not subject to section 74 to section 77 the Ministers may choose to add the substance to the Priority Substances List (PSL) for further assessment, recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act or take no further action. With respect to hydrazine, the Ministers propose to recommend the addition of hydrazine to the List of Toxic Substances in Schedule 1. As a result, the Ministers may develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

Hydrazine is not subject to virtual elimination and may be managed using a lifecycle approach, to prevent or minimize its release into the environment.

2. BACKGROUND

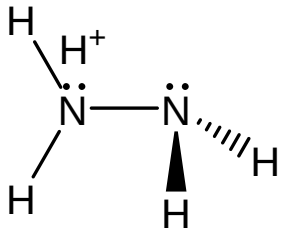
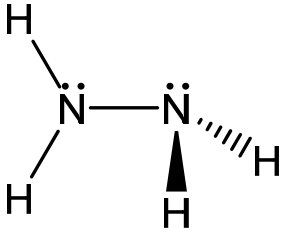
2.1 Substance Information

For the purposes of this document, this substance will be referred to as hydrazine. The identity of this substance is presented in Table 1. Most respondents to the section 71 Notice (Environment Canada 2009) imported aqueous solutions in which hydrazine is present at ~ 35% by weight, the form of the product commonly found on the market. The hydrated form is not considered to be chemically different from the anhydrous substance, but can be considered to represent a mixture of the substance with water. Therefore, the assessment report considers that hydrazine and hydrazine hydrate are the same substance. For the purposes of this document, the term hydrazine is used, and refers to both the anhydrous and hydrated forms.

Hydrazine is part of the chemical grouping discrete inorganics and the chemical sub grouping ammonia and ammonia-derived compounds.

Table 1 presents other names, trade names, the chemical formula, the chemical structure and the molecular mass for hydrazine.

Table 1. Identity of hydrazine

Chemical Abstracts Service Registry Number (CAS RN)	**302-01-2**
DSL name	**Hydrazine**
National Chemical Inventories (NCI) names	*Hydrazine* (AICS, ASIA-PAC, ECL, EINECS, ENCS, SWISS, NZIoC, PICCS, TSCA)
Other names	*Diamide* *Diamine* *Levoxine* *Nitrogen hydride* *Oxytreat 35* *UN 2029* *UN 2030* *H70*
Chemical formula	N_2H_4
Chemical structure	 Hydrazinium ion  Hydrazine
SMILES	NN
Molecular mass	32.0 g/mol

Abbreviations: AICS, Australian Inventory of Chemical Substances; ASIA-PAC, Asia-Pacific Substances Lists; CAS RN, Chemical Abstracts Service Registry Number; DSL, Domestic Substance List; ECL, Korean Existing Chemicals List; EINECS, European Inventory of Existing Commercial Chemical Substances; ENCS, Japanese Existing and New Chemical Substances; NCI, National Chemical Inventories; NZIoC, New Zealand Inventory of Chemicals; PICCS, Philippine Inventory of Chemicals and Chemical Substances; SMILES, simplified molecular input line entry system; SWISS, Swiss Giftliste 1 and Inventory of Notified New Substances; TSCA, *Toxic Substances Control Act* Chemical Substance Inventory. Source: NCI (2006).

3. WHY WE NEED ACTION

3.1 Characterization of Risk to Human Health

Based principally on the weight of evidence assessments of international or other national agencies (IARC 1987, 1999; US EPA 1991; ATSDR 1997; US NTP 2005; European Commission 2008), a critical effect for characterization of risk to human health for hydrazine is carcinogenicity. As shown in the "Health Effect Assessment" section of the final screening assessment report (Canada 2010), tumours in the respiratory tracts were observed in rats, mice and hamsters after inhalation and/or oral exposure to hydrazine, while liver tumours were noted in rats exposed to the hydrated form of hydrazine. Genotoxicity was observed in both *in vivo* and *in vitro* assays with hydrazine. Although the modes of action for the induction of tumours in rodents have not been fully elucidated, based on the weight of evidence of carcinogenicity and the genotoxicity of hydrazine, it cannot be precluded that the tumours observed may have resulted from direct interaction of hydrazine with genetic material.

