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## Accessible Version

October 9, 2015

The Honorable Edward Markey  
Ranking Member  
Subcommittee on Superfund, Waste Management, and Regulatory Oversight  
Committee on Environment and Public Works  
United States Senate

### **Chemicals Management: Observations on Human Health Risk Assessment and Management by Selected Foreign Programs**

Dear Senator Markey:

To manage the thousands of chemicals in commercial use, decision makers around the world rely on information derived from assessments that examine the risks these substances may pose to human health and the environment. The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program and others conduct such assessments. EPA's assessments provide a foundation for the agency's risk management decisions, such as whether to establish air and water quality standards to protect the public from exposure to particular toxic chemicals. Consequently, risk assessments are a critical component of EPA's capacity to support scientifically sound environmental decisions, policies, and regulations under a variety of statutes. Various foreign programs, such as Canada's Chemicals Management Plan (CMP), Australia's Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, and the World Health Organization's (WHO)<sup>1</sup> International Agency for Research on Cancer (IARC) Monographs Programme and International Programme on Chemical Safety (IPCS) also conduct risk assessments or components of risk assessments.<sup>2</sup> In addition, foreign programs and foreign countries, including Canada, take risk management actions to prevent and reduce threats posed by chemicals to human health and the environment.

We have repeatedly reported that EPA's ability to fulfill its mission of protecting public health and the environment is critically dependent on credible and timely assessments of the risks posed by chemicals.<sup>3</sup> In January 2009, we added transforming EPA's processes for assessing and

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<sup>1</sup>The WHO directs and coordinates international health within the United Nations' system. The United States is one of 194 WHO member states.

<sup>2</sup>Risk assessments typically include four components: hazard identification, dose-response assessment, exposure assessment, and risk characterization. According to their representatives, WHO's IARC Monographs Programme produces the hazard identification component of an assessment, while the other three programs produce all four components. Other foreign programs, including those in the European Union, also conduct risk assessments. Due to ongoing trade negotiations between the United States and the European Union that address, among other things, coordination of chemical regulatory regimes, we did not include European Union entities in our review.

<sup>3</sup>GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, [GAO-08-440](#) (Washington, D.C.: Mar. 7, 2008); *Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program*, [GAO-12-42](#) (Washington, D.C.: Dec. 9, 2011); and *Chemical Assessments: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments*, [GAO-13-369](#) (Washington, D.C.: May 10, 2013).

controlling toxic chemicals to the list of government operations that are high risk<sup>4</sup> based on our reports on EPA's IRIS Program and EPA's work under the Toxic Substances Control Act (TSCA).<sup>5</sup> Regarding the IRIS Program, we previously identified long-standing challenges in such areas as developing sufficient assessment information, and determining the program's need for people and resources. For example, as we reported in February 2015, after more than 2 years, EPA is still developing an action plan to address these capacity issues.<sup>6</sup> EPA has, however, made some progress in this area by continuing to monitor the IRIS Program and to implement our December 2011 recommendation to submit assessments for independent review to an entity with scientific and technical credibility. For example, EPA presented a plan for implementing the National Academies' suggestions for improving IRIS assessments, as stated in its "Roadmap for Revision" report.<sup>7</sup> In addition, EPA told us about its ongoing work to develop a new screening-level assessment product.<sup>8</sup> Regarding TSCA, EPA is authorized to obtain information on the risks of chemicals and to control those the agency determines pose an unreasonable risk.<sup>9</sup> As we also reported in June 2005 and February 2015, EPA has found much of TSCA difficult to implement, and the agency faced challenges to banning or placing limits on the production or use of chemicals due to a legal threshold that EPA has found difficult to meet.<sup>10</sup> Consequently, EPA has used its authority to limit or ban the use of only five existing chemicals or chemical classes since TSCA was enacted in 1976.<sup>11</sup>

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<sup>4</sup>GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009).

<sup>5</sup>Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976).

<sup>6</sup>[GAO-13-369](#), and *High-Risk Series: An Update*, [GAO-15-290](#) (Washington, D.C.: February 2015).

<sup>7</sup>Suggestions included, for example, that (1) draft assessments undergo rigorous editing to substantially reduce the volume of text, and (2) critical studies be thoroughly evaluated with standardized approaches. National Research Council of the National Academies, *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde* (Washington, D.C.: National Academies Press, 2011).

<sup>8</sup>According to EPA, RapidTox is under development to provide information in fiscal years 2016-2109 on data poor chemicals (i.e. those that are lacking the data EPA needs to make risk management decisions) and to reduce the time, cost and/or uncertainty of risk-based chemical management decisions. The goal is to deliver RapidTox assessments for large numbers of data poor chemicals and provide a range of information related to hazard, chemical properties, fate and transport, and exposure. The information will include data from traditional sources when available, as well as new data being developed by EPA. The project will investigate methods to integrate and distill data to support decisions. The first case study, developed in collaboration with EPA's Office of Chemical Safety and Pollution Prevention, is expected to have results in the fourth quarter of fiscal year 2016. Two additional case studies are being explored with the Office of Solid Waste and Emergency Response and the Office of Water for implantation in late 2016 and early 2017.

<sup>9</sup>GAO, *Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach*, [GAO-13-249](#) (Washington, D.C.: Mar. 22, 2013).

<sup>10</sup>As we reported, even when EPA has information on existing chemicals, the agency has said that it has had difficulty demonstrating that harmful chemicals pose an unreasonable risk and that they should be banned or have limits placed on their use. In order to regulate an existing chemical under TSCA, EPA must find that there is a reasonable basis to conclude that the chemical presents or will present an unreasonable risk of injury to health or the environment. Further, the regulation must apply the least burdensome requirement that will adequately protect against the risk. See GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, [GAO-05-458](#) (Washington, D.C.: June 13, 2005) and [GAO-15-290](#).

<sup>11</sup>Those five chemicals or chemical classes are polychlorinated biphenyls (PCB), fully halogenated chlorofluoroalkanes, dioxin, asbestos, and hexavalent chromium. One of these TSCA actions was overturned in court, while some others were superseded by later EPA regulations issued under other laws. For further information about these chemicals and chemical classes, see [GAO-05-458](#), appendix V, 58-60.

