Environment Canada Environnement Canada

Rapid Screening of Substances from Phase One of the Domestic Substances List Inventory Update

Results of the Final Screening Assessment

Environment Canada

Health Canada

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Synopsis

As part of the Government of Canada's Chemicals Management Plan (CMP), a section 71 notice for the first phase of the Domestic Substances List Inventory Update initiative was published in the *Canada Gazette*, Part I, in October 2009 to collect data on approximately 500 substances. As a result of the data collected, 140 substances were identified as candidates for rapid screening.

Following the application of a rapid screening approach to these 140 substances that were prioritized for assessment during the categorization of the Domestic Substances List (DSL), the Minister of the Environment and the Minister of Health conducted a screening assessment on and reached final conclusions for 117 of these substances pursuant to the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

The majority of the 140 substances met the categorization criteria for greatest potential for exposure (GPE) to humans or for persistence or bioaccumulation and inherent toxicity to human or non-human organisms (PiT or BiT) under subsection 73(1) of CEPA 1999. Additional substances considered in this assessment had been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

The substances included in this report were candidates for rapid screening because they were identified as being in commerce across Canada at a total of ≤ 1000 kg/year according to information submitted pursuant to section 71 of CEPA 1999 regarding commercial activity in Canada under Phase One of the DSL Inventory Update.

A rapid screening approach was applied that involved using conservative assumptions to identify substances that warrant further evaluation of their potential to cause harm to either human health or the environment, and those that are expected to have a low likelihood of causing harmful ecological or human health effects.

The ecological component of the rapid screening approach consisted of two main steps to identify substances that warrant further evaluation of their potential to cause harm. The first step involved applying different exposure scenarios using assumptions that are protective of the environment. The second step involved a mechanical process to identify whether or not a substance appears on any of a wide range of lists or in sources of information relating to ecological hazard or exposure. This step flagged substances that have been identified by domestic or international initiatives as possibly being of greater concern due to their ecological hazard properties or their elevated potential for environmental release.

The human health component of the rapid screening approach consisted of a process to determine whether the substance warrants further assessment from a human health perspective. A key element of the characterization of potential risk for human health is determination of the potential for exposure to the general population. Substances reported to be in commerce in Canada at ≤ 1000 kg/year are considered to warrant further assessment if there is evidence of direct exposure (e.g., exposure from products or food additives) of the general population in Canada. If the potential for exposure is considered to be negligible for a substance, it is concluded that that substance is unlikely to cause harm to human health at current levels of exposure.

In total, 23 substances were identified as requiring further assessment (9 identified for both ecological and human health considerations, 13 identified for human health considerations only, and 1 identified for ecological considerations only; see Appendix B). For the remaining 117 substances (Appendix C), this rapid screening approach indicated that current use patterns and quantities in commerce are unlikely to result in concerns for organisms or the broader integrity of the environment, or for human health in Canada. All in-commerce substances had calculated generic aquatic exposure values below the level of concern. Furthermore, application of the mechanical filters did not identify any additional ecological concerns.

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from the 117 substances identified in Annex C. It is concluded that the 117 substances do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA 1999 as they are not 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 or that constitute or may constitute a danger to the environment on which life depends.

From a human health perspective, indirect or direct exposure to the general population from environmental media (air, water, soil) to these 117 substances is expected to be negligible, and therefore the substances are unlikely to cause harm to human health at current levels of exposure.

Based on the information presented in this screening assessment, it is concluded that the 117 substances listed in Appendix C do not meet the criteria under paragraph 64(*c*) of CEPA 1999 as they are not 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.

Because these 117 substances are listed on the *Domestic Substances List*, their import and manufacture in Canada are not subject to notification under subsection 81(1) of CEPA 1999. Since 15 are recognized for their hazardous properties, there is suspicion that new activities that have not been identified or assessed could lead to these substances meeting the criteria set out in section 64 of CEPA 1999. Therefore, it is recommended to amend the *Domestic Substances List*, under subsection 87(3) of the Act, to indicate that the significant new activity (SNAc) provisions under subsection 81(3) of the Act apply with respect to the substances.

A significant new activity can include one that has not been conducted with the substance in the past or an existing one with a different quantity or in different circumstances that could affect the exposure pattern of the substance. The SNAc provisions trigger an obligation for industry to notify and the government to assess, information about a substance when a proponent proposes to use the substance in a significant new activity. The provisions are used to assess the risks associated with the proposed new activity before the new activity is undertaken. The Minister of the Environment and the Minister of Health assess the information provided by the notifier and other information available to them to determine whether the substance, if used in the proposed new activity, could pose a risk to the environment or human health, and if so, whether new or additional risk management is required. The notice of intent to apply the Significant New Activity

provisions to 15 substances covered under the current rapid screening approach will be developed later in 2014 in consultation with industry stakeholders.

Conclusion

It is concluded that the 117 substances listed in Appendix C do not meet any of the criteria set out in section 64 of CEPA 1999.

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that have met the categorization criteria set out in the Act to determine whether these substances present or may present a risk to the environment or human health.[1]

Under CEPA 1999, screening assessments focus on information critical to determining whether a substance meets the criteria for defining a chemical as toxic as set out in section 64 of the Act, where:

"**64.** [...] a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

> *(a)* have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
> *(b)* constitute or may constitute a danger to the environment on which life depends; or
> *(c)* constitute or may constitute a danger in Canada to human life or health."

The Government of Canada has identified 140 substances as candidates for a rapid screening approach. These substances were identified as being in commerce at a total across Canada of ≤ 1000 kg/year when subject to submission of information pursuant to section 71 of CEPA 1999 regarding commercial activity in Canada under Phase One of the Domestic Substances List (DSL) Inventory Update (Canada 2009). The majority of these substances met the categorization criteria for greatest potential for exposure (GPE), or for persistence or bioaccumulation and inherent toxicity (PiT or BiT) to human or non-human organisms under subsection 73(1) of CEPA 1999. Additional substances had been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity. Thirty of the 140 substances addressed herein were part of a previous draft rapid screening approach (Environment Canada 2007a). However, the conclusions for those 30 substances were not finalized at that time, as it had been determined that new information received through the Inventory Update could impact upon the conclusions. Therefore these substances, and the new information on them, are reconsidered in this assessment.

[1] A determination of whether one or more of the criteria of section 64 are met 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, but is not limited to, 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) is not relevant to, nor does it preclude, an assessment against the hazard criteria for the *Workplace Hazardous Materials Information System* (WHMIS) that are specified in the *Controlled Products Regulations* for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being taken under other sections of CEPA 1999 or other Acts.

Approach

Ecological component

The ecological component of the rapid screening approach, as illustrated in Figure 1, consists of multiple steps that address different factors relating to the potential for a substance to cause ecological harm. The approach is intended to be pragmatic, protective of the environment and fairly rapid, largely making use of available or easily obtainable data and either “mechanical” or simple “manual” evaluation of the data.