Based on the basis of the genotoxicity and carcinogenicity, for which there may be a probability of harm at any level of exposure, it is proposed that hydrazine (and its hydrate) should be considered to be a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

With respect to non-cancer effects after inhalation exposure, at the lowest LOAEC of 0.06 mg/m^3, inflammation significantly increased in trachea of male rats exposed to hydrazine. At a higher concentration of 0.3 mg/m^3, a significant increase in the number of lesions in multiple sites (liver, lymph nodes, kidney, thyroid and adrenal) in male hamsters were observed. No non-neoplastic effects were reported after chronic oral exposure to hydrazine. Since the toxicity of hydrazine and the hydrated form of hydrazine was considered to be comparable, the lowest LOEL of 0.3 mg hydrazine /kg bw/day based on increased incidence of bile duct proliferations in male rats exposed to the hydrated form of hydrazine in 2-year chronic studies, was determined to be the critical effect level. Hydrazine was not considered to be a developmental or reproductive toxicant, as effects specific to reproductive or developmental function occurred at higher dose levels (5 mg/kg bw/day via intraperitoneal injection or 6.5 mg/m^3 via inhalation) than the critical dose levels identified above.

A comparison of the critical non-neoplastic effect level for inhalation exposure in rats (0.06 mg/m^3), using the upper-bounding hydrazine concentration in ambient air (4.42×10^{-4} $\mu g/m^3$), results in a margin of exposure (MOE) of 135 746. This margin of exposure is considered adequate to address non-cancer effects.

The critical non-neoplastic effect level for oral exposure in rats was 0.3 mg hydrazine/kg bw/day based on evidence of bile duct proliferations in male rats exposed to the hydrated form of hydrazine. Comparison of the critical non-neoplastic effect level for oral exposure (0.3 mg/kg bw per day) with the upper-bounding total intake estimate of hydrazine for the most sensitive sub-population (4.0×10^{-4} µg/kg bw/day derived for formula fed infants), results in a MOE of 7.5×10^{5}. This margin of exposure is considered adequate to address non-cancer effects.

3.2 Characterization of Risk to the Environment

The approach taken in the ecological portion of the screening assessment was to examine the available scientific information and develop conclusions based on a weight-of-evidence approach and using precaution as required under CEPA 1999. Lines of evidence considered include results from conservative risk quotient calculations, as well as information on persistence, bioaccumulation, toxicity, sources, distribution and fate of the substance (Canada 2010).

Hydrazine does not meet the criteria for persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations*. However the frequent presence of this substance in aquatic ecosystems is expected to result in chronic exposure to aquatic organisms, particularly in cases where release events are close in time. The high importation volumes of aqueous solutions of hydrazine into Canada, along with information on their uses and evidence for environmental releases given by National Pollutant Release Inventory (NPRI) data and by data submitted under section 71 Notices (Environment Canada 2009), indicate the potential for widespread release into the Canadian environment. Once released into the environment, hydrazine may be found in air, water or soil, depending on medium of release and the hardness of receiving waters. Hydrazine has been demonstrated to have an elevated potential for toxicity to aquatic organisms (Canada 2010).

To determine whether there is potential for ecological harm in Canada, a risk quotient analysis, integrating estimates of exposure with toxicity information, was performed for aquatic ecosystems, which are the main environmental media receiving releases of hydrazine. Site-specific industrial exposure estimates based on monitoring data were available for three nuclear facilities located in Ontario. Several other site-specific exposure estimates were generated using an industrial exposure model for nuclear and fossil-fuel electric power facilities located elsewhere in Canada (Canada 2010).