In recent years, congressional committees have held a number of hearings and considered potential bills to reform TSCA.<sup>12</sup> In our February 2015 High-Risk Series report, we reported that EPA's Administrator and top management have demonstrated a strong leadership commitment by publicly stating their focus to improve the IRIS Program and implement TSCA as it currently exists.<sup>13</sup> In addition, the agency has publicly committed to responding to our recommendations, utilizing TSCA to the fullest extent of the law, and assisting congressional committees as they work to revise the 1976 law.

Given EPA's interest in addressing these long-standing problems and concern among lawmakers about how chemicals are assessed and managed, we gathered information about methods used by selected foreign programs. While each program operates within a different institutional structure, the descriptions in this report may offer perspectives that EPA and the Congress may find useful when considering improvements to the IRIS Program, TSCA, or other chemicals management efforts at EPA. We performed our work under the authority of the Comptroller General to assist Congress with its oversight responsibilities. This report examines: (1) how selected foreign programs conduct risk assessment activities to understand the human health risks of certain chemicals and (2) how Canada manages the human health risks of chemicals identified as toxic under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).<sup>14</sup>

To address these objectives, we took several steps. To determine how selected foreign programs conduct risk assessment activities to understand the human health risks of certain chemicals, we asked EPA officials and academics with relevant expertise for their views on which programs produce quality chemical assessments that we might consider for our study. From those, we selected four for further review: Canada's CMP, Australia's IMAP framework, and WHO's IARC Monographs Programme and IPCS. Due to ongoing trade negotiations between the United States and the European Union that address, among other things, coordination of chemical regulatory regimes, we did not include European Union programs in our review. We met with representatives from each of the four programs we selected and reviewed numerous documents with information on relevant laws, policies, and risk assessments. We also interviewed stakeholders representing three industry and three environmental groups—identified by consulting our prior work and by soliciting input from EPA officials and academics with relevant knowledge—to understand their views on selected programs' processes. Their views cannot be generalized to the population of these groups but provided valuable insights. To determine how Canada manages the human health risks of chemicals identified as toxic under CEPA 1999, we met with relevant officials from Canada and reviewed documentation provided by those officials and published on their website. We focused on the Canadian approach under CEPA 1999 because it is regularly discussed in the debate on reforming TSCA and because Environment Canada and Health Canada are the only programs in our study that also conduct risk management activities. Enclosure I provides a more detailed presentation of our objectives, scope, and methodology.

We conducted this performance audit from March 2014 to October 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and

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<sup>12</sup>For example, in June 2015, the House of Representatives passed H.R. 2576, TSCA Modernization Act of 2015, which would amend TSCA's provisions governing chemical testing, regulation, and data disclosure. The bill is pending in the Senate.

<sup>13</sup>[GAO-15-290](#).

<sup>14</sup>*Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 3, as amended (Can.) [hereinafter CEPA 1999].

perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Results in Brief

The foreign programs we reviewed—Canada’s CMP, Australia’s IMAP framework, and WHO’s IARC Monographs Programme and IPCS—assess the human health risks of chemicals using similar analytic approaches, such as using specific criteria to determine which assessments to prioritize. However, there are some key differences in what the programs emphasize in their assessments. Canada and Australia’s programs emphasize the use of screening assessments<sup>15</sup>—assessments that vary in complexity ranging from a rapid screen of information to using more complex approaches, depending on what officials determine is needed to adequately understand the risks of each chemical or other substance<sup>16</sup>—and WHO’s IARC Monographs Programme and IPCS emphasize review by international experts.

Canada has used various measures to manage the human health risks of toxic chemicals under CEPA 1999. Specifically, according to Canada’s guide to CEPA 1999 and Canadian officials, for chemicals and other substances determined to be toxic under CEPA 1999 and proposed for addition to CEPA 1999’s List of Toxic Substances,<sup>17</sup> Canada may use a variety of mechanisms to manage identified human health risks, such as regulations, pollution prevention plan notices, and Significant New Activity provisions.

## Background

Tens of thousands of chemicals are listed for commercial use with federal agencies in the United States, Canada, and Australia. These listed chemicals are often referred to as existing chemicals. In the United States, TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States. TSCA authorizes EPA to review chemicals already in commerce (existing chemicals) and chemicals yet to enter commerce (new chemicals). New chemicals are subject to premanufacture notice and EPA review, with some exceptions. This report focuses on existing chemical substances, which are not subject to new chemical notice and review requirements.<sup>18</sup>

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<sup>15</sup>Canadian officials use the term “screening assessments” to describe the assessments they conduct under the CMP. Australia’s IMAP assessments are referred to simply as “assessments.” For the purposes of this report, we use the term “screening assessments” to describe both.

<sup>16</sup>According to Canada’s guide to CEPA 1999, a substance includes any distinguishable kind of organic or inorganic matter, whether animate or inanimate, that is capable of being released as a single substance, an effluent, emission, waste or a mixture into the Canadian environment. Environment Canada, *A Guide to Understanding the Canadian Environmental Protection Act, 1999* (Dec. 10 2004), accessed July 27, 2015, [http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04\\_e.pdf](http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04_e.pdf).

<sup>17</sup>Substances that meet the definition of toxic under CEPA 1999 can be placed on the List of Toxic Substances. A substance’s presence on this list alone does not impose specific management measures on the use of the substance. The recommendation for a chemical’s addition to this list, however, triggers statutory obligations that generally require the Canadian government to contemplate and potentially issue chemical management measures for that chemical within specified periods.

<sup>18</sup>In addition, this report does not discuss chemicals and other substances that are regulated under other laws including certain nuclear materials, pesticides, foods, food additives, tobacco, and cosmetics.

Risk assessments characterize the potential adverse health effects of human exposures to environmental hazards, including chemicals, and are a key public policy tool for evaluating options for protecting public health and the environment. Risk management, as opposed to risk assessment, involves integrating risk assessment results with other information—such as economic information on the costs and benefits of mitigating the risk, technological information on the feasibility of managing the risk, and the concerns of various stakeholders—to decide what actions, if any, should be taken to protect public health. Examples of potential risk management actions include regulating how much of a chemical an entity may discharge into water or air, or creating guidelines for the use or disposal of specific chemicals.

