Screening Assessment for the Challenge

Chemical Abstracts Service Registry Numbers

CAS RN 475-71-8 (Benzo[h]benz[5,6]acridino[2,1,9,8-klmna]acridine-8,16-dione)

CAS RN 1326-05-2 (Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-3',6'-dihydroxy-, lead salt)

CAS RN 14295-43-3 (Benzo[b]thiophen-3(2H)-one, 4,7-dichloro-2-(4,7-dichloro-3-oxobenzo[b]thien-2(3H)-ylidene)-)

CAS RN 38465-55-3 (Nickel, bis[1-[4-(dimethylamino)phenyl]-2-phenyl-1,2-ethenedithiolato(2-)-S,S']-)

CAS RN 58161-93-6 (Benzoic acid, 4-[1-[[(2,4-dichlorophenyl)amino]carbonyl]-3,3-dimethyl-2-oxobutoxy]-)

Environment Canada
Health Canada

March 2010

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 2006), 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 Ministerial 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 were not considered to be a high priority 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
475-71-8	Benzo[h]benz[5,6]acridino[2,1,9,8-klmna]acridine-8,16-dione
1326-05-2	Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-3',6'-dihydroxy-, lead salt
14295-43-3	Benzo[b]thiophen-3(2H)-one, 4,7-dichloro-2-(4,7-dichloro-3-oxobenzo[b]thien-2(3H)-ylidene)-
38465-55-3	Nickel, bis[1-[4-(dimethylamino)phenyl]-2-phenyl-1,2-ethenedithiolato(2-)-S,S']-
58161-93-6	Benzoic acid, 4-[1-[[(2,4-dichlorophenyl)amino]carbonyl]-3,3-dimethyl-2-oxobutoxy]-

*CAS RN = Chemical Abstracts Service Registry Number

Screening assessments focus on information critical to determining whether a substance meets the criteria as set out in section 64 of CEPA 1999[1]. 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 March 14, 2009 (Canada 2009). 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 this substance. Based on the outcome of the Challenge, the Ministers of the Environment and of Health have conducted this screening assessment for these substances. The critical information and considerations upon which the assessment is based are summarized below.

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, 2006).

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, 2006a).

In response to this notice, there were 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 2005. However, some companies did identify themselves as having a stakeholder interest in these substances. 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 March 14, 2009, as part of the Challenge (Canada 2009) also revealed no reports of industrial activity (import or

[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) Challenge Batches 1-12 is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Controlled Products Regulations*, which is part of regulatory framework for the Workplace Hazardous Materials Information System [WHMIS] for products intended for workplace use.

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 these substances in Canada resulting from commercial activity is low. Other sources of entry into the environment have not been identified at this time.

Responses to the above notices and the accompanying questionnaire of March 2009 (Canada, 2006a; 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 PBiT properties made during categorization remain unchanged and accordingly these substances are considered to be highly hazardous to non-human organisms. 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 March 14, 2009 indicate 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).

Proposed Conclusion

Based on available information, and until new information is received indicating that these substances are entering, or may enter the environment, from commercial activity or from other sources, it is proposed that the above substances are currently not entering or 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 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 proposed that they do not meet any of the criteria 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 hazardous PBiT 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 this substance 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

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