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**Status Report**  
of the Commissioner of  
the Environment and  
Sustainable Development  
to the House of Commons

**MARCH**

**Chemicals Management**

**Chapter 1**

Substances Assessed Under the *Canadian  
Environmental Protection Act, 1999*



Office of the Auditor General of Canada

*The March 2008 Status Report of the Commissioner of the Environment and Sustainable Development comprises The Commissioner's Perspective—2008, Main Points—Chapters 1 to 14, Appendices, and 14 chapters. The main table of contents for the Report is found at the end of this publication.*

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Chapter

**1**

Substances Assessed under the  
*Canadian Environmental Protection Act,*  
1999

*All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.*

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# Chemicals Management

## Substances Assessed under the *Canadian Environmental Protection Act, 1999*

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### Main Points

#### What we examined

About 23,000 chemical substances used commercially in Canada were included in an inventory published in 1994, the Domestic Substances List. Under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999), Environment Canada and Health Canada are responsible for identifying which of these substances present an unacceptable risk to human health and the environment. Once identified as toxic, a substance is controlled according to the degree of risk it presents. By 1995, the government had listed 69 substances or groups of substances that it had determined were priorities for assessment.

In 2002, we reported that Environment Canada and Health Canada were taking too long to complete the assessments and publish decisions on all 69 substances so controls could be put in place for managing their risks when necessary.

For this status report, we examined the progress made by Environment Canada and Health Canada in managing risk assessments under CEPA, 1999, including the status of the 69 priority substances. We also looked at the departments' initiative for addressing new risk assessment priorities out of the 23,000 substances on the Domestic Substances List.

#### Why it's important

Chemical substances enter our air, water, land, and food from many sources. Because Canadians cannot always tell which chemical substances they may come in contact with, they rely on government to ensure that chemicals in the Canadian market present no unacceptable risks to their health and the environment.

#### What we found

- The federal government has made satisfactory progress since 2002 in managing risk assessments of chemical substances that could be toxic.
- In September 2006, as a result of an initial review of the Domestic Substances List, Environment Canada and Health Canada identified 4,300 substances that needed further assessment. To complete the assessments by 2020, the departments have adjusted the risk assessment process based on lessons learned from previous evaluations, set clear objectives and timelines, and identified

priorities, and they are taking steps to ensure that they will have enough resources to do the work.

- The risk assessments of priority substances that were underway in 2002 have been completed for the most part. However, the assessments of three of those substances have yet to be finalized—even though the departments have evidence that two of them are likely toxic and present risks to human health and the environment. Until the government concludes whether the outstanding chemical substances are toxic, no measures under CEPA, 1999 can be put in place to control the risks they may represent.

**The departments have responded.** Environment Canada and Health Canada have accepted our recommendation. Their detailed responses follow the recommendation in the chapter.

## Introduction

**Chemical substance**—For the purpose of this audit, we refer to all substances (chemical, radiological, and biological) that are assessed or managed under the *Canadian Environmental Protection Act, 1999* as chemical substances.

**Toxic substance**—A substance that 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.”

Source: Source: *Canadian Environmental Protection Act, 1999*, s. 64

**New chemical substances**—Substances that were introduced into the Canadian market after the *Canadian Environmental Protection Act* became law in 1988. The 1999 revised version of the Act ensures that all new substances are assessed to determine if they are toxic or capable of becoming toxic to the environment or human health. If they are, restrictions will be imposed. Substances that are not presently on the Domestic Substances List are considered to be new to Canada.