Canada's CMP is run jointly by two Canadian federal departments—Environment Canada and Health Canada—and assesses existing chemicals and other substances listed on the country's Domestic Substances List<sup>19</sup> to determine which ones pose a risk to Canadians or the environment. One of the primary legislative tools used by the CMP to guide its efforts is CEPA 1999, which, according to a program overview document, provides for the assessment and management of substances to protect the environment and health of Canadians. According to Canadian officials, a risk assessment is required under CEPA 1999 to determine details on the hazardous qualities of a chemical or other substance and the specific ways people or the environment can be exposed. In 2006, the Canadian government launched the CMP, which assesses environmental and human health risks posed by chemical substances and develops and implements measures to prevent or manage those risks.<sup>20</sup>

Australia's IMAP framework is managed by the Australian Department of Health's National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which conducts human health and environmental risk assessments of existing chemicals listed on the Australian Inventory of Chemical Substances (AICS).<sup>21</sup> According to its website, NICNAS aims to protect the Australian people and the environment by determining the risks to occupational health and safety, public health, and the environment that could be associated with the importation, manufacture, or use of industrial chemicals, and by maintaining a national standard for cosmetic products. Since 2012, NICNAS has used the IMAP framework to accelerate many of its assessments.

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<sup>19</sup>According to a program review document, Health Canada is responsible for assessing human health risks, and Environment Canada is responsible for assessment of ecological risks. According to Canada's guide to CEPA 1999, Canada's Domestic Substances List includes substances that were, between January 1, 1984, and December 31, 1986, in commerce in Canada, or were used for commercial manufacturing purposes, or were manufactured in or imported into Canada in a quantity of 100 kilograms or more in any one calendar year. According to Canadian officials, the Domestic Substances List currently contains approximately 23,000 substances from the original list along with an additional 4,470 substances that have been added to the list following assessments of new substances (1994-2014).

<sup>20</sup>According to Canadian officials, it does so by using tools from a broad suite of federal laws, including by using the most appropriate management tools from a broad suite of federal laws, including CEPA 1999, the *Canada Consumer Product Safety Act*, the *Food and Drugs Act*, the *Pest Control Products Act*, and others.

<sup>21</sup>The AICS is the legal device that distinguishes new from existing chemicals. See *id.* at s 11. According to the NICNAS website, the inventory is a listing of all industrial chemicals in use in Australia between January 1, 1977, and February 28, 1990. In addition, it includes new assessed chemicals and corrections, as well as chemicals that were regulated by other Australian regulators and have since become industrial chemicals. According to NICNAS officials, there are about 38,000 chemicals on the inventory. Industrial chemicals are defined as a chemical element, including a chemical element contained in a mixture; a compound or complex of a chemical element, including such a compound or complex contained in a mixture; and a naturally-occurring chemical or a substance of unknown or variable composition, complex reaction products or biological materials. The statute notes that this definition does not include an article, as defined by the Act, a radioactive chemical, or a mixture. *Industrial Chemicals Notification and Assessment Act 1989*, (Cth) S 6 (Austl.).

WHO's IARC aims to promote international collaboration in cancer research. According to the document that describes the scope and objectives of its monographs program, after receiving frequent requests for advice on the carcinogenic risk of chemicals, the agency's governing council recommended that the agency prepare monographs on the evaluation of chemicals' carcinogenic risk to humans in 1970. The objective of the IARC Monographs Programme is to prepare and publish critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures.

WHO's IPCS aims to establish the scientific basis for the sound management of chemicals and to strengthen national capabilities for public safety, according to the program website. To do this, the program publishes a number of documents, including risk assessments, methodology documents, guidelines, and training documents. In 2013, the program also established the WHO Chemical Risk Assessment Network, which, among other things, provides an international forum for scientific and technical exchange.

### Foreign Programs We Reviewed Assess the Health Risks of Chemicals Using Similar Analytic Approaches While Emphasizing Either Screening Assessments or Expert Review

In general, the programs we reviewed assess the human health risks of chemicals using similar analytic approaches, but they have some notable differences. Specifically, Canada and Australia's programs use screening assessments to characterize the risks of a large number of chemicals, and WHO's IARC Monographs Programme and IPCS emphasize expert review.<sup>22</sup>

#### **Programs Use Similar Analytic Approaches to Conduct Assessments**

In general, the programs we reviewed assess the human health risks of chemicals using similar analytic approaches. In terms of choosing what to assess, all four programs use specific criteria to determine priorities. For example, CEPA 1999 required the application of specific criteria to all substances on Canada's DSL to prioritize those for further assessment. These included chemicals that were inherently toxic to humans or nonhuman organisms and were persistent or bioaccumulative according to regulations.<sup>23</sup> In addition, each program works to identify basic information on a chemical—such as information on its properties and uses—before diving into deeper questions on human health risks. Each program also conducts literature searches to gather relevant information. Enclosure II provides a more detailed description of the risk assessment processes for each selected program.

#### Canada and Australia's Programs Emphasize Assessing a Large Number of Chemicals

Canada's CMP risk assessment activities for existing chemicals emphasizes the assessment of thousands of chemicals and other substances from Canada's DSL. According to Canadian

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<sup>22</sup>WHO's IARC Monographs Programme does this through the use of scientific principles and general operating procedures published in a IARC Monographs Preamble document. See World Health Organization, International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble* (Lyon France: 2006), accessed November 4, 2014, <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

<sup>23</sup>Persistence refers to an attribute of a substance that describes the length of time that the substance remains in a particular environment before it is physically removed or chemically or biologically transformed. Bioaccumulation refers to the progressive increase in the amount of a substance in an organism or part of an organism that occurs because the rate of intake exceeds the organism's ability to remove the substance from the body.

officials, these assessments look to determine the potential harm or danger a substance can cause to human health, the environment, or both, and the ways in which such harm or danger can happen. Pursuant to CEPA 1999, officials completed a process of prioritizing those roughly 23,000 chemicals and other substances to identify those that warranted further assessment. According to a Canadian government website, that multiyear process was completed in 2006 and identified about 4,300 substances for further review. A Canadian government report showed that, among those, about 1,200 were identified based on human health concerns.<sup>24</sup> Canadian officials told us that, under the CMP, the government aims to address all of the approximately 4,300 substances by 2020 to determine whether they are toxic or capable of becoming toxic as defined by CEPA 1999.<sup>25</sup> According to CEPA 1999, officials shall apply the precautionary principle, which states that lack of full scientific certainty shall not be used as a reason for postponing action when a chemical or other substance may pose a threat of serious or irreversible damage. According to the CMP's spring 2015 progress report, they are currently on track to meet their goals and reported that, as of June 2015, they have completed screening assessments for about 2,700 substances (about 63 percent). Furthermore, since implementing the CMP, officials told us that they have added about 50 substances or groups of substances to Canada's List of Toxic Substances, which currently has 132 entries. Enclosure II provides a more detailed description of the risk assessment processes used by Canada's CMP.