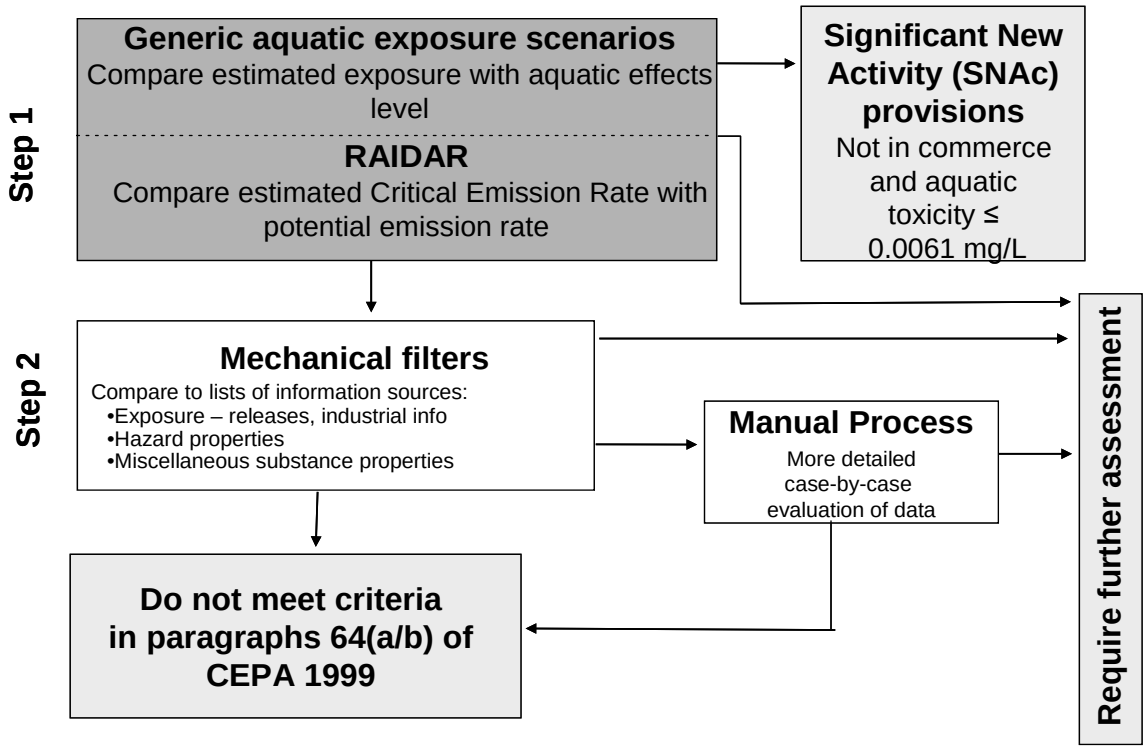

Figure 1: Overview of the ecological rapid screening approach

Step 1: Modelled exposure scenarios

The first step in the ecological component involves applying different scenarios or fate models to estimate environmental exposure. Two generic aquatic exposure scenarios were applied (described hereafter as scenarios A and B) to identify potential concerns near the point of discharge of a substance to the environment. These involve comparing conservative (i.e., ecologically protective) estimates of exposure in receiving waters with an effects threshold to evaluate whether a chemical is expected to cause harm to the local aquatic environment. A regional multi-media model named RAIDAR (Risk Assessment, IDentification And Ranking) is also applied. This fugacity-based model (described hereafter as Scenario C) takes into account the combined characteristics of the substance in estimating potential harm in different environmental media (water, soil and air), as well as in food chains. Figure 2 illustrates these exposure estimation approaches.

These approaches make use of available data from DSL categorization activities and Phase One of the DSL Inventory Update. Data from the DSL Inventory Update include use and quantity information from each reporting facility. Data collected or estimated during categorization include pivotal values for acute aquatic toxicity (iT), persistence and bioaccumulation, as well as physical-chemical properties.

While the generic aquatic exposure scenarios (A and B) have been developed to be conservative overall, the level of conservatism applied to individual parameters is moderate, since it is recognized that:

- a high level of conservatism applied to each parameter can easily compound into an excessively conservative overall exposure scenario;
- it is very unlikely that each parameter would be "worst case" at the same time; and
- interdependency of some parameters exists.

Rather, values in keeping with an overall worst-case scenario have been used.

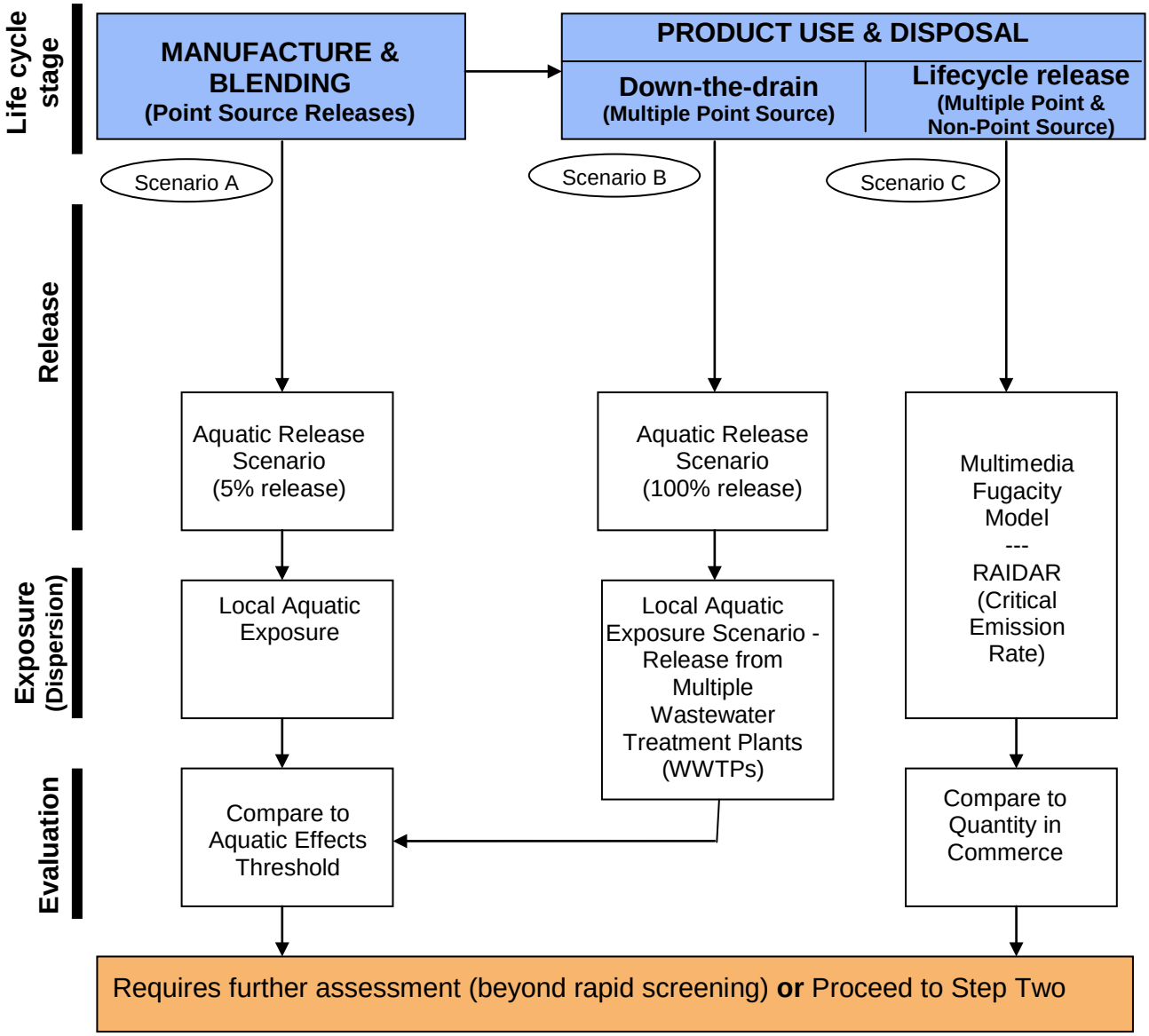

Figure 2: Overview of ecological exposure scenarios

Scenario A: Industrial point source aquatic release
Scenario A is based on release from an industrial facility that is manufacturing the substance and/or using it in the preparation of products. This scenario assumes the release of 5% of the substance from manufacturing and handling, based on conservative estimates for loss from cleaning of container residues (3%), transfer lines (1%) and process equipment (1%) (US EPA 1992). A conservative estimate of exposure (predicted environmental concentration [PEC]) resulting from the release of the substance to the aquatic environment from such an industrial point source is calculated as shown in the following equation. The aquatic predicted no-effect concentration (PNEC) is derived as shown in the second equation. Parameters used in Exposure Scenario A are described in Table 1.

$$\text{PEC (mg/L)} = \frac{\text{Qty x Loss x (1 – Wastewater Removal)}}{\text{Duration x (River flow + Wastewater flow)}} \times \frac{1000}{86400}$$

$$\text{Aquatic PNEC (mg/L)} = \frac{\text{CTV}}{\text{AF}}$$

The PEC is then compared to the PNEC to determine a risk quotient (PEC / PNEC). If the risk quotient is greater than 1, this indicates that the conservatively estimated concentration in water exceeds the aquatic estimated no-effect level and that there exists a potential to cause harm in the aquatic ecosystem. A value below 1 indicates that concentrations that may cause an effect to sensitive aquatic organisms are not reached, and therefore harm to aquatic organisms is unlikely under this scenario.