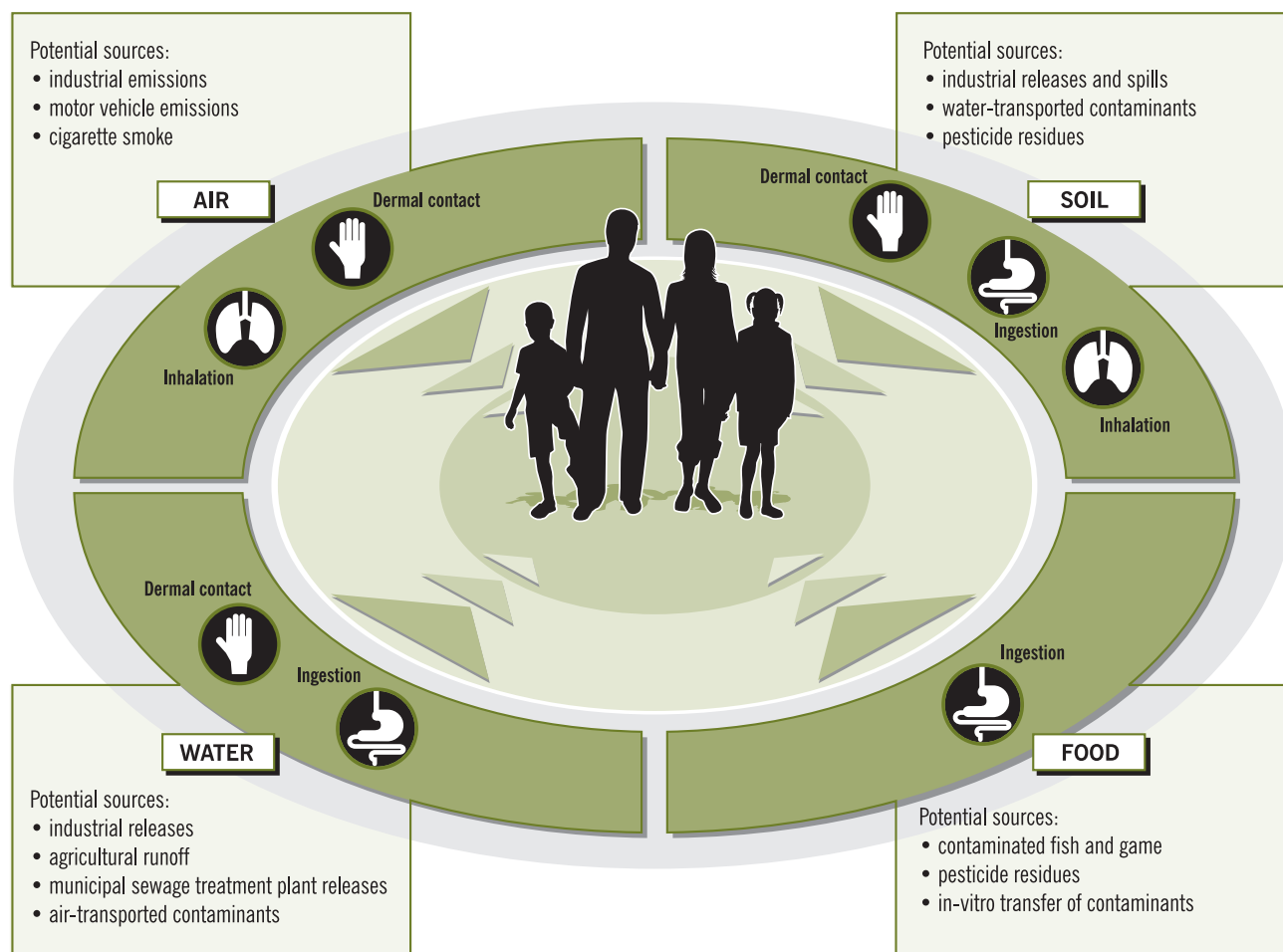
**1.1 Chemical substances** are used and found everywhere in Canadian society—in our homes, cars, farms, industries, computers, hospitals, clothing, and food. They contribute to our quality of life, economic well-being, and industrial competitiveness.

**1.2** Chemical substances enter our air, water, land, and food from many sources, including industries, agricultural runoff, contaminated sites, vehicle emissions, and consumer products. However, some chemical substances are harmful or could be harmful to the health of Canadians and to their environment (Exhibit 1.1). **Toxic substances** have been linked to lung disease, reproductive problems and birth defects, cancer, developmental disorders, and other illnesses or disorders. There are various types and definitions of toxic substances. While the term “toxic” has an everyday meaning, it can also have a precise legal meaning (for example, in legislation such as the *Canadian Environmental Protection Act, 1999*).

**1.3** In Canada, all levels of government play a role in managing chemical substances. The federal government’s main responsibilities in managing chemical substances are to identify which substances pose a risk to human health or the environment and to determine what must be done to avoid or minimize the use and release of toxic substances. The *Canadian Environmental Protection Act, 1999*, which replaced the earlier environmental protection legislation enacted in 1988, is one of the primary federal legal tools for assessing and managing chemical substances. Among other things, the Act requires the ministers of the Environment and of Health to identify and determine which existing chemical substances in Canada pose a risk to human health and the environment.