According to the IMAP framework document, Australia's program also emphasizes the assessment of existing chemicals that have been used in Australia without prior assessment.<sup>26</sup> Modeled in part on Canada's CMP, officials told us that the IMAP framework prioritized for assessment between 2012 and 2016 about 3,000 chemicals<sup>27</sup> from the AICS, which officials told us includes about 38,000 chemicals. The stated goal of the framework is to more rapidly assess chemicals, through screening assessments, to enhance information on whether the industrial use of selected chemicals poses an unreasonable risk to the public, workers, or the environment.<sup>28</sup> Officials told us that as of June 2015, they have assessed 3,185 unique chemicals on the AICS, completing their assessment goal well ahead of their 2016 schedule. Enclosure II provides a more detailed description of the risk assessment processes used by the IMAP framework.

### WHO's IARC Monographs Programme and IPCS Emphasize Expert Review of Selected Chemicals

WHO's IARC Monographs Programme uses international experts to review selected chemicals and make determinations specifically about their human cancer risks through the use of published scientific principles and general operating procedures. Program officials appoint

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<sup>24</sup>Health Canada, *Final Integrated Framework for the Health-Related Components of Categorization of the Domestic Substances List Under CEPA 1999* (Ottawa, Canada: 2009).

<sup>25</sup>Under CEPA 1999, a substance is considered "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. CEPA 1999 § 64.

<sup>26</sup>Australian Government, Department of Health, National Industrial Chemicals Notification and Assessment Scheme, *Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework* (August 2013), accessed April 21, 2014, <http://www.nicnas.gov.au/chemical-information/imap-assessments/the-imap-framework>.

<sup>27</sup>Program officials developed their initial focus on about 3,000 chemicals based on what is currently known about their effects on human health or the environment.

<sup>28</sup>An IMAP assessment goes to one of three levels of depth: Tier I, Tier II, and Tier III. The data used, assessment approach, and output for each tier reflects the increasing resources needed for the assessment.

expert working groups to evaluate existing information on selected chemicals and other agents<sup>29</sup> and come to a determination about their carcinogenic risks to humans. Each working group is composed of internationally recognized experts chosen based on their knowledge and experience,<sup>30</sup> and meets for 7 to 8 days to discuss and finalize their evaluations, with the goal of forging consensus. According to its website, since 1971, the IARC Monographs Programme has assessed the carcinogenic risks of more than 900 chemicals and other agents. Enclosure II provides a more detailed description of the risk assessment processes used by this program.

WHO's IPCS also emphasizes using internationally recognized experts to review selected chemicals and make determinations about their human health risk, according to program guidelines.<sup>31</sup> Assessment drafts undergo peer review by internationally selected experts to help provide reasonable assurance of completeness and accuracy. As a specific example, to conduct assessments, an initial draft assessment is reviewed first by a panel of international peer reviewers selected for their scientific expertise, and revisions are expected to take peer review comments into account.<sup>32</sup> According to a program official, assessments are subject to approval by WHO senior management, but are published as the opinion of the panel of peer reviewing experts rather than as the official policy of WHO. According to its website and a program official, since 1976, IPCS has completed about 287 assessments. Enclosure II provides a more detailed description of the risk assessment processes used by WHO's IPCS.

### Canada Has Used Various Measures to Manage the Human Health Risks of Toxic Chemicals under CEPA 1999

According to Canadian officials and Canadian government websites, Canada has used a variety of measures, including regulations, pollution prevention plan notices, and Significant New Activity Notices to manage the human health risks of chemicals determined to be toxic under CEPA 1999. For a substance determined to be toxic, Canadian officials told us that their current policy is to propose that the substance be added to CEPA 1999's List of Toxic Substances, if CEPA 1999 may be used to manage the risks identified. According to Canada's guide to CEPA 1999, CEPA 1999 requires that a draft and final risk management instrument be published in the *Canada Gazette* within 24 and 42 months, respectively, of the decision to propose addition to its List of Toxic Substances.<sup>33</sup> Measures used to manage risks associated with the 132

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<sup>29</sup>Over time, the scope of the program has expanded beyond chemicals to include other potentially cancer-causing agents, such as occupational exposures, lifestyle factors (e.g., smoking), and other potentially carcinogenic exposures. The program reviews agents, which are defined to include specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposures, cultural or behavioral practices, biological organisms, and physical agents.

<sup>30</sup>The program also chooses working group members who have no real or apparent conflicts of interests and gives consideration to demographic diversity and balance of scientific findings and views.

<sup>31</sup>For example, WHO International Programme on Chemical Safety, *Guidelines for the Preparation of Concise International Chemical Assessment Documents* (May 2002), accessed July 31, 2015, [http://www.who.int/ipcs/publications/cicad/en/CICAD\\_Guidelines\\_sept-2002.pdf](http://www.who.int/ipcs/publications/cicad/en/CICAD_Guidelines_sept-2002.pdf).

<sup>32</sup>IPCS produces different types of assessments and, according to an IPCS official, these different types of assessments generally follow similar processes. However, some assessments undergo an additional step following peer review in which a standing program board provides guidance on how to address peer review comments and determines whether those comments have been appropriately addressed. Other assessments do not undergo review by this standing board.