Predicted Environmental Concentrations (PEC) were estimated using measured and modeled concentrations of hydrazine in effluent. Predicted No Effect Concentrations (PNEC) were derived for freshwater and marine organisms based on the empirical toxicity data available. The resulting risk quotients (PEC/PNEC) range from 1.3×10^{-3} to 8.9. Four sites have risk quotients (RQs) that are above the level of concern of one, and a few sites have RQs that are close to this level (between 0.1 and 1). Even if these latter sites are below the level, they are considered as being of concern mainly due to the uncertainties associated with the PEC estimates (Canada 2010).

In addition, the number of facilities included in this assessment represents about one fifth of the total number of power generating plants potentially using hydrazine in Canada. Therefore, other sites could be of concern in addition to the ones identified in this assessment.

The above information indicates that hydrazine has a potential to cause ecological harm in Canada.

4. CURRENT USES AND INDUSTRIAL SECTORS

According to information submitted under section 71 of CEPA 1999, hydrazine was not manufactured by any company in Canada in the 2006 calendar year above the 100-kg reporting threshold. However, between 10 000 and 100 000 kg of hydrazine were reported to have been imported in 2006 above the 100-kg reporting threshold. The major use of hydrazine is its industrial use in boiler water treatment as a corrosion inhibitor and oxygen scavenger used mainly at power generating facilities. Exposure of the general population to hydrazine is expected to be low (Canada 2010).

Hydrazine is thought to occur naturally in algae and tobacco plants and be formed during the combustion of tobacco products; however, the major source of hydrazine in the environment is attributed to anthropogenic activities (Canada 2010).

In Canada and elsewhere, hydrazine may be used as a raw material or an intermediate in the production of pesticides and other agricultural chemicals (Liu et al. 1974; Newsome 1980; ATSDR 1997), pharmaceuticals (Lovering et al. 1982, 1985; Matsui et al. 1983; ATSDR 1997; Choudhary and Hansen 1998), and in the manufacture of chemical blowing agents (ATSDR 1997; Choudhary and Hansen 1998; CERI 2007). According to information submitted under section 71 of CEPA 1999, in addition to publicly available information, there are no direct consumer end-use products identified for hydrazine itself. However, the substance may be found in final products at trace levels as an unintended residual, when used as a raw material or intermediate in the formulation of consumer products. Such products may include pesticides and other agricultural chemicals, pharmaceuticals, adhesives, chemical blowing agents, plastic resins and films, and polymers such as polyvinyl pyrrolidone (PVP). Hydrazine has also been used as a liquid propellant for spacecraft and as a fuel for emergency power units in military aircraft (2009 personal communication from National Defence Headquarters, Department of National Defence to Risk Management Bureau, Health Canada; unreferenced).

Hydrazine is found at < 1 to 2.4 ppm, in maleic hydrazide (CAS RN 123-33-1), which is a registered technical pesticide active ingredient in Canada, under the *Pest Control Products Act* (Health Canada 2009).

Hydrazine derivatives used in drugs may contain hydrazine associated with hydrolytic decomposition reactions or with the production process. For example, hydrazine contents of less than 1% were measured in isoniazid injection solutions and dihydrazine sulphate formulations for human use (Lovering et al. 1982; Matsui et al. 1983). Isoniazid (CAS RN 54-85-3) is an active ingredient in antituberculosis agents used in Canada (DPD 2010).

In addition to its use in medication, dihydrazine sulphate (2:1) (CAS RN 13464-80-7) has been used in Canada as a formulation component, and in plating and surface finishing. The total quantity of dihydrazine sulphate (2:1) imported in 1986 was in the range 100 to 1000 kg (Environment Canada 1988).

Evaluation of risk to human health involves consideration of data relevant to the estimation of exposure (non-occupational) of the general population, as well as information on health hazards.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

In response to a Notice issued under section 71 of CEPA 1999, during 2006, 123 kg and 1865 kg of hydrazine were reported to have been released to the atmosphere and hydrosphere, respectively. In addition to environmental releases of hydrazine, 1076 kg were transferred to hazardous waste facilities for disposal in 2006 (Environment Canada 2009).