**1.4** Prior to 1988, chemical substances were manufactured or imported into Canada without a systematic assessment of their effects on human health and the environment. This changed in 1988 with the creation of the *Canadian Environmental Protection Act*. Since 1988, all **new chemical substances** must pass a risk assessment by Environment Canada and Health Canada to determine if they are toxic or capable of becoming toxic, before they are permitted to enter the Canadian market. However, there are about 23,000 chemical substances in the Canadian market that did not undergo this assessment as these substances were in Canadian commerce prior to introduction of the Act in 1988. These substances are listed on the Domestic Substances List—an inventory of about 23,000 substances manufactured in, imported into, or used in Canada on a commercial scale. The List was published in 1994.

**Exhibit 1.1 Major pathways of human exposure to environmental contaminants**



**Risk assessment**—An investigation of environmental and human health risks that involves the analysis of data on a substance's life cycle: entry into the environment; the concentration to which humans, animals, and plants are exposed; and the substance's effects on organisms and ecosystems. A risk assessment compares exposure concentrations with concentrations causing effects to determine if adverse effects are likely.

1.5 To address this legacy of existing substances, Environment Canada and Health Canada assess and manage environmental and human health risks in two distinct phases. Scientists must first conduct a **risk assessment** to determine whether a substance is “toxic” (or capable of becoming toxic) as defined under the *Canadian Environmental Protection Act, 1999*, based on available data. In the majority of cases to date, when a substance meets the criteria for being toxic under the Act, the ministers of the Environment and of Health have recommended its addition to the **List of Toxic Substances** in Schedule 1 of the Act. The decision to add the substance to Schedule 1 rests with the **Governor in Council**. The second phase consists of moving the substance into the risk management stage. Adding a substance to Schedule 1 empowers the Government of

**List of Toxic Substances**—A list of toxic substances, in Schedule 1 of the *Canadian Environmental Protection Act, 1999*, which are deemed to pose a risk to human health or the environment. The list is available and periodically updated on the CEPA Environmental Registry website.

**Governor in Council**—The Governor General acting on the advice of the Privy Council, as the formal executive body that gives legal effect to those decisions of Cabinet that are to have the force of law.

Canada to develop and implement risk management measures that reduce or eliminate harmful effects that the toxic substance poses to human health or the environment throughout its life cycle.

**1.6** The ministers of the Environment and of Health created two priority substances lists, one in 1989 and another in 1995. From the two lists, a total of 69 substances (or groups of substances) were identified as needing to be assessed for the toxicity risk that they pose to the health of Canadians and their environment. These assessments were to be done within five years of being identified.

### What we found in 2002

**1.7** In 2002, we followed up on our 1999 audit and found that Environment Canada and Health Canada still had not reached conclusions on the toxicity risks of about 20 of the 69 substances that were identified as requiring priority assessments by the year 2000. We noted that the departments were taking too long to complete these assessments and recommended that they quickly reach formal conclusions. The departments made a commitment to continue strengthening their capacity to complete the assessments within available resources, but they did not indicate the specific actions they would take.

### Events since 2002

**1.8** As required under the *Canadian Environmental Protection Act, 1999*, Environment Canada and Health Canada completed an initial review of the approximately 23,000 chemical substances on the Domestic Substances List by September 2006. As a result, they identified about 4,300 substances needing further assessment to determine if they are toxic or capable of becoming toxic to human health or the environment.

**1.9** On 8 December 2006, the government announced Canada's new Chemicals Management Plan initiative. With this initiative, the government aims to complete the toxicity risk assessments of the 4,300 substances by 2020.

### Focus of the audit

**1.10** The objective of our audit was to assess the progress that Environment Canada and Health Canada had made in addressing key findings and a recommendation made in prior audits on the management of toxicity risk assessments of existing substances under

**Weight-of-evidence approach**—The use of several lines of evidence to determine overall uncertainties in making decisions in all phases of a risk assessment.

**Precautionary principle**—A principle that is to be applied to ensure that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

the *Canadian Environmental Protection Act, 1999*, including determining the status of the initial 69 priority substances. We also looked at the initiative in place for assessing the set of about 4,300 priority substances identified in September 2006 as needing further toxicity risk assessments. We examined whether the departments have clear objectives and timelines, sufficient human resource capacity, and guidelines for applying a **weight-of-evidence approach** and the **precautionary principle** to fast-track the toxicity risk assessments of the 4,300 substances identified.