<sup>33</sup>The *Canada Gazette* is the official newspaper of the Government of Canada and publishes regularly, among other things, new and proposed regulations, and an assortment of government notices.



entries on CEPA 1999's List of Toxic Substances, according to relevant Environment Canada websites, include but are not limited to:

- **Regulations.** Canada has promulgated regulations (55 as of September 2015) that impose restrictions on an activity related to a chemical or other substance, or set limits on the concentrations of a chemical or substance that can be used, released to the environment or be present in a product.<sup>34</sup>
- **Pollution prevention plan notices.** Pollution prevention plan notices (13 as of September 2015) require affected people (e.g. industrial facility operators) to prepare and implement a plan that outlines actions to prevent or minimize the creation or release of pollutants and waste.<sup>35</sup>
- **Administrative agreements.** Administrative agreements (2 as of September 2015) are work-sharing arrangements between the Canadian federal government and its provincial, territorial, or aboriginal governments to streamline efforts in administering CEPA 1999 regulations. The agreements usually cover topics such as inspections, monitoring, and reporting.<sup>36</sup> A Canadian official told us that implementing administrative agreements do not meet CEPA 1999 deadlines for drafting and finalizing risk management instruments.
- **Significant New Activity Provisions (Orders and Notices).** Significant New Activity provisions (28 as of September 2015 associated with the CMP), when issued, trigger an obligation for a person to provide the Canadian federal government with information about a substance when proposing to use, import or manufacture the substance for a significant new activity.<sup>37</sup> The government then assesses the substance for potential risks to human health, the environment, or both. Officials told us that a Significant New Activity provision is essentially an obligation to report an activity (i.e., manufacture/import/use) 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, allowing for future management as needed.
- **Guidelines, objectives, and codes of practice.** Guidelines, objectives, and codes of practice may be developed to give industries and regulators clear direction on how to reduce emissions, effluents, and wastes.<sup>38</sup> Guidelines are used, for example, to help limit releases of specified substances into the environment from works, undertakings, or activities. A code of practice is typically used, for example, to communicate detailed technical information.
- **Environmental emergency plans under the *Environmental Emergency Regulations*.** Persons who own or manage specified toxic chemicals and other

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<sup>34</sup>Environment Canada, *Regulations and Other Instruments*, accessed August 6, 2015, <http://ec.gc.ca/lcpe-cepa/eng/regulations/default.cfm?n=9E7794D4-1>.

<sup>35</sup>Environment Canada, *Pollution Prevention (P2) Plans*, accessed June 29, 2015, <http://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=BC71EA4E-1>.

<sup>36</sup>Environment Canada, *Administrative Agreements*, accessed June 17, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=9A610C9B-1>.

<sup>37</sup>Environment Canada, *The Significant New Activity Provisions under CEPA 1999*, accessed June 30, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?Lang=En&n=9EFCCB36-1>.

<sup>38</sup>Environment Canada, *Guidelines, Objectives and Codes of Practice*, accessed June 29, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=2952CB83-1>. The website also notes that guidelines or objectives (but not codes of practice) may also be prepared to indicate government policy direction.

substances at or above specified thresholds must (1) provide required information on those substance(s) and their quantities and (2) prepare and implement environmental emergency plans that must address the types of emergencies that might reasonably occur, including both on-site and off-site consequences, and the associated prevention, preparedness, response, and recovery issues.<sup>39</sup> Persons must provide information on the quantity of the substance, facility location, a report that a plan has been prepared, and a notice that the plan has been implemented within specified time frames.

Enclosure III provides more detailed information on selected risk management measures used to address risks related to chemicals and other substances identified as toxic under CEPA 1999 and includes examples of chemicals addressed using those measures.

### Agency and Third-Party Comments

We provided copies of this draft report to the Environmental Protection Agency for review and comment, and to officials from Canada, Australia, and WHO for their review. The Environmental Protection Agency and officials from Canada, Australia, and WHO provided technical comments that we incorporated, as appropriate.

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We are sending copies of this report to the appropriate congressional committees, the EPA Administrator, and other interested parties. In addition, this report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or [gomezj@gao.gov](mailto:gomezj@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in enclosure IV.

Sincerely yours,



J. Alfredo Gómez  
Director, Natural Resources and Environment

Enclosures – 4

Enclosure I

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<sup>39</sup>Environment Canada, *Environmental Emergency (E2) Plans*, accessed June 17, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=77C8541E-1>.

## Objectives, Scope, and Methodology

This report examined: (1) how selected foreign programs conduct risk assessment activities to understand the human health risks of certain chemicals and (2) how Canada manages the human health risks of chemicals identified as toxic under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).<sup>40</sup>

To identify foreign programs to review, we contacted Environmental Protection Agency (EPA) officials and academics with relevant expertise, and stakeholders in environmental and industry groups for their views on foreign programs that may produce quality chemical risk assessments. The four programs outside of the European Union that were identified most often by those we spoke with as having quality chemical assessment programs, and which we therefore selected, were: Canada, Australia, and the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) Monographs Programme and International Programme on Chemical Safety (IPCS). Due to ongoing trade negotiations between the United States and the European Union, which include, among other things, negotiations concerning the coordination of their respective chemical regulatory regimes, we did not include European Union programs in the scope of this review. Within Canada, we focused on Canada's Chemicals Management Plan (CMP), which is run jointly by Environment Canada and Health Canada. Within Australia, we focused on the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, implemented within Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS). We focused on these programs because they are the main bodies in their countries conducting assessments of existing chemicals—those that have been in use without having been assessed.<sup>41</sup> At WHO, we focused on the IARC Monographs Programme and IPCS because they were the specific programs suggested by those we contacted.

To determine how the foreign programs we selected conduct risk assessment activities to understand the human health risks of certain chemicals, we worked with representatives from each selected program: once for preliminary information, again to gather responses to a standard set of questions and again as needed for follow-up questions. We also reviewed documents provided by officials from each program and information posted on their websites. This documentation included information on relevant laws, policies, and risk assessments. In addition, we talked with a number of academics with relevant knowledge on EPA and our selected programs' assessment processes. Last, we interviewed stakeholders representing an equal number of environmental and industry groups to understand their views on selected programs' practices and processes. We identified these stakeholders by consulting our prior work and by soliciting input from EPA officials and academics with relevant knowledge. We then

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<sup>40</sup> *Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 3, as amended (Can.) [hereinafter CEPA 1999].