Table 1: Parameters used in Exposure Scenario A

Abbrev.	Parameter	Value	Units	Notes
Qty	Maximum quantity of substance used at one facility	100 or 1000	kg	Substance specific
Loss	Loss of substance during manufacturing or handling	5	%	Based on conservative estimates of loss from cleaning of container residues (3%), transfer lines (1%) and reactors (1%)
Wasterwater removal	Wastewater treatment plant (WWTP) removal efficiency	70	%	Conservative value for secondary treatment, recognizing biodegradation and sludge adsorption
Duration	Duration over which substance is released	150	days	Assumes seasonal use of substance
Wastewater flow	WWTP flow rate	0.04	m^3/s	10th percentile of municipal WWTP flow rates
River flow	Flow of receiving watercourse	1.84	m^3/s	15th percentile of the distribution of receiving watercourse flows in the

Abbrev.	Parameter	Value	Units	Notes
				country (based on the distribution of the 50th percentile of flow rates); weighted by number of industries releasing to the receiving watercourse
-	Factor combining conversion from kg to mg and m^3 to L	1000		
-	Conversion factor from days to seconds	86 400		
CTV	Critical toxicity value		mg/L	Substance specific; acute aquatic toxicity from categorization (iT pivotal value)
AF	Application factor	100		To account for acute to chronic; lab to field; inter-species variability

Scenario B: Down-the-drain aquatic release from consumer products
The second scenario (residential releases to municipal wastewater) considers the down-the-drain release of 100% of the substance that is contained in a consumer product, from multiple point sources (i.e., municipal wastewater discharges). Under this scenario, a value for the PEC from down-the-drain releases of a substance contained in products is calculated, as well as a value for the aquatic PNEC, as defined in the equations below. Parameters used in Exposure Scenario B are described in Table 2 below.

$$\text{PEC (mg/L)} = \frac{\text{Qty x Loss x (1 – Wastewater Removal) x Population}}{\text{Duration x RPE(River flow + Wastewater flow)}} \times \frac{1000}{86400}$$

$$\text{Aquatic PNEC (mg/L)} = \frac{\text{CTV}}{\text{AF}}$$

As was the case for Scenario A, the PEC and the PNEC are combined to determine a risk quotient (PEC / PNEC), which indicates a potential risk if the value is above 1 in this conservative scenario.

Note that river flow distributions used in the two scenarios are different. The likelihood of harm from industrial releases (Scenario A) is dependent on the number of industrial facilities releasing to a water body. In that scenario, a distribution of the dilution capacities of receiving waters (river flow) was generated with a weighting by the number of industrial facilities releasing to the water body. The likelihood of harm from down-the-drain releases of consumer products (Scenario B) is dependent on the human population that may be releasing a substance to a municipal wastewater treatment plant. In this scenario, a distribution of the ratio of population of the community to the dilution capacity of the receiving water body was generated. As a result, the parameters “population,” “wastewater

flow rate" and "river flow" are interconnected. In this scenario, it is this ratio that is important, not the actual values of the population or flow rates.

Table 2: Parameters used in Exposure Scenario B

Abbreviation	Parameter	Value	Units	Notes
Qty	Total quantity of substance used in Canada	Up to 1000	kg	Substance specific
Loss	Loss of substance from product during use	100	%	Complete loss for down-the-drain products assumed
Wastewater removal	WWTP removal efficiency	70	%	Conservative value for secondary treatment, recognizing biodegradation and sludge adsorption
Population	Population of representative community	100 000	persons	Value corresponding to the 10th percentile of the distribution of receiving watercourses weighted by population
Duration	Duration over which substance is released	150	days	Assuming seasonal use of substance
RPE	Regional product effect	2 000 000	persons	Value set to represent population of a Canadian region in which total quantity of product could be used
Wastewater flow	WWTP flow rate	0.66	m^3/s	Value corresponding to the 10th percentile of the distribution of receiving watercourses weighted by population
River flow	Flow of receiving watercourse	3.58	m^3/s	Value corresponding to the 10th percentile of the distribution of receiving watercourses weighted by population
-	Factor combining conversion from kg to mg and m^3 to L	1000		
-	Conversion factor from days to seconds	86 400		
CTV	Critical toxicity value	-	mg/L	Substance specific; acute aquatic toxicity from categorization (iT pivotal value)
AF	Application factor	100		To account for acute to chronic; lab to field; inter-species variability

Scenario C: Life-cycle release

Scenario C uses a fugacity-based multimedia modelling approach to address possible release of the substance over its full life cycle. Such models allow substances released to the environment to be distributed throughout a unit world, and are thus suitable for a disperse release scenario from all stages of the substance life cycle (Mackay 2001).

This modelling approach also provides a “safety net” scenario, since it accounts for the combined effects of a substance’s physical-chemical and hazard properties as well as considerations for different environmental media (water, air, soil, sediment) and organisms.

RAIDAR is a peer-reviewed fugacity-based model developed by the Canadian Environmental Modelling Network (CEMN) to assess chemicals for risk by estimating environmental fate and transport, bioaccumulation and exposure to organisms, and determining a critical emission rate (Arnot et al. 2006).

A Level III fugacity model scenario was used to model the release of substances into the environment. In this model, the substance is assumed to be continuously discharged at a constant rate and achieves a steady-state condition in which input and output rates are equal. The loss processes are degrading reactions and advection. Unlike the simpler Level II fugacity model, equilibrium between media is not assumed and, in general, each medium is at a different fugacity. The Level III fugacity model scenario was run assuming a 33% release of the substance to each of air, water and soil for interpretation of RAIDAR results in this rapid screening approach.

Representative food webs are included in RAIDAR to assess organisms’ routes of exposure to chemicals in the environment. The food web model takes the output from the fate and transport calculations for the substance (the concentration in the different environmental media) and estimates internal concentrations in some 20 biotic groups including plankton, vegetation, domestic animals, fish and wildlife, using data on the nature and quantity of diets, respiration, and growth rates. Essentially, each organism absorbs the chemical by respiring air (or by exchange at the gill-water interface in the case of fish) or by consuming water and other organisms (plants or animals). The concentration of the substance in each organism is generally calculated using these rates, absorption efficiencies, and the concentration in the respective media. The steady-state concentration in the organism is calculated from an input-output mass balance. The result is an estimate of fugacity and concentrations in the biota.

Using a multi-level, multi-media foodchain, the most sensitive endpoint is identified (based on toxicity and exposure potential) and a “critical emission rate” is calculated based on that sensitive endpoint. The estimated critical emission rate is then compared with an estimated potential emission rate (based on quantities in commerce) to determine a “risk assessment factor” or RAF.

Substances are ranked according to their critical emission rates and their RAF values. Substances identified as having greater potential for harm are thus also identified as requiring further assessment. The model output also indicates substances whose releases to the environment through their life cycle are unlikely to be of concern.

As outlined in a report on the application of RAIDAR in rapid screening (Arnot and Mackay 2007), there are some classes of substances (e.g., inorganic substances) for which

application of the model was not designed or may not be appropriate. Substances belonging to such classes were identified and the model was not applied to them. A more detailed description of RAIDAR is contained in Environment Canada (2007b).

For the purpose of the rapid screening approach, the critical emission rate, the RAF and the media of concern are the most important outputs of RAIDAR. The use of the critical emission rate and the RAF allows identification of chemicals that are unlikely to be of concern because of their limited potential for exposure. Additionally, the identification of the most sensitive ecological endpoint allows consideration of environmental media and/or types of organisms that may not have been previously addressed in rapid screening exposure scenarios A and B.

Possible outcomes from Step 1

There are three possible outcomes from Step 1:

- If the scenarios indicate a potential harmful effect to aquatic or terrestrial organisms, and the substance is in commerce based on information collected under the DSL Inventory Update, the substance is identified as requiring further assessment.
- If the scenarios indicate a potential harmful effect to aquatic or terrestrial organisms, and the substance is believed not to be in commerce based on information collected under the DSL Inventory Update, the substance may be designated for application of the Significant New Activity (SNAc) provisions under subsection 83(1) of CEPA 1999.
- If the scenarios indicate a low likelihood of harm to organisms, the substance proceeds to the next step of rapid screening.

The application of SNAc provisions in the rapid screening approach is made when a Significant New Activity in relation to a substance may result in the substance being released in amounts or under conditions that could result in it meeting one or more criteria set out in section 64 of the Act. In the ecological portion of this screening assessment, a SNAc provision may be triggered for substances that are not currently in commerce (based on information collected under the DSL Inventory Update), but that could have a risk quotient value above 1 if as little as 100 kg of the substance was brought into commerce. Based on back-calculation using the conservative ecological rapid screening exposure scenarios A (Industrial Point Source Aquatic Release) or B (Down-the-Drain Aquatic Release from Consumer Products), such a situation could occur if a substance has an acute aquatic toxicity value (lethal concentration to 50% of study organism (LC_{50}) or equivalent) ≤ 0.0061 mg/L. The SNAc provisions would require that adequate additional information be provided by any person who wishes to manufacture, import or use the substance in Canada at > 100 kg per year. The additional information would allow Environment Canada and Health Canada to assess the potential environmental and human health risks associated with the new activities before they are undertaken.

Step 2: Mechanical filters and manual process

The second step of the ecological rapid screening approach uses “filters” (i.e., various information sources) and involves identifying whether or not a substance appears on different lists or sources of information relating to hazard or exposure. This step flags

substances that may have an elevated potential for environmental release or that have been identified by domestic or international sources as possibly being of greater concern due to their hazard properties.

Depending on the nature of the information sources, substances flagged by the filters may be further evaluated manually within rapid screening. This manual process involves case-by-case evaluation to decide, for example, whether the information in the source that flagged the substance is relevant to the situation in Canada. It may also involve the collection and review of information from other sources that are not as amenable to evaluation using a mechanical approach. The manual process involves evaluation of the weight and relevance of information obtained from the full range of sources identified.