1.11 More details on the audit objective, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

## Observations and Recommendation

### Priority Substances Lists

#### Environment Canada and Health Canada reached conclusions on the toxicity of most priority substances

1.12 In 2002, we noted that Environment Canada and Health Canada did not meet their timelines to complete the assessments of substances on the priority substances lists, many of which could be endangering human health or the environment. Since 2002, we found that Environment Canada and Health Canada have reached conclusions on the toxicity of 66 out of 69 priority substances on the two priority substances lists (Exhibit 1.2). Of these substances, 42 were declared toxic, and control measures were put in place by the federal government.

**Exhibit 1.2** Progress in addressing our 1999 recommendation and 2002 finding on priority risk assessments is satisfactory

Recommendation and finding	Progress
<p><b>Recommendation.</b> Environment Canada and Health Canada should forthwith reach a formal conclusion on the toxicity of substances for which they have not yet done so. (1999 Report of the Commissioner of the Environment and Sustainable Development (CESD), Chapter 3, see paragraph 3.128).</p>	Satisfactory
<p><b>Finding.</b> It is taking too long to complete the assessments of priority substances on the priority substances lists, many of which could be endangering the environment or human health. It is important that their assessment be completed so that management controls can be put in place. (2002 CESD Report, Chapter 1, see paragraph 1.44)</p>	Satisfactory

**Satisfactory**—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation and finding were made.

**Unsatisfactory**—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the recommendation and finding were made.

### An alternative approach has changed how some toxic substances are controlled

**Radionuclides**—Uranium and uranium compounds contained in effluents from uranium mines and mills.

**Used crankcase oil**—Lubricating oil removed from the crankcase of internal combustion engines.

**1.13** Road salts, **radionuclides**, and **used crankcase oil**, although found to be toxic, as defined under the *Canadian Environmental Protection Act, 1999*, (CEPA, 1999) were not listed on Schedule 1 of the Act.

**1.14** In 2001, the ministers of the Environment and of Health published their intent to recommend that road salts be added to Schedule 1. While road salts have not been added to Schedule 1, Environment Canada has developed a code of practice designed to help municipalities and other road authorities better manage the use of road salts. The Department reported that about 200 road authorities across Canada have agreed to implement measures such as preparing salt management plans to reduce the effects that road salts may have on the environment.

**1.15** The ministers of the Environment and of Health have set a precedent in how they have chosen to deal with radionuclides and used crankcase oil. These substances were assessed as toxic under the Act, but the ministers did not recommend their addition to Schedule 1 as they are being controlled by other federal or provincial/territorial legislation.

**1.16** Environment Canada initiated this alternative approach so that risks would be managed by the federal law or by the level of government best situated to take action. Under this new approach, Environment Canada and Health Canada are responsible for monitoring whether these other means are sufficient to control the risks to human health and the environment, and assessing if the decision not to list the substances in Schedule 1 of the Act should be revisited.

**1.17** We found that although radionuclides and used crankcase oil have not been listed on Schedule 1, Environment Canada demonstrated that risk management measures are in place for those substances. For radionuclides, controls are to be enforced under the *Nuclear Safety and Control Act* at the two sites identified as problematic in the risk assessment. In the case of used crankcase oil, Environment Canada indicated that the four areas of concern identified in the risk assessment are being managed by provincial and territorial governments, and it has received assurance that control measures are in place.

**1.18** At the time of our audit, Environment Canada's website reported on actions taken to manage the risks of radionuclides, but it did not mention used crankcase oil. These substances are not in Schedule 1 of the *Canadian Environmental Protection Act, 1999*, and there is currently no legal requirement to list these substances in the CEPA

Environmental Registry. As well, there is no public reporting on Environment Canada’s website to provide assurance that these substances are being adequately controlled.

**1.19 Recommendation.** Environment Canada and Health Canada should make publicly available the list of those substances that have been assessed as toxic under the *Canadian Environmental Protection Act, 1999* but are not listed in Schedule 1 and are being risk managed outside the Act. This list should also include information on what controls are in place.

**Environment Canada’s response.** Environment Canada accepts this recommendation and will make such a list available in 2008 through the Government of Canada’s Internet website for the Chemicals Management Plan and the CEPA Environmental Registry.

**Health Canada’s response.** Health Canada will give the recommendation favourable consideration in consultation with Environment Canada and in the context of the Parliamentary Review of the *Canadian Environmental Protection Act, 1999*, which is currently under way.

