

Screening Assessment for the Challenge

626-39-1
944-61-6
68551-44-0

Environment Canada
Health Canada

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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.

Based on the information obtained through the categorization process, the Ministers identified a number of substances as high priorities for action. These include substances that

- met all of the ecological categorization criteria, including persistence (P), bioaccumulation potential (B) and inherent toxicity to aquatic organisms (iT), and were believed to be in commerce in Canada; and/or
- met the categorization criteria for greatest potential for exposure (GPE) or presented an intermediate potential for exposure (IPE), and 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 Ministers therefore published a notice of intent in the *Canada Gazette*, Part I, on December 9, 2006 (Canada 2006a), that challenged industry and other interested stakeholders to submit, within specified timelines, specific information that may be used to inform risk assessment, and to develop and benchmark best practices for the risk management and product stewardship of these substances identified as high priorities.

The substances listed below were identified as high priorities for screening assessment and were included in the Challenge because they were found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity to non-human organisms and were believed to be in commerce in Canada. These substances are not considered to be high priorities for assessment of potential risks to human health, based upon application of the simple exposure and hazard tools developed by Health Canada for categorization of substances on the *Domestic Substances List* (DSL).

CAS RN*	DSL Name
626-39-1	Benzene, 1,3,5-tribromo-
944-61-6	Benzene, 1,2,3,4-tetrachloro-5,6-dimethoxy-
68551-44-0	Fatty acids, C ₆₋₁₉ -branched, zinc salts

*CAS RN = Chemical Abstracts Service Registry Number

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 CEPA 1999. Screening assessments examine scientific information and develop conclusions by incorporating a weight-of-evidence approach and precaution.

The Notice for the Challenge for the above substances was published in the *Canada Gazette* on January 31, 2009 (Canada 2009a,b). The Substance Profiles were released at the same time. The Substance Profiles presented the technical information available prior to December 2005 that formed the basis for categorization of these substances. Based on the outcome of the Challenge, the Ministers of the Environment and of Health have conducted this screening assessment for these substances.

Summary of Information Used as Basis for this Screening Assessment

Based on categorization results, the substances listed in this report have been found to meet the ecological criteria for persistence, bioaccumulation and inherent toxicity to non-human organisms (PBiT). These substances were not found to meet the human health categorization criteria (Environment Canada 2006a).

To establish whether certain high priority substances, including PBiT substances, were currently being manufactured in or imported into Canada, a survey was conducted by issuing a *Notice with Respect to Selected Substances Identified as Priority for Action* pursuant to paragraphs 71(1)(a) and (b) of CEPA 1999. The Notice was published in Part I of the *Canada Gazette* on March 4, 2006 (Canada 2006b).

In response to this notice, CAS RN 944-61-6 and CAS RN 68551-44-0 were reported to be imported in Canada above the reporting threshold of 100 kg, for the specified reporting year of 2005 (Environment Canada 2006b). There were no reports of industrial activity (import or manufacture) with respect to CAS RN 626-39-1 in Canada, above the reporting threshold of 100 kg, for the specified reporting year of 2005. Additionally, some companies identified themselves as having a stakeholder interest in the substances (Environment Canada 2006b). Therefore, these substances were believed to be potentially in commerce in Canada and were included in the Challenge.

Results from a similar notice issued under paragraph 71(1)(b) of CEPA 1999 on January 31, 2009, as part of the Challenge (Canada 2009b; Environment Canada 2009) revealed no reports of industrial activity (import or manufacture) with respect to these substances in Canada, above the reporting threshold of 100 kg, for the specified reporting year of 2006. These results indicate that currently these substances are not in use above the specified reporting threshold, and therefore the likelihood of exposure to humans or the environment from these substances in Canada resulting from commercial activity is low. It is recognized that CAS RN 944-61-6 may be formed in the environment to some extent through the degradation of other substances. This potential environmental source will be considered when precursors of this substance are addressed in future. Other sources of entry into the environment have not been identified at this time.