<sup>41</sup> In Canada, such chemicals are on the Domestic Substances List, which, according to Canada's guide to CEPA 1999, includes substances that were, between January 1, 1984, and December 31, 1986, in commerce in Canada, or were used for commercial manufacturing purposes, or were manufactured in or imported into Canada in a quantity of 100 kilograms or more in any one calendar year. A substance as defined under Canadian law includes any distinguishable kind of organic or inorganic matter, whether animate or inanimate, that is capable of being released as a single substance, an effluent, emission, waste, or a mixture into the Canadian environment. In Australia, those are on the Australian Inventory of Chemical Substances (AICS) is the legal device that distinguishes new from existing chemicals. See *id.* at s 11. According to NICNAS documentation, the AICS is a listing of all industrial chemicals in use in Australia between January 1, 1977, and February 28, 1990. In addition, it includes new assessed chemicals and corrections, as well as chemicals that were regulated by other Australian regulators and have since become industrial chemicals. Also according to NICNAS documentation, industrial chemicals include chemicals used in solvents, adhesives, plastics, paints, inks, fuels, or laboratory reagents, as well as in refrigeration, cosmetics, and household cleaning.

selected three stakeholders representing environmental groups and three representing industry groups, choosing first those for whom we had received at least two recommendations and then contacting all others and interviewing those who responded first. The views of these particular environmental and industry groups cannot be generalized to all other environmental and industry groups, but they provided valuable insights to our work. We did not evaluate the effectiveness of any of the programs described. In addition, we did not evaluate the scientific content or quality of selected foreign programs' assessments. We did not compare any elements of these programs' assessment programs to EPA's Integrated Risk Information System (IRIS) Program or other EPA chemical assessment programs.

To determine how Canada manages the human health risks of chemicals identified as toxic under CEPA 1999, we met with relevant officials from Canada and reviewed documentation provided by those officials and published on their website. We chose to focus on Canada—rather than on all selected programs—for a few reasons. First, Canada's CEPA 1999 is regularly discussed in the debate on reforming Toxic Substances Control Act (TSCA) in the United States. In addition, Environment Canada and Health Canada, which run Canada's CMP, are the only programs in our study that also conduct risk management activities. According to Australian officials, NICNAS is not responsible for managing chemical risks; instead, Australian officials told us that other Australian federal, provincial, territorial, and aboriginal governments conduct risk management work. WHO's IARC Monographs Programme and IPCS also do not conduct risk management work, which is the purview of WHO member countries. To select sample chemicals to demonstrate how chemicals are managed as discussed in enclosure III, we first identified four types of risk management measures that may be used by Canada to manage risks associated with chemicals on CEPA 1999's List of Toxic Substances. We chose to focus on these four types because officials have created readily available lists of the chemicals associated with those types of actions on Environment Canada websites. In addition, in the case of Significant New Activity Notices, officials told us that it is the risk management measure they use most often to address substances determined to be toxic. For each of these risk management measures, we used lists of chemicals associated with those measures as presented by Environment Canada websites. We then randomly ordered those lists. Starting with the first randomly-ordered chemical, we determined (1) whether it was on CEPA 1999's List of Toxic Substances and (2) if it was managed for human health reasons—the focus of this report—as opposed to environmental reasons. If those two things were true, we used it as an example. We chose to report on one example for each type of management measure. We did not compare what we learned about Canada to how EPA or other U.S. agencies manage the human health risks of chemicals.

We conducted this performance audit from March 2014 to October 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Enclosure II: Information from Canada, Australia, and the World Health Organization about Selected Risk Assessment Processes

A description of the risk assessment processes for existing substances used by programs implementing Canada's Chemicals Management Plan (CMP), Australia's Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, and the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) Monographs Programme and International Programme on Chemical Safety (IPCS) follows. For each program, we examined

- the main determination<sup>42</sup> made by each program's assessments;
- the criteria for choosing which chemicals to assess; and
- involvement by external experts, stakeholders, and/or the public.

### **1. Canada's CMP**

#### Main Determination Made by Each Program's Assessments

As part of its CMP, officials in Canada conduct screening assessments to determine whether chemicals and other substances on its Domestic Substances List<sup>43</sup> are toxic according to the definition set forth in the *Canadian Environmental Protection Act, 1999* (CEPA 1999).<sup>44</sup> CEPA 1999 defines a substance as 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. Program officials told us that assessments incorporate several elements, including information on each chemical's physical and chemical properties, uses and sources, hazard identification, exposure assessment, and a risk characterization. They also told us they use comprehensive information gathering approaches to support their assessments, and that they review chemicals for their human health effects of concern to the general public rather than for specific populations such as workers in a particular industry. They also told us that they focus their review on what would be considered "reasonable, foreseeable" uses. If an

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<sup>42</sup>By determination, we are referring to each program's bottom-line assessment regarding a chemical's human health effects.

<sup>43</sup>According to Canada's guide to *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Domestic Substances List includes substances that were, between January 1, 1984, and December 31, 1986, in commerce in Canada, or were used for commercial manufacturing purposes, or were manufactured in or imported into Canada in a quantity of 100 kilograms or more in any one calendar year. CEPA 1999 includes any distinguishable kind of organic or inorganic matter, whether animate or inanimate. The list is regularly amended to include additional substances that have been assessed under the act and allowed into Canada. According to Canadian officials, the Domestic Substances List currently contains approximately 23,000 substances from the original list along with an additional 4,470 substances that have been added to the list following assessments of new substances (1994-2014). Environment Canada, *A Guide to Understanding the Canadian Environmental Protection Act, 1999* (Dec. 10, 2004), accessed July 27, 2015, [http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04\\_e.pdf](http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04_e.pdf).

<sup>44</sup>*Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 3, as amended (Can.) [hereinafter CEPA 1999]. In 2006, the Canadian government launched the CMP, which is aimed at reducing the risks posed by chemicals to human health and the environment. For more information on the CMP, see Government of Canada, *Overview of the Chemicals Management Plan*, accessed February 9, 2015, [http://chemicalsubstanceschimiques.gc.ca/alt\\_formats/pdf/fact-fait/overview-vue-eng.pdf](http://chemicalsubstanceschimiques.gc.ca/alt_formats/pdf/fact-fait/overview-vue-eng.pdf).

assessment determines that a substance is toxic under CEPA 1999, officials may take one of three actions: (1) add the substance to CEPA 1999's List of Toxic Substances<sup>45</sup> and, if applicable, to CEPA 1999's Virtual Elimination List;<sup>46</sup> (2) add the substance to CEPA 1999's Priority Substances List, which identifies substances that must undergo further assessment within five years; or (3) take no further action. In practice, officials told us that their policy has been to take action on chemicals by adding them to the List of Toxic Substances, which then can lead to risk management actions, including regulations, although exceptions exist where action is not taken under CEPA 1999 authority. According to CEPA 1999, in interpreting the results of a screening assessment, officials shall apply the precautionary principle, which states that lack of full scientific certainty shall not be used as a reason for postponing action when a chemical or other substance may pose a threat of serious or irreversible damage.