**Toxicity risk assessments of three substances remain outstanding**

**1.20 Two risk assessments are overdue.** Aniline and chlorinated paraffins (Exhibit 1.3) were assessed as either toxic or likely to be toxic and yet were not listed in Schedule 1 of the *Canadian Environmental Protection Act, 1999*. These assessments were to have been completed 14 years ago.

**Exhibit 1.3 Common uses and potential impacts of aniline and chlorinated paraffins**

Aniline	Chlorinated paraffins
<ul style="list-style-type: none"> <li>Aniline is used to produce rubber and polymers. About 1.1 tonnes of aniline are released into the Canadian environment each year.</li> <li>Potential impacts include headache, abnormally rapid heart rate, confusion, convulsions, coma, and death.</li> </ul>	<ul style="list-style-type: none"> <li>Chlorinated paraffins are used mainly as plasticizers and flame retardants, as well as additives in lubricating oils and in metal-working fluids to lower the heat and allow faster metal working.</li> <li>The total reported annual use of chlorinated paraffins in Canada was about 3,000 tonnes in 2000 and 2001.</li> <li>Impacts include a potential carcinogen and bioaccumulation in aquatic organisms.</li> </ul>

Source: Environment Canada and Health Canada

**1.21** An initial risk assessment report issued in 1994 found that aniline is not harmful to the environment, but due to insufficient data, the report was unable to conclude whether the substance represents a danger to human health. A follow-up risk assessment report in 2002 provided additional evidence that aniline is likely toxic to human health. At the time, Health Canada invited companies using aniline to provide relevant data and specified that failing to do so would result in the substance being declared toxic under the Act; the data was not received. On 5 October 2002, the Department formally announced its intention to recommend that the substance be listed on Schedule 1. Five years later, aniline does not appear in Schedule 1 and Health Canada is still conducting assessment work to establish sources of exposure. The Department plans to complete the toxicity risk assessment for aniline by mid-2008.

**1.22** Risk assessments carried out by Environment Canada and Health Canada in 1993, 2003, and 2004 indicated that chlorinated paraffins should be considered toxic under the Act. However, only in June 2005, 12 years after the first report was issued, did the ministers finally recommend that the substance be listed in Schedule 1. However, this has not been done yet. As of April 2007, Environment Canada had completed its final assessment and Health Canada was still completing its assessment work.

**1.23** After 18 years of risk assessment work and recurring evidence of toxicity, the federal government has not added aniline and chlorinated paraffins to the List of Toxic Substances in Schedule 1. As a result, control measures to manage risks to both human health and the environment are not in place for those substances under the Act.

**1.24 Two risk assessments were suspended.** In 2000, complete information on the effects of ethylene glycol and aluminum salts (Exhibit 1.4) on human health was not available, and the risk assessments of these substances were suspended for five and six years respectively. Environment Canada concluded that both substances are unlikely to be toxic to the environment. Health Canada recently completed its assessment of the human health impacts of ethylene glycol. As a result, in December 2007, the ministers of the Environment and of Health proposed to recommend that ethylene glycol be added to Schedule 1 of CEPA, 1999. Health Canada plans to complete its assessment of aluminum salts by the end of 2008.

**1.25** Only when the outstanding assessments are completed will the government be able to implement management controls where warranted under CEPA, 1999.

**Exhibit 1.4 Common uses and potential impacts of aluminum salts and ethylene glycol**

Aluminum salts	Ethylene glycol
<ul style="list-style-type: none"> <li>• Municipalities use aluminum salts to treat both drinking water and wastewater. This use accounted for about 75 percent of the 270,000 tonnes of aluminum salts used in Canada in 1996.</li> <li>• Aluminum salts are also used in preparing antiperspirants, manufacturing rubber, and waterproofing leather and textiles.</li> <li>• Potential impacts include links to Alzheimer's disease.</li> </ul>	<ul style="list-style-type: none"> <li>• Ethylene glycol is used in antifreeze products, windshield washer solution, heat transfer fluids, and the manufacture of polyester.</li> <li>• The highest reported use is for de-icing aircraft. In 1996, about 7,700 tonnes of ethylene glycol were used for de-icing aircraft in Canada.</li> <li>• Potential impacts include kidney damage.</li> </ul>

Source: Environment Canada and Health Canada

### Domestic Substances List

**1.26** A review of the Domestic Substances List was completed in 2006. This categorization process did not aim to establish the risks to the environment or human health. It was a mechanical process designed to systematically identify substances that would qualify for a risk assessment. As a result, Environment Canada and Health Canada identified about 4,300 substances, from about 23,000 chemical substances, as needing further assessment to determine if they were toxic to human health or the environment. Given the slow progress to assess the first 69 priority substances, the revised *Canadian Environmental Protection Act* of 1999 introduced provisions that would lead to faster assessment of a greater number of substances.