Many sources of information were evaluated. In selecting which lists or information sources to apply in rapid screening, there was an effort to limit the amount of overlap between lists. For example, secondary sources of information were removed if the primary source of information was also included. A list of the sources of information that were retained for the purpose of rapid screening can be found in Appendix A. A number of information sources were judged to be relevant for rapid screening but were not amenable to being searched mechanically. These sources were included among those verified at the manual stage.

Human health component

The process used to determine whether substances warrant further assessment from a human health perspective within the rapid screening approach is illustrated in Figure 3.

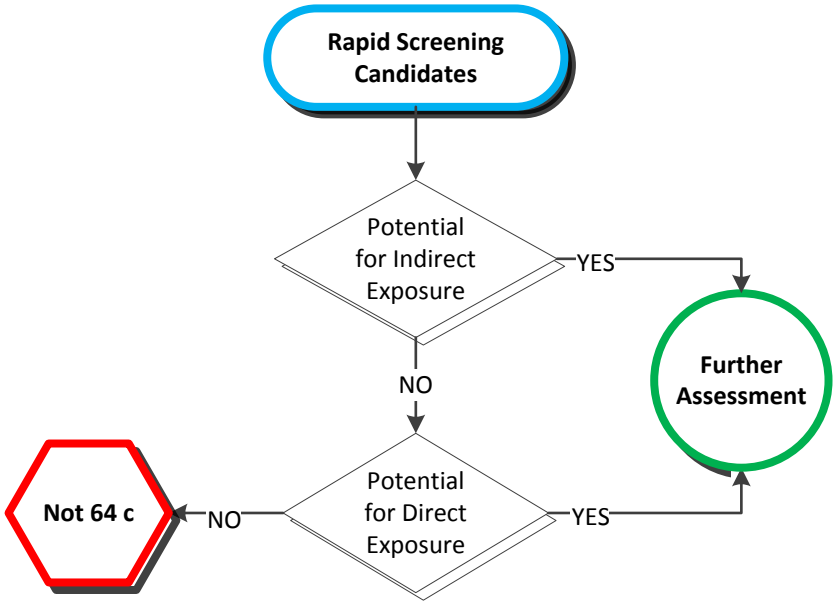

Figure 3: Overview of rapid screening approach – human health considerations

A key element of the characterization of potential risk to human health is the determination of potential for exposure to the general population. Substances reported to be in commerce in Canada at ≤ 1000 kg/year were considered to result in potential exposure to the general population if there was evidence of direct exposure (e.g., exposure from products or food

additives). Otherwise, exposure to the general population was considered to be negligible and it can be concluded that the substance is unlikely to cause harm to health at current levels of exposure and, as such, does not at this time meet the criterion set out in paragraph 64(*c*) of CEPA 1999.

Given the reported quantities in commerce in Canada (≤ 1000 kg) of these substances, indirect exposure to the general population from environmental media (air, water, soil) is not expected to be significant. Release of a substance to specific environmental media (i.e., water, air, soil) depends on factors such as where the substance is released and its physical-chemical properties. Conservative modelling estimates using a fugacity-based modelling tool for applicable substances (ChemCan 2003) indicate—assuming 100% release of a substance (i.e., the maximum possible release for these substances of 1000 kg) to either air, water or soil—that potential exposures would be predicted to be less than 10^{-6} mg/kg-bw/day (i.e., < 1 ng/kg-bw/day). This represents a negligible exposure potential from indirect sources for these substances.

Depending on the use of the substance, direct exposure to the general population may be possible. Considerations for determination of direct exposure potential are described below and outlined in Figure 4.

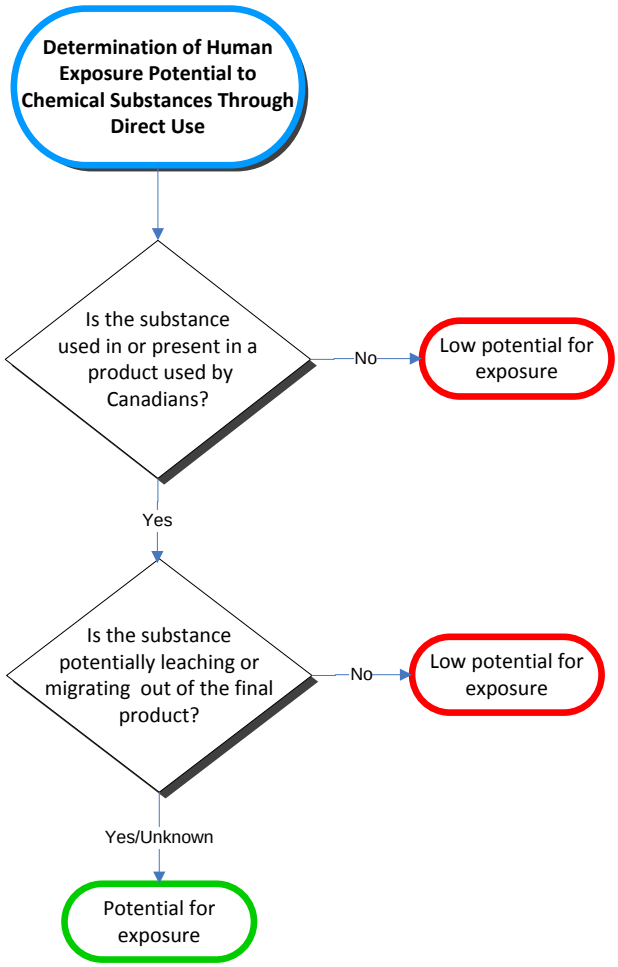

Figure 4: Considerations for the determination of direct human exposure potential to chemical substances through direct use

The term “direct use” refers to the use of a chemical substance that is sold to or made available to Canadians for their use, either directly or as part of a mixture, product or manufactured item,

”Direct use" does not include exposures from chemical products used by workers in an industrial setting or other workplace.

A user is considered to be anyone from the general public who has access to a product that is advertised, imported or sold in Canada.[2]

To determine if a substance is used in or present in a product used by Canadians, the following resources were consulted:

- Information from a mandatory CEPA 1999 section 71 survey under Phase One of the DSL Inventory Update (Canada 2009)
- Health Canada’s Cosmetic Notification System (CNS 2010)
- Health Canada’s Lists of Permitted Food Additives as regulated under the *Food and Drugs Act* (Health Canada 2013)
- Health Canada’s Natural Health Products Ingredients Database (NHPID 2011)
- Health Canada’s Licensed Natural Health Products Database (LNHPD 2011)
- Health Canada’s Drug Product Database (DPD 2011)
- Everything Added to Food in the United States database (EAFUS 2011)
- Household Products Database (HPD 2011)
- Hazardous Substances Data Bank (HSDB c1993-2008)
- Pest Management Regulatory Agency Product Information Database (PMRA 2011)
- Pest Management Regulatory Agency List of Formulants (PMRA 2010)
- National and international assessments and databases
- Other publicly available resources

Based on the information identified from these resources, together with other available information on the substances, the following considerations were used to determine potential for direct exposure:

1. Substances to which direct exposures to the general population are not expected include, but are not limited to, substances that are
    - used only as intermediates in the manufacturing process
    - used only for industrial use
    - used only for research purposes

2. Substances with potential for direct exposure to the general population include those that are present, either intentionally or unintentionally, in products or manufactured

[2] http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cccr-2001-rpccc/ref_man/index-eng.php#a1.1

items that are commonly used by Canadians. These include, but are not limited to, substances used in

- products intended for use by children, including manufactured items such as plastic or wooden toys
- personal care products
- commercial paints and inks
- commercial adhesives
- hobby activities or do-it-yourself products
- clothing, fabric and other textiles, including bedding and furniture
- cleaning products
- food additives
- fragrances

3. Information on potential for the substance to migrate from products was also considered, including the type of product in which that the substance is present, the substance's functional use in that product, as well as the substance's physical-chemical properties. For example, direct exposure would not be expected to occur for a substance used as a curing agent in a polymer, as the substance would be reacted into the stable matrices of the cured polymer and would therefore not typically be available for migration. If this information is not known for a substance, it was assumed that the substance may be migrating out of the final product, which may lead to direct exposure for users.

Screening Assessment Results

Assessment of potential to cause ecological harm

In this section, an overview of the results obtained at each rapid screening step of the substances covered under this assessment is provided. These results are summarized in Figure 5.