CEPA 1999 also allows officials to review decisions from other jurisdictions. Specifically, were Canada's Minister of the Environment to receive information that another government<sup>47</sup> has specifically prohibited or substantially restricted a substance for environmental or health reasons, the federal Ministers of the Environment and Health must review that decision. The review is to determine whether the substance is toxic or capable of becoming toxic according to CEPA 1999, unless the decision relates to a substance the only use of which in Canada is regulated under another Act of Parliament that provides for environmental and health protection. Program officials told us that they have implemented a process to conduct this work. According to Canada's guide to CEPA 1999, this process allows Canada to benefit from the sharing of scientific data, the capacity of other governments, and efforts by others to develop risk management measures.

Program officials told us that prior to implementation of the CMP in 2006, assessments were largely identified under their Priority Substances Assessment Program. There have been two priority substances lists (PSL) associated with this program—PSL1 and PSL2. Under CEPA 1999, PSL substances are required to be assessed within 5 years of their addition. PSL1 covered 44 substances, and PSL2, which covered 25 substances, was derived from recommendations made by an expert advisory panel.<sup>48</sup>

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<sup>45</sup>According to Canada's guide to CEPA 1999, substances that meet the definition of toxic under CEPA 1999 can be placed on the List of Toxic Substances. A substance's presence on this list alone does not impose specific management measures on the use of the substance. The recommendation for a chemical's addition to this list, however, triggers statutory obligations that require the Canadian government to contemplate and potentially issue chemical management measures for that chemical within specified periods.

<sup>46</sup>According to an Environment Canada website, Section 65 of CEPA 1999 mandates the Ministers of the Environment and of Health to compile a list to be known as the Virtual Elimination List. The Ministers must specify the level of quantification for each substance on the list and, having done so, must prescribe the quantity or concentration of the substance that may be released into the environment either alone or in combination with any other substance from any source or type of source. The list currently includes two substances: (1) hexachlorobutadiene, commonly referred to as HCB, which was added in 2006, and (2) perfluorooctane sulfonate, commonly referred to as PFOS, and its salts, which was added in 2009. Environment Canada, *Virtual Elimination List*, accessed July 20, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=2F918AD5-1>.

<sup>47</sup>Other governments include those within Canada or a member state, or subdivision of a member state, of the Organisation for Economic Co-operation and Development.

<sup>48</sup>Environment Canada, *Priority Substances List*, accessed July 17, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=C6C230D5-1>.

## Criteria for Choosing What to Assess

According to Canada's guide to CEPA 1999, between passage of the act and 2006, the program went through a process to prioritize all of the approximately 23,000 chemicals and other substances on the Domestic Substances List to choose which should be further assessed (officials referred to this as a 'categorization exercise'). To do so, pursuant to CEPA 1999 officials identified those substances that (1) are persistent or bioaccumulative according to the regulations and inherently toxic to human beings or nonhuman organisms, as determined by laboratory or other studies; or (2) may present to individuals in Canada the greatest potential for exposure.<sup>49</sup> This process resulted in about 4,300 chemicals and other substances being prioritized for further assessment, about 1,200 of which were for human health reasons.

In 2014, officials in Environment Canada and Health Canada formalized an approach to prioritize existing chemicals and other substances for further assessment.<sup>50</sup> According to the document outlining this approach, the objective of ongoing prioritization is to selectively identify substances for which there are indications that the substance should be considered as a new priority for assessment or further work. This could include identifying chemicals or other substances that had previously been assessed. The document also states priority setting decisions are based on a set of guiding principles and considerations, such as whether new information gathered is relevant and scientifically reliable, and whether recently acquired information refutes a key assumption in a past decision or recommendation. Officials told us that they intend to go through a process to consider new priorities on a yearly basis, but that assessments prioritized using this new approach may not begin in earnest until they have completed their work to address the approximately 4,300 substances they have already committed to review by 2020. Officials told us that they can also determine new priorities (using criteria such as new scientific evidence) on an ad hoc basis.

## Involvement by External Experts, Stakeholders, or the Public

To involve stakeholders and/or the public during the assessment process, officials use a variety of mechanisms. A program document identifies stakeholders as representatives of industries and industry associations, nongovernmental organizations, environmental and health groups, and labor and consumer organizations. The document also states that officials involve stakeholders at several points in the assessment process, including during the process of identifying which chemicals and other substances to assess, problem formulation/issue identification, and expert peer review. Officials also publish notices in the *Canada Gazette*<sup>51</sup> when assessments are available for public comment. Canadian government officials told us that industry stakeholders are sometimes involved in the assessment development process when officials require industry members to provide data on the properties and uses of specific

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<sup>49</sup>Persistence refers to an attribute of a substance that describes the length of time that the substance remains in a particular environment before it is physically removed or chemically or biologically transformed. Bioaccumulation refers to the progressive increase in the amount of a substance in an organism or part of an organism that occurs because the rate of intake exceeds the organism's ability to remove the substance from the body.

<sup>50</sup>Environment Canada and Health Canada, *Approach for identification of chemicals and polymers as risk assessment priorities under Part 5 of the Canadian Environmental Protection Act, 1999 (CEPA 1999)*, (2014), accessed December 4, 2014, <http://www.ec.gc.ca/ESE-EES/DEFAULT.ASP?LANG=EN&N=A10191AD-1>.

<sup>51</sup>The *Canada Gazette* is the official newspaper of the Government of Canada and publishes, among other things, new and proposed regulations and an assortment of government notices.

chemicals.<sup>52</sup> Officials told us they also obtain input from standing committees composed of stakeholders and experts such as through the CMP Science Committee and CMP Stakeholder Advisory Committee.

To involve external experts, a program document states that draft assessments are sent for scientific review to a variety of Canadian and international experts, selected from academia, government, industry, and/or environmental groups. A revised report is subsequently prepared, taking into account the comments of these expert reviewers. Officials told us they also engage experts to review full draft assessments or specific aspects of an assessment on an as-needed basis.

According to Canada's guide to CEPA 1999, if stakeholders or others are unsatisfied with the outcome of an assessment, they may file a notice of objection and request that a Board of Review be established to inquire into the nature and extent of the danger posed by the substance in respect of which the decision is made. Depending on the nature of the information received, Canada's Minister of the Environment then determines if further discussions or a Board of Review are warranted. If the Minister establishes a Board of Review, the board then inquires into the nature and extent of the danger posed by the substance that is the subject of the order or the proposed regulation. According to officials from Health Canada, they have received about 10 requests for a Board of Review in their history of conducting assessments, and the Minister of the Environment has approved 1 request. Officials told us that these requests can be granted based on receipt of what they understand to be "significant" new information.