Release of hydrazine and its salts in Canada was reported to the National Pollutant Release Inventory (NPRI) by four to five facilities per year from 2004 to 2008: three nuclear power generating facilities, one producer of specialty chemicals and one manufacturer of chemical products (NPRI 2008). Nearly all the emissions to air, water and soil were associated with the operation of nuclear power generating facilities (NPRI 2008), which are known to release hydrazine to the environment (Environment Canada 2009). More than 90% of these emissions were to water. Quantities disposed of were mainly sent off-site for incineration or physical or chemical treatment.

These NPRI data are consistent with the fact that cooling water circuits of boilers of nuclear reactor facilities generate a liquid effluent containing hydrazine, which is released to the environment (Hirzel 1998). Indeed, there is partial removal of water from the steam-generating systems with replacement by fresh, demineralized water to maintain dissolved solids concentrations at constant low levels. This water removal, called ‘blowdown,’ becomes part of the final effluent from facilities and contains hydrazine because this substance is used in stochiometric excess to ensure removal of dissolved oxygen from the make-up water used to compensate the blown down steam (Collins 2000, Environment Canada 2009, James 1989). The frequency of these blowdown events varies from one facility to the other. This blowdown process also occurs in those fossil-fuelled power generating facilities in Canada that use hydrazine in their boiler feed water systems. This constitutes the major use of hydrazine in both nuclear and fossil-fuelled power facilities, but smaller quantities of hydrazine are also used by these facilities for corrosion and pH control in a variety of systems, including auxiliary boiler water, re-circulating cooling water, emergency coolant injection and boiler layup. In principle, these other systems can also generate and release liquid effluents to the receiving environment (Environment Canada 2009). Nuclear power is produced in New Brunswick, Quebec and Ontario. Fossil-fuelled power generating facilities are present in every province, with the largest production being in the Atlantic provinces, Ontario, Saskatchewan and Alberta (CEA 2006).

Hydrazine fuel that is used in aircraft can be released into air and water as a result of accidental discharges on airfields (MacNaughton et al. 1981). During international training exercises, allied countries flying F-16 aircraft may use and store small quantities of hydrazine fuel at Canadian Forces bases. These countries are responsible for the management of the fuel and, in the event of an accidental discharge, for spill response.

Hydrazine which may be present in human pharmaceuticals may reach aquatic environments via wastewater systems, the incorrect disposal of unused drugs, and to a lesser extent via waste and spills during production (Jones et al. 2004).

5.2 Exposure Sources

Any exposure to the general population from the sources identified (including, but not limitted to, pesticides and other agricultural chemicals, pharmaceuticals, adhesives, chemical blowing agents, plastic resins and films, and polymers such as polyvinyl pyrrolidone (PVP), liquid propellant for spacecraft and military aircraft) is considered to be negligible. Canadians may also be exposed to hydrazine from inhalation of tobacco smoke.

The final screening assessment report indicates that the primary source of ecological exposure and ecological risk from hydrazine occurs from aquatic releases of hydrazine to freshwater and marine water from nuclear and fossil-fuelled power facilities (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Hydrazine is listed

- under Schedule 3 of the *Transportation of Dangerous Goods Regulations* under the *Transportation of Dangerous Goods Act* (Canada 2009a);
- in the *Environmental Emergency Regulations* under Part 8 of CEPA 1999 (Canada 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;
- as a pure form, on Schedule 7, Part 2, of the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under CEPA 1999 (Canada 2005);
- on the Cosmetic Ingredient Hotlist (Canada 2009b); and
- on Schedule 1 as a pollutant on the *Regulations for the Prevention of Pollution from Ships and for Dangerous Chemicals* under the *Canada Shipping Act* (Canada 2001).

There is no specific limit for hydrazine/PVP in food packaging materials. However, the safety of all materials used for packaging foods is controlled under Division 23 of the Food and Drug Regulations. Section B.23.001 of the Regulations prohibits the sale of foods in packages that may impart harmful substances to their contents.