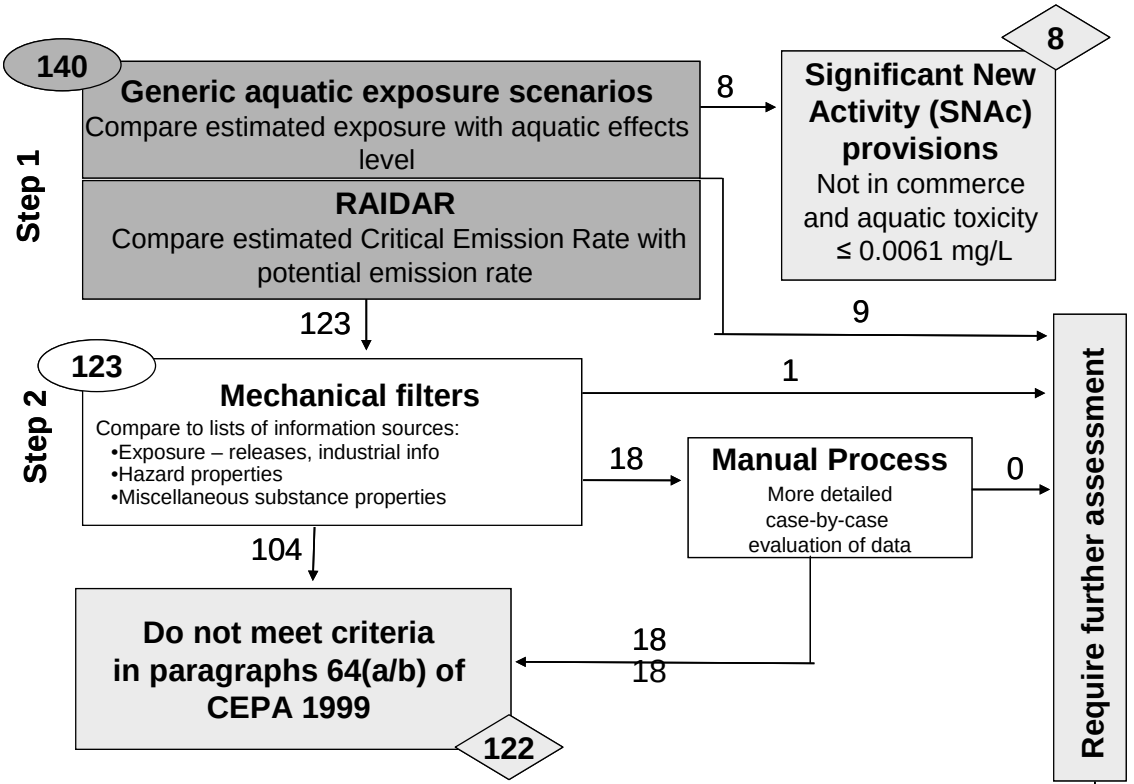

Figure 5: Summary of screening assessment results – ecological considerations

Step 1: Modelled exposure scenarios

In this assessment, quantities that were used in the exposure scenarios were obtained through Phase One of the DSL Inventory Update (Canada 2009).

Generic aquatic scenarios

The industrial releases scenario (Scenario A) identified 38 substances as being of potential concern, while the residential releases scenario (Scenario B) identified 25 substances, all of which were also identified by the industrial release scenario. These 38 substances (or 27% of the 140 evaluated) were initially identified by these scenarios as requiring further assessment. However, results from the first phase of the DSL Inventory Update indicate that 29 of these 38 substances are no longer in commerce in Canada above the reporting threshold (i.e., 100 kg). As indicated in the ecological component portion of the Approach section of this report, activities with as low as 100 kg per year of a substance could pose a risk if that substance has an acute aquatic toxicity value (LC_{50} or equivalent) of ≤ 0.0061 mg/L. As a result of their high ecotoxicity, consideration is therefore given to application of the SNAc provisions of CEPA 1999 to these 29 substances.

Of the above-mentioned 29 substances, 21 are metal-containing substances where the pivotal inherent toxicity value identified during categorization of the DSL,and applied in this rapid screening evaluation, was based on the ecotoxicity of the free metal ion expected to be liberated during dissolution/transformation of the substance under natural conditions. For example, an organic metal salt will dissolve and liberate a metal cation and an anionic organic moiety when present in water. However, in the case of these 21 substances—all of which are believed to have very little or no commercial presence at this time—becoming a significant contributor to the presence of the total metal moiety in the environment in the future, relative to other sources of release, is unlikely. Therefore only 8 of these substances are proposed for application of the SNAc provisions of CEPA 1999 (see Appendix C, ecological SNAc candidates).

RAIDAR

RAIDAR and similar models are not applicable to all categories of substances encountered on the DSL. RAIDAR was applied to substances in 5 of the 14 categories described in Arnot and Mackay (2007): conventional organics, dissociating organic acids, dissociating organic bases, gases and involatile organics. Therefore, of the 140 substances evaluated in Step 1, 77 (or 55%) were modelled using RAIDAR. However, higher confidence was only achieved with the modelling of the organic substances. The results for organic metal salts (35 substances) were used as additional evidence only.

A spreadsheet includes all input values and results from application of RAIDAR to these substances (ARC 2011). As with other models, results from RAIDAR depend on the quality and quantity of the available substance-specific data.

In order to identify which substances are unlikely to have the potential to cause ecological harm, it is necessary to select a cut-off value for the RAF. A value of 0.001 was selected, which is equivalent to an uncertainty factor of 1000. Selection of this conservative value allows for up to a 1000-fold error in the model results owing to uncertainties in the quantity of the substance in commerce and other model inputs, such as physical-chemical properties. The ability of RAIDAR to discriminate potential for ecological harm based on the characteristics of substances is discussed further in Environment Canada (2007a).

Based on the described model scenario and the selected RAF cut-off value, 10 of the 77 substances that were evaluated using RAIDAR were identified as requiring further assessment, as shown in Figure 6. Of these, four were organic substances and six were organic metal salts. All four organic substances and two of the six organic metal salts were also identified by the generic aquatic scenarios discussed above. The organic metal salt modelling is used only as additional evidence (i.e., for consideration during the manual process).

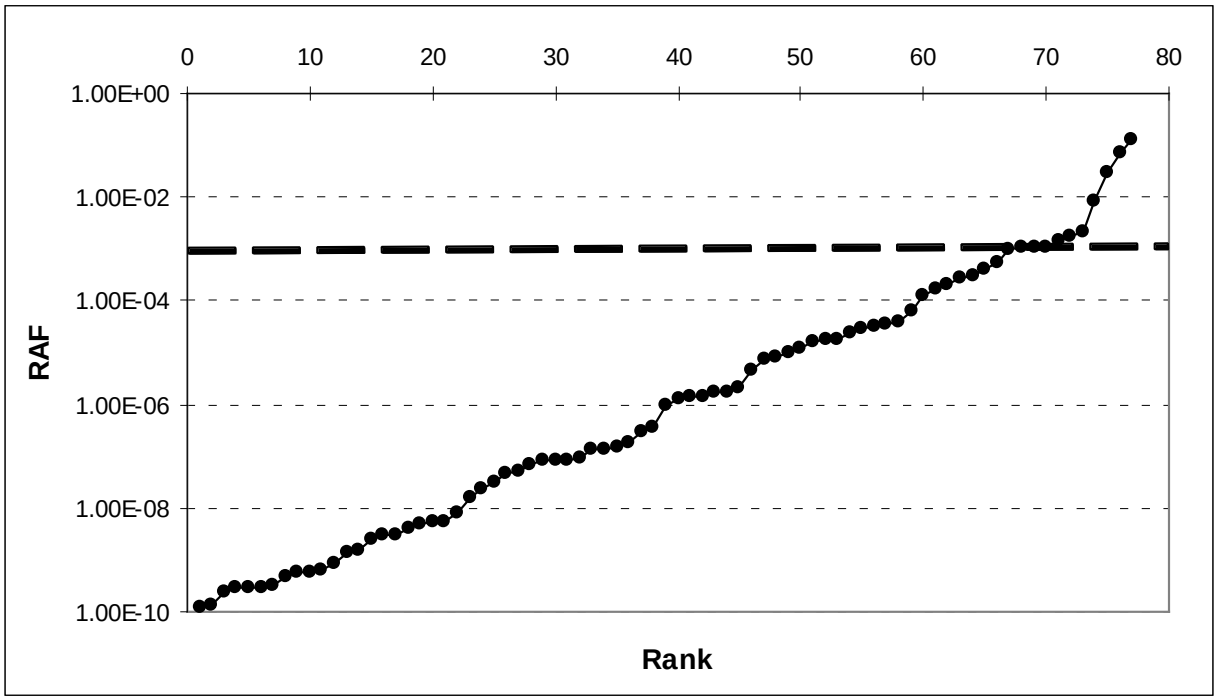

Figure 6: Risk assessment factor (RAF) results based on the RAIDAR model. (The dashed line represents the RAF cut-off of value of 0.001.)