**1.27** For this audit, we expected both Environment Canada and Health Canada to have identified clear objectives and timelines to fast-track the assessment of these 4,300 substances. We also expected that they would have addressed resources and governance impediments identified in past audits, and developed clear and consistent guidance on applying the precautionary principle.

#### **An initiative is in place to assess 4,300 substances of concern on the Domestic Substances List**

**1.28** On 8 December 2006, the federal government announced its Chemicals Management Plan initiative to improve how chemical substances are managed and to minimize threats to human health and the environment. The initiative set a timeline to evaluate by 2020 all 4,300 substances identified as requiring further assessment. The Chemicals Management Plan initiative requires Environment

Canada and Health Canada to report in the 2010–11 fiscal year on the results and cost-effectiveness of this initiative so that adjustments can be made if necessary.

### **Making government information public**

Environment Canada's and Health Canada's methodologies, results, and plans for toxicity risk assessment are available through the government's Chemicals Management Plan website (also available on the CEPA Environmental Registry website). Risk assessments are subject to peer reviews and also to public comments through the *Canada Gazette*.

The *Canada Gazette* provides official public notices to Canadians on regulations and acts of Parliament from government departments and agencies.

### **Recent results from risk assessments**

To date, risk assessments aimed at addressing the 4,300 substances of concern on the Domestic Substances List led to the prohibition or proposed prohibition of three categories of substances found to be toxic under the *Canadian Environmental Protection Act, 1999*:

- flame retardants (Polybrominated Diphenyl Ethers, commonly referred to as PBDEs);
- repellents and fire-fighting foams (Perfluorooctane Sulfonate, commonly referred to as PFOS); and
- cleaning solvents; thermal treatments; and electric transformer fluids (respectively, 2-Methoxyethanol, Pentachlorobenzene, and Tetrachlorobenzenes).

According to Environment Canada, regulations are being put in place to restrict the manufacture, import, and use of these substances under the Act.

**1.29** In the majority of cases, Environment Canada and Health Canada do not intend to conduct exhaustive reviews of all available data, as was done for the 69 priority substances on the two priority substances lists. Environment Canada officials have indicated that the reviews will rely on the use of conservative assumptions and focus on the most critical studies in order to reach a conclusion on toxicity, unless an in-depth risk assessment is required.

**1.30** Environment Canada and Health Canada have been piloting a new approach with substances from the Domestic Substances List. We found that Environment Canada extracted lessons learned from the pilot assessments in producing draft guidance documents for assessors. As of April 2007, Health Canada had not yet produced such guidance for its assessors but was planning to do so.

**1.31** To plan the assessment of the 4,300 substances, Environment Canada and Health Canada developed a priority-setting process. Using this process, they identified 200 substances that present the greatest risk. These 200 substances are currently being assessed as part of the Ministerial Challenge Program, which requires industry to provide relevant information on each substance within six months of request by the government. Both departments plan to assess the risk of these substances by 2010, and the departments believe that the substances will likely require new controls to reduce or eliminate the harmful effects they pose to human health or the environment.

**1.32** Of the 4,300 substances identified for further assessment, Environment Canada indicated that it has already assessed 50 that are high priority. It has also selected about 1,200 substances of less concern for rapid screening. The rapid screening exercise was completed, and the results were released in June 2007. The results identified about 750 substances that are unlikely to cause environmental harm, and about 450 substances that will require further assessment to determine if they are toxic under the *Canadian Environmental Protection Act, 1999*.

**1.33** To address the remaining substances, Environment Canada and Health Canada will assess about 900 high- and medium-priority substances by grouping together classes of chemicals and undertaking joint reviews with other countries. An additional 865 substances, reported to be no longer used commercially in Canada, will be subject to a separate assessment process under the Significant New Activity

Controls of CEPA, 1999 if the substances are reintroduced. The remaining 1,085 substances will be assessed at a pace of about 110 assessments a year between 2010 and 2020 (Exhibit 1.5).