There are no specific provisions for hydrazine under the *Food and Drug Regulations* for use as a food additive. However, PVP, which may contain impurities of the substance hydrazine, is listed in the *Food and Drug Regulations* under Part B, Division 16, Table VIII with provisions for use as a food additive (C.R.C., c.870). Additionally, there are specifications in the Food Chemicals Codex that outline the limits for hydrazine contamination in PVP when used in food additive applications (FCC 2010).

Releases, disposals and transfers for recycling for hydrazine and its salts are reportable to the National Pollutant Release Inventory (NPRI 2009).

Hydrazine concentration objectives in the discharges of cooling water for the Point Lepreau Nuclear Generation Station in New Brunswick and the power generating facilities in Ontario are specified in certificates of approval for the individual facilities. The effluent concentration limit for Point Lepreau is 75 ppb (0.075 mg/L) and the effluent concentration objective for Ontario facilities is 0.1 mg/L (Environment Canada 2009).

6.2 Existing International Risk Management

In the United States, hydrazine:

- is considered by the Environmental Protection Agency to be a hazardous waste product under Part 261 of the Identification and Listing of Hazardous Waste, and is subject to regulation as such (US EPA 2008);
- is subject to the regulations for substances listed in Part 68 of the Chemical Accident Prevention Provisions, determined by the Environmental Protection Agency (US EPA 2008);
- is on the list of Volatile Hazardous Air Pollutants and the list of Pollutants Excluded From Use in Cleaning and Washoff Solvents, from Part 63 – National Emission Standards for Hazardous Air Pollutants for Source and Subpart JJ – National Emission Standards for Wood Furniture Manufacturing(US EPA 2008);
- is a chemical found on List 1, Inerts of Toxicological Concern from a notice by the Environmental Protection Agency for pesticide products (US EPA 1987); and
- is reportable to the Toxics Release Inventory – releases, disposals and transfers for recycling of hydrazine and its salts (US TRI 2009).

In the European Union:

- Hydrazine has been tabled as a phase-out substance by the Swedish Chemicals Agency, based on carcinogenicity, environmental hazards, long-term effects and allergenic properties. All newly produced articles should not contain phase-out substances (Sweden 2009).
- Hydrazine is listed in Annex 2 of the European Union Cosmetic Regulation No 1223/2009 (76/768/EEC) (EU 1982), and on Schedule 4 of New Zealand's Hazardous Substances and New Organisms Act 1996 (New Zealand 1996), as a substance that must not form part of the composition of cosmetic products.

In New Zealand, hydrazine (both the anhydrous and the hydrated forms) meets the requirements for Dangerous Goods and Scheduled Toxic Substances Requiring Approved Handler and Tracking Controls, listed by the Environmental Risk Management Authority (New Zealand 2004).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

The power generating industry has identified several potential alternative 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. Corrosion properties of the identified alternatives are reported to be inferior to those of hydrazine. Also, some of these alternatives may break down or cause an increase in concentration of other undesirable chemical components that is significant enough to affect the safety of the system (Environment Canada 2009). It is important to note that one of these substitutes, 2-butanone oxime, has undergone an assessment, and was considered to meet the criteria under section 64*(c)* of CEPA 1999 (Canada 2010b).

7.2 Alternative Technologies and/or Techniques

One fossil-fuel power company took a process approach utilizing monitoring and management to control corrosion in their boiler rather than using hydrazine or an alternative substance.

Both fossil fuel and nuclear companies reported factors that limit the release of hydrazine to the environment (Environment Canada 2010). Many companies reported that their standard boiler operating temperatures destroy hydrazine. However, Environment Canada expects that releases of hydrazine are still likely and the degree of chemical consummation will vary among facilities because of the use of various types of boilers and steam generators, and of operations at different pressures and temperatures (Bellows 2006). Additional release management techniques were also reported by companies. For example, before releasing boiler water effluent to the environment, facilities may use sodium hypochlorite to neutralize remaining quantities of hydrazine, ensuring the neutralization process has been successful by testing the effluent prior to release. Some facilities send boiler water containing hydrazine to a settling lagoon where hydrazine further degrades. The concentration of hydrazine is monitored until levels are sufficiently low before discharge to the environment. Finally, one company reported that zero discharge of hydrazine to the environment is achieved at one of its facilities by using a closed-loop water management system (Environment Canada 2010).