Step 2: Mechanical filters and manual process

Appendix A shows the number of substances that were flagged by each of the mechanical filters for the 140 substances that were evaluated in this rapid screening exercise. In contrast to the previous rapid screening approach (Environment Canada 2007b), the appearance of a substance on one or more of the six international lists of high production

volume (HPV) chemicals did not automatically result in the substance being identified for further assessment, due to the availability of recent Canadian data (Canada 2009) on these substances. However, presence on these lists was used as a consideration at the manual screening stage. One substance was flagged for further evaluation at the mechanical filter stage and 18 were identified to proceed to the manual process stage (see Figure 5).

Substance-by-substance evaluation at the manual process stage was based on consideration of the available information to evaluate whether the substance has hazard properties or characteristics, or an elevated potential for environmental release, that may not have been adequately addressed using the exposure scenarios in Step 1.

Only those substances that were reported to be in commerce in Canada at the reporting threshold underwent manual screening. As a result of this further evaluation, no substances were identified as requiring further screening assessment. A summary of the basis for the decision on each of the 18 substances evaluated using the manual process is presented in the detailed results spreadsheet (Environment Canada 2012).

Summary of results from ecological assessment

In total, 10 of the substances evaluated using the ecological rapid screening approach were identified as warranting further screening assessment from an ecological perspective. A list of these substances is provided in Appendix B. The other substances, listed in Appendix C, were identified as posing a low risk of harm to organisms or the broader integrity of the environment at current levels of exposure. Eight of these substances were proposed to be subject to SNAc provisions as a result of their relatively high ecotoxicity.

Assessment of potential to cause harm to human health

For the 140 substances examined from a human health perspective, 22 substances were identified as having the potential to result in direct exposure to the general population, and therefore further assessment of the exposure and hazard potential of these substances will be completed to determine if they meet the criteria set out in section 64 of CEPA 1999. A list of the substances with potential for direct exposure to the general population, and therefore requiring further assessment, is provided in Appendix B.

Exposure to the general population was considered to be negligible for the remaining 118 substances. These substances, listed in Appendix C, were identified as being unlikely to cause harm to human health at current levels of exposure.

However, seven substances not identified for further assessment at this time are proposed to be subject to SNAc provisions (identified in Appendix C) based on high hazard concerns. These substances have been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity (see Appendix D).

Summary of Uncertainties

It is recognized that conclusions resulting from the use of a rapid screening approach have associated uncertainties. However, the use of a wide range of filters (relating to both

exposure potential and hazard concerns identified for a substance), as well as the use of different conservative exposure scenarios, give confidence that substances identified as not requiring further assessment are unlikely to be of concern.

Values for physical-chemical and hazard properties derived during categorization of the DSL were used as input for the modelling work for the ecological assessment. As is recognized in documentation associated with categorization, there are uncertainties in these values, in particular with those that have been estimated using different modelling approaches. Extreme values that were estimated by models were replaced by limiting values of physical-chemical properties or alternatively derived toxicity values, prior to using them as input for RAIDAR modelling as part of rapid screening (ARC 2011).

Conclusion

In total, from both ecological and human health assessments, 23 of the 140 substances were identified as requiring further assessment (Appendix B).

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from the 117 substances identified in Annex C. It is concluded that the 117 substances do not meet the criteria under paragraphs 64(*a*) or (*b*) of CEPA 1999 as they are not 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 or that constitute or may constitute a danger to the environment on which life depends.

Based on the information presented in this screening assessment, it is concluded that the 117 substances listed in Appendix C do not meet the criteria under paragraph 64(*c*) of CEPA 1999 as they are not 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.

It is concluded that these 117 substances (Appendix C) do not meet any of the criteria as set out in section 64 of CEPA 1999.

Because these 117 substances are listed on the Domestic Substances List, their import and manufacture in Canada are not subject to notification under subsection 81(1) of CEPA 1999. Since 15 are recognized for their hazardous properties, there is suspicion that new activities that have not been identified or assessed could lead to these substances meeting the criteria set out in section 64 of CEPA 1999. Therefore, it is recommended to amend the *Domestic Substances List*, under subsection 87(3) of the Act, to indicate that the significant new activity (SNAc) provisions under subsection 81(3) of the Act apply with respect to the substances.

A significant new activity can include one that has not been conducted with the substance in the past or an existing one with a different quantity or in different circumstances that could affect the exposure pattern of the substance. The SNAc provisions trigger an obligation for industry to notify and the government to assess, information about a substance when a proponent proposes to use the substance in a significant new activity. The provisions are used to assess the risks associated with the proposed new activity

before the new activity is undertaken. The Minister of the Environment and the Minister of Health assess the information provided by the notifier and other information available to them to determine whether the substance, if used in the proposed new activity, could pose a risk to the environment or human health, and if so, whether new or additional risk management is required. The notice of intent to apply the Significant New Activity provisions to 15 substances covered under the current rapid screening approach will be developed later in 2014 in consultation with industry stakeholders.

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Appendix A: Number of substances flagged by each mechanical filter

Mechanical Filters	Number of Substances
Exposure – quantities, releases and industrial information	
OECD HPV	23
EU HPV	12
ICCA HPV	4
US HPV	18
US EXTENDED HPV	1
Japan HPV	4
Australia HPV	0
REACH Dossier Published/disseminated	11
Toxic Substances Control Act – 12(b) Export Notification (US)	2
National Pollutant Release Inventory (CA)	3
Toxics Release Inventory (US)	6
National Pollutant Inventory (AU)	0
Pollutant Release & Transfer Register (JN)	5
Hazardous substances lists or substance profiles	
(NClassification) R52 (EU)	3
(NClassification) R53 (EU)	0
(NClassification) R52,53 (EU)	3
(NClassification) N; R50 (EU)	28
(NClassification) N: R50,53 (EU)	27
(NClassification) N: R51,53 (EU)	6
Banned or Severely Restricted Pesticides (US)	0
PBT List (US)	0
Priority Substances List (EU)	1
EU PBT List (EUROPE)	1
List of Substances Banned/Severely restricted in EU (EUROPE)	0
Great Lakes Binational Toxics List (CA/US)	0
PIC List (UN)	0
CEPA 1999 section 200 Environmental Emergencies List (CA)	0
PSL2 Nomination Dossiers (CA)	0
ARET List (CA)	1
Great Lakes 211 Air Toxics (CA/US)	1
NAPS (CA)	2
Pest Control Products Act Registered Active Ingredients (CA)	1
Air Toxics / Hot Spots Chemicals (California)	5
Clean Water Act Priority Pollutants (US)	1
Superfund Site Chemicals (US)	11
Hazardous Constituents Under RCRA (US)	0
Nordic Council List of Chemicals Hazardous to Environment (EU)	37
OSPAR List (EU)	2
UNEP/FAO/WHO Inchem Pesticide Classification (UN)	0
Toxic Chemicals List (China)	1
Camford Product Information Profiles (CA)	1
BUA Reports (DE)	4
UNEP EHC (UN)	8
RAIS Tox Profile (US)	0
TSCATS (US)	21
Miscellaneous properties and hazard databases	
HSDB Record (US)	30
NTP Reports / Studies (US)	17
IUCLID (EU)	0
ECOTOX (US)	23
ChemFate – Syracuse Research Corporation (US)	1

Mechanical Filters	Number of Substances
Datalog – Syracuse Research Corporation (US)	2
CESARS – Ontario Database (CA/US)	5

Discrepancies may occur between the values presented in this table and the specific values identified at each step in the text due to the table being based on the original list of 140 substances that were candidates for rapid screening.