**Exhibit 1.5 Progress in addressing our finding on assessing the substances on the Domestic Substances List is satisfactory**

Finding	Progress
We expect that the departments have ensured that substances of concern are fast-tracked through the risk assessment process. (2002 Report of the Commissioner of the Environment and Sustainable Development, Chapter 1, see paragraph 1.86)	Satisfactory

**Satisfactory**—Progress is satisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

**Unsatisfactory**—Progress is unsatisfactory, given the significance and complexity of the issue, and the time that has elapsed since the finding was made.

**Human resource capacity is being developed**

**1.34** In our 1999 and 2002 audits, we noted a growing gap between demands for toxicity risk assessments and actual resources to complete them. We reported that shortages in scientific capacity would impede the government’s capacity to fulfill its mandate. As well, on many occasions, Health Canada reported insufficient staffing levels to fulfill its responsibilities under the *Canadian Environmental Protection Act, 1999*, and stressed that resource shortfalls represented an ongoing risk to complete toxicity risk assessments.

**1.35** In 2004, Health Canada reported that its working relationship with Environment Canada to implement the requirements of CEPA, 1999 was weak and dysfunctional, and that communications and coordination between the two departments were fragmented. As a result, in March 2007, senior management from both departments formalized their intention to work together by aligning priorities, coordinating program delivery, and developing a human resources management strategy. The strategy includes, among other things, the recruitment of about 350 scientists over the next four years.

**1.36** The Chemicals Management Plan initiative announced in December 2006 provides about \$40 million initially over four years for both departments to conduct toxicity risk assessments. Officials from both departments indicated that this initial funding should be sufficient to build capacity and put them on a path to complete by 2020 the assessment of the 4,300 substances identified from the Domestic Substances List (Exhibit 1.5).

### **Guidance on applying the precautionary principle has been completed**

**1.37** Section 76.1 of the *Canadian Environmental Protection Act, 1999* directs the ministers to apply a weight-of-evidence approach and the precautionary principle (see margin definitions on page 1-6) when conducting and interpreting the results of the toxicity assessments. Our previous audits raised concerns about the lack of clear and consistent guidance on applying the precautionary principle in weighing scientific uncertainty in decision making. We identified substances of concern to human health or the environment for which the precautionary principle had not been applied due to unclear guidance. As a result, no controls for these substances had been put in place.

**1.38** Since our 2002 audit, we found that Environment Canada and Health Canada have produced guidance on using a weight-of-evidence approach for risk assessments. They also have developed guidance to use the precautionary principle in making decisions about toxicity (Exhibit 1.5). This guidance describes how the scientific research and risk assessment practices are to support the precautionary principle. As well, it describes actions that may be taken to reduce the threat of serious or irreversible damage from a substance. The guidance aims to reduce risks to human health and the environment in a cost-effective and transparent manner.

## **Conclusion**

**1.39** Since 2002, Environment Canada and Health Canada have made satisfactory progress in managing toxicity risk assessments under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999).

**1.40** Our 2002 audit identified a backlog of about 20 of 69 priority substances for which no conclusion on toxicity had been reached. This assessment process was to have been completed in 2000. In this follow-up audit, we found that Environment Canada and Health Canada have reached conclusions on toxicity for 66 out of 69 priority substances. Two of the remaining substances—*aniline* and *chlorinated paraffins*—have been under assessment for 18 years and were found to be either toxic or likely to be toxic to human health or the environment. The risk assessment for *aluminum salts* was suspended and is now scheduled to be completed by the end of 2008. Only when the outstanding assessments are completed will the government be able to implement controls to manage the risks to human health or the environment where warranted under CEPA, 1999.

**1.41** In September 2006, an initial review of about 23,000 substances on the Domestic Substances List identified about 4,300 substances requiring an assessment by 2020 to determine if they are toxic. To ensure that the 4,300 substances that need to be assessed are fast-tracked through the risk assessment process, Environment Canada and Health Canada have developed clear objectives and timelines under the Chemicals Management Plan initiative, and they have adjusted the risk assessment process based on lessons learned from previous evaluations. As well, the departments have developed guidance to assessors on how to apply the precautionary principle. The additional funding announced as part of the Chemicals Management Plan initiative is expected to address resource and governance issues that were raised in past audits and put the departments on a path to complete the assessment of the 4,300 substances by 2020.