Responses to the above notices and the accompanying questionnaire of January 2009 (Environment Canada 2006b; Environment Canada 2009) also revealed no new information relevant to the PBiT properties of these substances. Given the lack of any significant commercial activity for these substances, no further collection or analysis relevant to the persistence, bioaccumulation and ecological

effects of these substances, beyond what was done for categorization, has been conducted. Therefore, the decisions on PBT properties made during categorization remain unchanged. These substances are thus considered to be highly hazardous to aquatic organisms ($LC50/EC50 \leq 1$ mg/L). They are also considered to meet the criteria for both persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

As mentioned above, since the results from notices issued under paragraph 71(1)(b) of CEPA 1999 in January 31, 2009 suggest that these substances are not currently in use above the specified reporting threshold, the likelihood of exposure to the general population in Canada is considered to be low; hence the potential risk to human health is considered to be low. Furthermore, these substances were not 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. Also, they are not on the European Union's Candidate List of Substances of Very High Concern for Authorisation (EU 2009).

Conclusion

Based on available information, and until new information is submitted indicating that these substances are entering, or may enter the environment, from commercial activity or from other sources, it is concluded that the above substances are currently not entering nor are likely to enter 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 a danger to the environment on which life depends or that constitute a danger in Canada to human life or health. Therefore, it is concluded that they do not meet the definition of toxic as set out in section 64 of CEPA 1999.

As substances listed on the DSL, import and manufacture of these substances in Canada are not currently subject to notification under subsection 81(1). Given their potential hazardous properties, there is concern that new activities for the above substances which have not been identified or assessed under CEPA 1999 could lead to the substances meeting the criteria set out in section 64 of the Act. Therefore, it is recommended that the above substances be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of these substances in quantities greater than 100 kg/year is notified and will undergo ecological and human health assessments as specified in section 83 of the Act, prior to the substances being considered for introduction into Canada.

In addition and where relevant, research and monitoring will support verification of assumptions used during this screening assessment.

References

Canada. 1999. *Canadian Environmental Protection Act, 1999*. S.C., 1999, c. 33, Canada Gazette. Part III. vol. 22, n° 3. Available from: <http://www.gazette.gc.ca/archives/p3/1999/g3-02203.pdf>

Canada. 2000. *Canadian Environmental Protection Act: Persistence and Bioaccumulation Regulations*, P.C. 2000-348, 23 March, 2000, SOR/2000-107, Canada Gazette. Part II, vol. 134, n° 7, p. 607–612. Available from: <http://gazette.gc.ca/archives/p2/2000/2000-03-29/pdf/g2-13407.pdf>

Canada, Dept. of the Environment, Dept. of Health. 2006a. *Canadian Environmental Protection Act, 1999: Notice of intent to develop and implement measures to assess and manage the risks posed by certain substances to the health of Canadians and their environment*. Canada Gazette, Part I, vol. 140, n° 49, p. 4109 – 4117. Available from: <http://www.gazette.gc.ca/archives/p1/2006/2006-12-09/pdf/g1-14049.pdf>

Canada, Dept. of the Environment. 2006b. *Canadian Environmental Protection Act, 1999: Notice with respect to selected substances identified as priority for action*. Canada Gazette, Part I, vol. 140, n° 9, p. 435–459. Available from: <http://www.gazette.gc.ca/archives/p1/2006/2006-03-04/pdf/g1-14009.pdf>

Canada, Dept. of the Environment, Dept. of Health. 2009a. *Canadian Environmental Protection Act, 1999: Notice of eighth release of technical information relevant to substances identified in the Challenge*. Canada Gazette, Part I, vol. 143, no. 5, p. 192–196. Available from: <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-01-31/pdf/g1-14305.pdf>

Canada, Dept. of the Environment. 2009b. *Canadian Environmental Protection Act, 1999: Notice with respect to Batch 8 Challenge substances*. Canada Gazette, Part I, vol. 143, no. 5, p. 196–213. Available from: <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-01-31/pdf/g1-14305.pdf>

Environment Canada. 2006a. CEPA DSL Categorization Overview and Results [CD-ROM]. Gatineau (QC): Environment Canada, Existing Substances Division. Available on request.

Environment Canada. 2006b. Data for selected substances collected under the *Canadian Environmental Protection Act, 1999*, Section 71: *Notice with respect to selected substances identified as priority for action*. Data compiled by: Environment Canada, Program Development and Engagement Division.

Environment Canada. 2009. Data for Batch 8 substances collected under the *Canadian Environmental Protection Act, 1999*, Section 71: *Notice with respect to certain Batch 8 Challenge substance*, Canada Gazette Part I, vol. 143, no. 5, p. 196–213. Data compiled by: Environment Canada, Program Development and Engagement Division.

[EU] European Union. 2009. Candidate List of Substances of Very High Concern for Authorisation. European Chemicals Agency. Available from: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp (accessed November 2009)