No alternative control technologies have been identified for the uses of hydrazine which have the potential to result in human exposure.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

Socio-economic considerations for hydrazine:

Hydrazine is listed on the 2004 and 2007 Organisation for Economic Co-operation and Development (OECD) lists of high production volume (HPV) chemicals (OECD 2004, OECD 2009) and is listed as an HPV chemical in Europe (ESIS 2010). The major reported use of hydrazine in Canada in 2006 was as a corrosion inhibitor and oxygen scavenger mainly at power generating facilities, which accounted for 87% of reported uses (Environment Canada 2009). These facilities belong to the Fossil Fuel Electric Power Generation industry (NAICS 221112) and the Nuclear Electric Power Generation Industry (NAICS 221113) (Statistics Canada 2010). The Canadian Fossil Fuel Electric Power Generation Industry comprises establishments primarily engaged in the generation of utilities using fossils fuels such as coal, gas or oil (Statistics Canada 2007). The Canadian Nuclear Power Generation industry comprises establishments primarily engaged in the generation of electric power using nuclear-powered generating facilities (Statistics Canada 2007). There is nuclear generation in Ontario, Quebec and New Brunswick (National Energy Board 2010).

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received and the expected uses of hydrazine, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental and Human Health Objectives

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for hydrazine is to minimize human exposure to the greatest extent practicable.

The proposed environmental objective is to prevent or minimize releases of hydrazine to water.

8.2 Risk Management Objectives

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). 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.

In order to prevent or minimize releases of hydrazine to water, the proposed environmental risk management objective is to achieve the lowest level of releases of hydrazine to water that is technically and economically feasible, taking into consideration socio-economic factors.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instruments

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation,*[3] and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management instrument was selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

To achieve the risk management objective and to work towards achieving the human health objective, **(1) 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.

In order to work towards achieving the environmental objective, the Government of Canada plans to **(2) 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. In addition, (3) the Government of Canada proposes to lower the regulated threshold for the preparation and implementation of environmental emergency plans under the *Environmental Emergency Regulations***.

[3] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

9.2 Implementation Plan

The proposed instruments for hydrazine will be published in the *Canada Gazette*, Part I, no later than December 2012, as per the timelines legislated in CEPA 1999.

Monitoring and surveillance for hydrazine in the environment will be considered under a comprehensive monitoring and surveillance strategy under the Chemicals Management Plan.

Environment Canada is developing Federal Environmental Quality Guidelines for hydrazine in water to protect aquatic life. Federal Environmental Quality Guidelines provide benchmarks for the quality of the environment and can be used to aid in the interpretation of any future monitoring data collected for hydrazine or to assist in assessing the performance of risk management activities.

10. CONSULTATION APPROACH

The risk management scope document for hydrazine, which summarized the proposed risk management under consideration at that time, was published on June 26, 2010. Industry and other interested stakeholders were invited to submit comments on the risk management scope document during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the proposed risk management approach documents will involve publication on January 15, 2011, and a 60-day public comment period.

The primary stakeholders include:

- power generating facilities using hydrazine
- non-governmental organizations
- the Canadian Nuclear Safety Commission

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	January 15, 2011 to March 16, 2011
Response to comments on the proposed risk management approach document	No later than the time of publication of the proposed instrument
Consultation on the draft instrument	Fall/Winter 2012
Publication of the proposed instrument	No later than January 2013
Formal public comment period on the proposed instrument	No later than Summer 2013
Publication of the final instrument	No later than June 2014

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to March 16, 2011, since the risk management of hydrazine will be moving forward after this date. During the development of regulations, instrument(s) and tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Substances@ec.gc.ca

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