## About the Audit

### Objectives

Our overall audit objective was to determine whether Environment Canada and Health Canada have made satisfactory progress in addressing key findings and a recommendation made in prior audits with respect to managing risk assessments of selected substances under the *Canadian Environmental Protection Act, 1999*.

Our sub-objectives were to determine whether Environment Canada and Health Canada have made satisfactory progress in

- completing the assessment of substances on the priority substances lists, pursuant to paragraph 1.44 of the 2002 Commissioner of the Environment and Sustainable Development (CESD) Report and the recommendation in paragraph 3.128 of the 1999 CESD Report; and
- ensuring that substances of concern on the Domestic Substances List, identified as priorities in 2006, are fast-tracked through the risk assessment process, pursuant to paragraph 1.86 of the 2002 CESD Report.

### Scope and approach

In 1999 and 2002, we made observations on a broad range of government operations intended to manage chemical substances, including scientific research, monitoring, risk assessment, and risk management activities in eight federal departments and agencies. In this follow-up audit, we focused on progress that Environment Canada and Health Canada had made on toxicity risk assessments that were under way in 1999 and 2002, and we examined their initiative to conduct risk assessments of about 4,300 existing substances that have not yet been assessed. Issues that we examined in this audit were selected based on their current relevance and significance.

In carrying out our audit, we interviewed government officials from Environment Canada and Health Canada and reviewed relevant internal documentation and public reporting.

We used the conclusions for each re-audited issue as well as professional judgment to arrive at a rating to indicate whether the departments have made satisfactory or unsatisfactory progress in addressing each of the selected original findings and the recommendation.

In our audit, we did not consider new substances, which are subject to a different process, and we did not examine the implementation of risk management measures for substances already declared toxic. We followed up on past observations on the lack of operational guidance in applying the precautionary principle but did not consider the actual implementation of such guidance in interpreting the results of toxicity risk assessments. We also did not consider the evaluations of pesticides, which are managed under the *Pest Control Products Act*. Chapter 2 of this report deals with pesticide safety and accessibility.

## Criteria

We expected that the toxicity risk assessments for identified substances on the priority substances lists that were not complete in 2002 would have now been completed. As appropriate, we looked at the rationale for decisions made; factors underlying unfinished work, including related risks and implications; and timelines for completion.

The criteria for the audit of substances on the priority substances lists were derived from a recommendation and findings from the 1999 and 2002 Reports of the Commissioner of the Environment and Sustainable Development (CESD) on Toxic Substances.

The criteria for the audit of substances on the Domestic Substances List were derived from the *Canadian Environmental Protection Act, 1999*, the Federal Council of Science and Technology Advisors, and findings from the Auditor General's December 2002 Report, Chapter 9.

We also expected that, in undertaking risk assessments for substances on the Domestic Substances List, Environment Canada and Health Canada would have the following in place:

- clear objectives and timelines;
- sufficient human resource capacity;
- a process for setting priorities for the assessments to be undertaken;
- arrangements to openly communicate and share information from toxicity risk assessments with industry, other jurisdictions, and the public;
- provisions for peer review;
- guidelines for applying a weight-of-evidence approach and the precautionary principle; and
- mechanisms for reasonable review and adjustment.

Audit work for this chapter was substantially completed on 15 June 2007.

## Audit team

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## Appendix List of recommendations

The following recommendation is found in Chapter 1. The number in front of the recommendation indicates the paragraph number where it appears in the chapter. The numbers in parentheses indicate the paragraph numbers where the topic is discussed.

Recommendation	Response
<b>Priority Substances Lists</b>	
<p><b>1.19</b> Environment Canada and Health Canada should make publicly available the list of those substances that have been assessed as toxic under the <i>Canadian Environmental Protection Act, 1999</i> but are not listed in Schedule 1 and are being risk managed outside the Act. This list should also include information on what controls are in place. (1.13–1.18)</p>	<p><b>Environment Canada’s response.</b> Environment Canada accepts this recommendation and will make such a list available in 2008 through the Government of Canada’s Internet website for the Chemicals Management Plan and the CEPA Environmental Registry.</p> <p><b>Health Canada’s response.</b> Health Canada will give the recommendation favourable consideration in consultation with Environment Canada and in the context of the Parliamentary Review of the <i>Canadian Environmental Protection Act, 1999</i>, which is currently under way.</p>



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