Appendix B: Substances identified as requiring further assessment

CAS RN[i]	DSL Name[ii]	Ecological	Human Health
62-44-2	Acetamide, N-(4-ethoxyphenyl)-		X
77-47-4	1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-	X	X
87-66-1	1,2,3-Benzenetriol		X
95-55-6	Phenol, 2-amino-		X
106-92-3	Oxirane, [(2-propenyloxy)methyl]-		X
288-88-0	1H-1,2,4-Triazole		X
333-41-5	Phosphorothioic acid, O,O-diethyl O-[6-methyl-2-(1-methylethyl)-4-pyrimidinyl] ester	X	
556-52-5	Oxiranemethanol		X
630-20-6	Ethane, 1,1,1,2-tetrachloro-		X
632-99-5	Benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-2-methyl-, monohydrochloride		X
1314-22-3	Zinc peroxide ($Zn(O_2)$)	X	X
2223-95-2	Octadecanoic acid, nickel(2++) salt		X
2475-45-8	9,10-Anthracenedione, 1,4,5,8-tetraamino-		X
4035-89-6	Imidodicarbonic diamide, N,N',2-tris(6-isocyanatohexyl)-	X	X
7789-36-8	Magnesium borate		X
7803-55-6	Vanadate (VO31-), ammonium		X
15337-18-5	Zinc, bis(dipentylcarbamodithioato-S,S')-, (T-4)-	X	X
24308-84-7	Benzenesulfinic acid, zinc salt	X	X
24887-06-7	Zinc, bis(hydroxymethanesulfinato-OS,O1)-, (T-4)-	X	X
28629-66-5	Zinc, bis(O,O-diisooctyl phosphorodithioato-S,S')-		X
37300-23-5	C.I. Pigment Yellow 36	X	X
68527-01-5	Alkenes, C_{12-30} α-, bromo chloro	X	X
73398-89-7	Xanthylium, 3,6-bis(diethylamino)-9-[2-(methoxycarbonyl)phenyl]-, (T-4)-tetrachlorozincate(2-) (2:1)	X	X

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[ii] Domestic Substances List

Appendix C: Substances identified as not meeting the criteria under section 64 of CEPA 1999

CAS RN[iii]	DSL Name[iv]	Met s. 73(1) criteria	Potential SNAc candidate (and basis for concern)[v]
56-49-5	Benz[j]aceanthrylene, 1,2-dihydro-3-methyl-	Yes	
78-13-7	Silicic acid (H_4SiO_4), tetrakis(2-ethylbutyl) ester	Yes	
86-74-8	9H-Carbazole	Yes	
87-62-7	Benzenamine, 2,6-dimethyl-	Yes	Yes (Health)
99-09-2	Benzenamine, 3-nitro-	Yes	
108-44-1	Benzenamine, 3-methyl-	Yes	
112-76-5	Octadecanoyl chloride	Yes	
120-95-6	Phenol, 2,4-bis(1,1-dimethylpropyl)-	Yes	
121-19-7	Arsonic acid, (4-hydroxy-3-nitrophenyl)-	Yes	
127-85-5	Arsonic acid, (4-aminophenyl)-, monosodium salt	Yes	
150-68-5	Urea, N'-(4-chlorophenyl)-N,N-dimethyl-	No	Yes (Health)
507-28-8	Arsonium, tetraphenyl-, chloride	Yes	Yes (Ecological)
543-90-8	Acetic acid, cadmium salt	Yes	
553-72-0	Benzoic acid, zinc salt	Yes	
554-00-7	Benzenamine, 2,4-dichloro-	Yes	
557-09-5	Octanoic acid, zinc salt	Yes	
557-21-1	Zinc cyanide ($Zn(CN)_2$)	Yes	
557-28-8	Propanoic acid, zinc salt	Yes	
603-32-7	Arsine, triphenyl-	Yes	
637-03-6	Arsine, oxophenyl-	Yes	
1153-05-5	Arsine oxide, triphenyl-	Yes	
1191-79-3	Octadecanoic acid, barium cadmium salt (4:1:1)	Yes	
2191-10-8	Octanoic acid, cadmium salt	Yes	
2223-93-0	Octadecanoic acid, cadmium salt	Yes	
2605-44-9	Dodecanoic acid, cadmium salt	Yes	
3026-22-0	Benzoic acid, cadmium salt	Yes	
4167-05-9	Benzoic acid, 4-(1,1-dimethylethyl)-, cadmium salt	Yes	
4454-16-4	Hexanoic acid, 2-ethyl-, nickel(2++) salt	Yes	Yes (Health)
4980-54-5	Benzoic acid, 4-(1,1-dimethylethyl)-, zinc salt	Yes	
4995-91-9	Octanoic acid, nickel(2++) salt	Yes	Yes (Health)
5530-30-3	Phenol, 4-butyl-2,6-bis(1,1-dimethylethyl)-	Yes	
6362-80-7	Benzene, 1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bis-	Yes	
6427-86-7	Hexadecanoic acid, cadmium salt	Yes	
7580-31-6	Hexanoic acid, 2-ethyl-, nickel salt	Yes	Yes (Health)

CAS RN[iii]	DSL Name[iv]	Met s. 73(1) criteria	Potential SNAc candidate (and basis for concern)[v]
7647-18-9	Antimony chloride ($SbCl_5$)	Yes	
7779-86-4	Dithionous acid, zinc salt (1:1)	Yes	
10196-67-5	Tetradecanoic acid, cadmium salt	Yes	
10468-30-1	9-Octadecenoic acid (Z)-, cadmium salt	Yes	
10595-60-5	1,2-Ethanediamine, N-(1,3-dimethylbutylidene)-N'-[2-[(1,3-dimethylbutylidene)amino]ethyl]-	Yes	Yes (Ecological)
11071-15-1	Antimonate(2-), bis[μ-[2,3-dihydroxybutanedioato(4-)-O1,O2:O3,O4]]di-, dipotassium, stereoisomer	Yes	
11112-10-0	Antimony sodium oxide	Yes	
13438-45-4	Benzenesulfonic acid, 4-methyl-, zinc salt	Yes	
13497-94-4	Silver vanadium oxide ($AgVO_3$)	Yes	
14024-63-6	Zinc, bis(2,4-pentanedionato-O,O')-, (T-4)-	Yes	
14239-68-0	Cadmium, bis(diethylcarbamodithioato-S,S')-, (T-4)-	Yes	Yes (Ecological)
14263-89-9	Benzenediazonium, 4-chloro-2-nitro-, tetrachlorozincate(2-) (2:1)	Yes	
14516-71-3	Nickel, (1-butanamine)[[2,2'-thiobis[4-(1,1,3,3-tetramethylbutyl)phenolato]](2-)-O,O',S]-	Yes	
14639-97-5	Zincate(2-), tetrachloro-, diammonium, (T-4)-	Yes	
14639-98-6	Zincate(3-), pentachloro-, triammonium	Yes	
15317-78-9	Nickel, bis[bis(2-methylpropyl)carbamodithioato-S,S']-, (SP-4-1)-	Yes	
15521-65-0	Nickel, bis(dimethylcarbamodithioato-S,S')-, (SP-4-1)-	Yes	
15337-60-7	Dodecanoic acid, barium cadmium salt	Yes	
15751-00-5	Nickel(2++), hexakis(1H-imidazole-N3)-, dichloride, (OC-6-11)-	Yes	
15874-52-9	Phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, antimony(3++) salt	Yes	
18015-76-4	Methanaminium, N-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, ethanedioate	No	Yes (Health)
19900-65-3	Benzenamine, 4,4'-methylenebis[2-ethyl-	No	Yes (Health)
20437-10-9	Nickel, [[1,1'-[1,2-phenylenebis(nitrilomethylidyne)]bis[2-naphthalenolato]](2-)-N,N',O,O']-, (SP-4-2)-	Yes	
24345-02-6	Benzenesulfinic acid, 4-methyl-, zinc salt	Yes	
25168-05-2	Benzene, chloromethyl-	Yes	
25537-17-1	Phosphonic acid, (1-hydroxyethylidene)bis-, zinc salt	Yes	
25640-78-2	1,1'-Biphenyl, (1-methylethyl)-	Yes	
27251-75-8	1,2,4-Benzenetricarboxylic acid, triisooctyl ester	Yes	
27288-44-4	Acetic acid, mercapto-, isooctyl ester, antimony(3++) salt	Yes	
27342-69-4	Cyclotetrasiloxane, tetraethenyltetramethyl-	Yes	

CAS RN[iii]	DSL Name[iv]	Met s. 73(1) criteria	Potential SNAc candidate (and basis for concern)[v]
27574-34-1	Nickel, [[2,2'-thiobis[4-(1,1,3,3-tetramethylbutyl)phenolato]](2-)-O,O',S]-	Yes	
28214-91-7	Naphthalenesulfonic acid, dinonyl-, lithium salt	Yes	
29204-84-0	Nickel, bis[2,3-bis(hydroxyimino)-N-phenylbutanamidato-N2,N3]-	Yes	
30172-67-9	Benzene, bis(phenylmethyl)-	Yes	
30260-72-1	Benzenesulfonic acid, dodecyl(sulfophenoxy)-	Yes	
30947-30-9	Phosphonic acid, [[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]-, monoethyl ester, nickel(2++) salt (2:1)	Yes	
33684-80-9	Methanesulfonic acid, zinc salt	Yes	
38656-51-8	Benzenediazonium, 2,5-diethoxy-4-[(4-methylphenyl)thio]-, (T-4)-tetrachlorozincate(2-) (2:1)	Yes	
39455-80-6	Ammonium sodium vanadium oxide	Yes	
42405-40-3	Zinc, bis[3,5-bis(1,1-dimethylethyl)-2-hydroxybenzoato-O1,O2]-, (T-4)-	Yes	
43126-83-6	tert-Dodecanethiol, silver(1++) salt	Yes	
49757-42-8	Benzene, 1,1',1''-(chloromethylidyne)tris[4-methoxy-	Yes	Yes (Ecological)
50594-66-6	Benzoic acid, 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitro-	Yes	
50851-34-8	Benzene, dimethylbis(phenylmethyl)-	Yes	
51731-04-5	Octadecanoic acid, zinc salt, basic	Yes	
52108-54-0	Phosphoric acid, 2-ethylhexyl ester, zinc salt	Yes	
52434-90-9	1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-tris(2,3-dibromopropyl)-	Yes	Yes (Ecological)
52572-38-0	Benzenediazonium, 3-methyl-4-(1-pyrrolidinyl)-, trichlorozincate(1-)	Yes	
55700-14-6	Cyclohexanebutanoic acid, cadmium salt	Yes	
57866-49-6	Lignosulfonic acid, zinc salt	Yes	
60580-61-2	1,3-Benzenedicarboxylic acid, 5-nitro-, zinc salt (1:1)	Yes	
61789-34-2	Naphthenic acids, cadmium salts	Yes	
61951-96-0	Neodecanoic acid, cadmium salt	Yes	
63568-30-9	Naphthalenesulfonic acid, diisononyl-, lead(2++) salt	Yes	
63589-47-9	Phenoxazin-5-ium, 3,7-bis(diethylamino)-, (T-4)-tetrachlorozincate(2-) (2:1)	Yes	
65046-95-9	Zinc, bis(2-methoxybenzoato-O1,O2)-, (T-4)-	Yes	
68092-45-5	Benzoic acid, 3-methyl-, cadmium salt	Yes	
68092-46-6	Benzoic acid, 3-methyl-, zinc salt	Yes	
68442-22-8	Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl and iso-Bu) esters, zinc salts	Yes	

CAS RN[iii]	DSL Name[iv]	Met s. 73(1) criteria	Potential SNAc candidate (and basis for concern)[v]
68478-53-5	Cadmium, benzoate p-tert-butylbenzoate complexes	Yes	
68512-49-2	Cadmium zinc sulfide ((Cd,Zn)S), copper chloride-doped	Yes	
68540-77-2	1-Anthracenediazonium, 9,10-dihydro-9,10-dioxo-, chloride, compd. with zinc chloride ($ZnCl_2$)	Yes	
68611-72-3	Zinc, C6-19-branched carboxylate naphthenate complexes	Yes	
68815-09-8	Naphthenic acids, vanadium salts	Yes	
68988-46-5	Phosphorodithioic acid, mixed O,O-bis(iso-Bu and isooctyl and pentyl) esters, zinc salts	Yes	
68988-62-5	Zinc, benzoate p-tert-butylbenzoate complexes	Yes	
69121-20-6	Octadecanoic acid, 12-hydroxy-, cadmium salt (2:1)	Yes	
69304-37-6	Disiloxane, 1,3-dichloro-1,1,3,3-tetrakis(1-methylethyl)-	Yes	Yes (Ecological)
71889-22-0	Nickel, [μ-(piperazine-N1:N4)]bis[3-[1-[(4,5,6,7-tetrachloro-1-oxo-1H-isoindol-3-yl)hydrazono]ethyl]-2,4(1H,3H)-quinolinedionato(2-)]di-	Yes	
72102-51-3	3H-Indolium, 2-[2-[4-(diethylamino)phenyl]ethenyl]-1,3,3-trimethyl-, trichlorozincate(1-)	Yes	
72333-14-3	Benzenediazonium, 2-chloro-5-(4-chlorophenoxy)-4-(diethylamino)-, (T-4)-tetrachlorozincate(2-) (2:1)	Yes	
73003-83-5	Arsonium, tetraphenyl-, chloride, compd. with hydrochloric acid (1:1)	Yes	Yes (Ecological)
77245-35-3	Nickel, bis[[didecyl (1,2-dicyano-1,2-ethenediyl)bis[carbamato]](2-)]-	Yes	
84370-79-6	tert-Decanoic acid, zinc salt	Yes	
85203-81-2	Hexanoic acid, 2-ethyl-, zinc salt, basic	Yes	
85298-60-8	Zinc, bis(diisononylcarbamodithioato-S,S')-	Yes	
85298-61-9	Nickel, bis(diisononylcarbamodithioato-S,S')-	Yes	
92221-02-8	Vanadium, tetrachloro(2-pyridinamine-N1)-	Yes	
101747-77-7	Phosphorodithioic acid, mixed O,O-bis(iso-Bu and iso-Pr and pentyl) esters, zinc salts	Yes	
114792-68-6	Benzene, trimethylbis(phenylmethyl)-	Yes	Yes (Ecological)
125275-86-7	Nickelate(1-), (formato-O)[sulfato(2-)-O]-, hydrogen	Yes	
125275-87-8	Nickelate(1-), (acetato-O)[sulfato(2-)-O]-, hydrogen	Yes	
125494-58-8	Zinc, C9-28-neocarboxylate 2-ethylhexanoate naphthenate complexes	Yes	

[iii] Chemical Abstracts Service Registry Number
[iv] Domestic Substances List
[v] Significant New Activity

Appendix D: Substances not subject to further assessment that were identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity

CAS RN[vi]	DSL name[vii]	Classified for carcino-genicity[viii]	Classified for developmental toxicity	Classified for genotoxicity	Classified for reproductive toxicity
87-62-7	Benzenamine, 2,6-dimethyl-	x			
150-68-5	Urea, N'-(4-chlorophenyl)-N,N-dimethyl-	x			
4454-16-4	Hexanoic acid, 2-ethyl-, nickel(2++) salt	x		x	x
4995-91-9	Octanoic acid, nickel(2++) salt	x		x	x
7580-31-6	Hexanoic acid, 2-ethyl-, nickel salt	x		x	x
18015-76-4	Methanaminium, N-[4-[[4(dimethylamino) phenyl] phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, ethanedioate		x		
19900-65-3	Benzenamine, 4,4'-methylenebis[2-ethyl-	x			

[vi] Chemical Abstracts Service Registry Number
[vii] Domestic Substances List
[viii] For more information on the criteria used to determine substance classifications, see below.

Criteria Used for Obtaining Results from the DSL Categorization's Simple Hazard Tool

Carcinogenicity is determined by one or more of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to be carcinogenic to humans)
- Category 2 (Regarded as if carcinogenic to humans)
- Category 3 (Causes concern for humans owing to possible carcinogenic effects)

International Agency for Research on Cancer (IARC 2013)

- Group 1 (Carcinogenic to humans)
- Group 2A (Probably carcinogenic to humans)
- Group 2B (Possibly carcinogenic to humans)

National Toxicology Program (NTP 2011)

- Known to be a human carcinogen
- Reasonably anticipated to be a human carcinogen

United States Environmental Protection Agency (US EPA) 1986 Carcinogenicity Guidelines (US EPA 1987)

- Group A (Human carcinogen)
- Groups B1 and B2 (Probable human carcinogen)
- Group C (Possible human carcinogen)

US EPA 2003 Carcinogenicity Guidelines (US EPA 2003)

- Carcinogenic to humans
- Likely to be carcinogenic to humans
- Suggestive evidence of carcinogenicity, but not sufficient to assess
- Human carcinogenic potential

Developmental toxicity is determined by one of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to cause developmental toxicity in humans)
- Category 2 (Regarded as if they cause developmental toxicity in humans)
- Category 3 (Causes concern for humans owing to possible developmental toxic effects)

Genotoxicity is determined by one of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to be mutagenic to humans)
- Category 2 (Regarded as if mutagenic to humans)
- Category 3 (Causes concern for humans owing to possible mutagenic effects)

Reproductive toxicity is determined by one of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to impair fertility in humans)
- Category 2 (Regarded as if they impair fertility in humans)
- Category 3 (Causes concern for human fertility)

European Commission: Carcinogenic, mutagenic or toxic to reproduction (CMR) substances identified as substances of very high concern (SVHC), as defined in Article 57 of the Regulation (EC) No 1907/2006 ("the REACH Regulation"). CMRs are designated as SVHC where they meet the criteria for classification in category 1 or 2 in accordance with Directive 67/548/EEC, which has recently been replaced by regulation (EC) No 1272/2008 on classification, labeling and packaging of chemical substances and mixtures, or the "CLP Regulation." Under the new CLP Regulation these substances are now classified as 1a and 1b.

- Carcinogenicity 1a: Chemicals known to have carcinogenic potential for humans
- Carcinogenicity 1b: Chemicals presumed to have carcinogenic potential for humans
- Mutagenic substances 1a: Chemicals known to induce heritable mutations in germ cells of humans
- Mutagenic substances 1b: Chemicals which should be regarded as if they induce heritable mutations in germ cells of humans
- Toxic for reproduction 1a: Chemicals known human reproductive toxicant
- Toxic for reproduction 1b: Chemicals presumed human reproductive toxicant