## **2. Australia's IMAP Framework**

### **Main Determination Made by Each Program's Assessments**

Based on the program's website, Australia's IMAP framework is used by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), and works to identify whether industrial chemicals<sup>53</sup> from the Australian Inventory of Chemical Substances (AICS)<sup>54</sup> are likely to pose an unreasonable risk to workers, the general public, and/or the environment, and—if

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<sup>52</sup>According to officials, these mandatory calls for information from industry are authorized under Sections 70 and 71 of CEPA 1999. According to program documentation, Section 70 puts the onus on industries to provide information they possess that reasonably supports the conclusion that a substance is "toxic" or capable of becoming "toxic" as defined under CEPA 1999. Section 71 allows the Minister of the Environment to require all parties engaged in activity involving a substance to provide information for the purpose of assessing whether the substance is toxic or is capable of becoming toxic, or for the purpose of assessing whether to control, or the manner in which to control a substance. This includes the authority to request existing information or to require sampling, testing, and the generation of new data.

<sup>53</sup>According to NICNAS documentation, industrial chemicals include chemicals used in solvents, adhesives, plastics, paints, inks, fuels, or laboratory reagents, as well as in refrigeration, cosmetics, and household cleaning. The *Industrial Chemicals (Notification and Assessment) Act 1989* defines the term chemical as a chemical element, including a chemical element contained in a mixture; a compound or complex of a chemical element, including such a compound or complex contained in a mixture; or a naturally-occurring chemical or a UVCB substance (a substance of unknown or variable composition, complex reaction products or biological materials). The statute notes that this definition does not include an article, as defined by the Act, a radioactive chemical, or a mixture. See *Industrial Chemicals (Notification and Assessment) Act 1989, (Cth) S 6 (Austl.)*.

<sup>54</sup>The AICS is the legal device that distinguishes new from existing chemicals. See *id.* at s 11. According to NICNAS documentation, the inventory is a listing of all industrial chemicals in use in Australia between January 1, 1977, and February 28, 1990. In addition, it includes new assessed chemicals and corrections, as well as chemicals that were regulated by other Australian regulators and have since become industrial chemicals.



so—what recommendations should be made to reduce that risk. According to the IMAP framework’s main policy document, if an assessment concludes that a chemical may pose an unreasonable risk to the general public, workers, or the environment, the assessment includes recommendations to manage those risks.<sup>55</sup> According to an Australian policy document, assessments may recommend that chemicals be placed on Australia’s Poisons Standard—a compilation of decisions recommending restrictions or prohibitions to manage public health risks for certain chemicals and medicines, among other things.<sup>56</sup> According to the documentation and NICNAS officials, Australian state and territory governments are responsible for imposing legislative controls on the supply and use of such chemicals. For example, according to NICNAS officials, under the Poisons Standard, chemicals may be subjected to labeling requirements, prohibition of some or all uses, or both. To improve worker health, assessments may recommend adding information about a chemical to Australia’s Hazardous Chemical Information List to facilitate getting the proper information on safety data sheets and labels, which are provided to help industry members understand health and safety hazards.<sup>57</sup>

According to its main policy document, the IMAP framework was created following a review of NICNAS’ program to review existing chemicals between 2003 and 2006. The review examined the program against emerging national and international trends to determine if it was sufficiently responsive and flexible in meeting the national needs and priorities of NICNAS’s stakeholders, while ensuring continued efficient and effective use of resources. The review’s major concerns were that (1) most chemicals on the AICS were initially listed based on their history of use, and most had not since been assessed for their effects on human health and the environment, and (2) the current assessment process for those chemicals was not flexible enough to respond adequately, or in a resource-efficient manner, to stakeholder concerns. Based on those concerns, NICNAS began working with stakeholders and technical experts in 2008 to develop a framework to more quickly prioritize and assess chemicals on the inventory. One key element in this framework includes using overseas data to reduce duplication of assessment effort and increase efficiency.

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<sup>55</sup>Australian Government Department of Health, National Industrial Chemicals Notification and Assessment Scheme, *Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework* (Aug. 27, 2013), accessed April 21, 2014, <http://www.nicnas.gov.au/chemical-information/imap-assessments/the-imap-framework>.

<sup>56</sup>Australian Health Ministers’ Advisory Council, *Scheduling Policy Framework for Medicines and Chemicals*, effective date February 1, 2015, accessed June 3, 2015, <https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>. According to this website, the framework sets out the scheduling process, guidance for amending the Poisons Standard, the classification system for medicines and chemicals, as well as guidelines for applications, public consultation and confidential information as these relate to scheduling applications. Australian Government Department of Health, Therapeutic Goods Administration, *Poisons Standard June 2015*, accessed June 25, 2015, <https://www.comlaw.gov.au/DETAILS/F2015L00749/DOWNLOAD>. The Poisons Standard June 2015 is made under paragraph 52D(2) (b) of Australia’s Therapeutic Goods Act 1989.

<sup>57</sup>Safe Work Australia, *GHS Hazardous Chemical Information List*, accessed July 23, 2015, [http://hsis.safeworkaustralia.gov.au/GHSInformation/GHS\\_Hazardous\\_Chemical\\_Information\\_List](http://hsis.safeworkaustralia.gov.au/GHSInformation/GHS_Hazardous_Chemical_Information_List).

## Criteria for Choosing What to Assess

According to its main policy document, the IMAP framework is currently in its first stage of implementation and used three criteria to prioritize for assessment 3,000 chemicals on the AICS during this first stage: those that have (1) exposure data available to NICNAS, (2) been identified as a concern or for which action has been taken overseas, or (3) been detected in umbilical cord blood. Officials used various sources of information to consider these criteria. For example, to prioritize chemicals that have been identified as a concern or for which action has been taken overseas, officials used information on chemicals assessed by Canada's CMP and chemicals with U.S. Environmental Protection Agency action plans.<sup>58</sup> To prioritize chemicals that have been detected in umbilical cord blood, program documentation indicates that officials used information from a study by international sources.

## Involvement by External Experts, Stakeholders, or the Public

According to the IMAP framework's main policy document, officials consult with external experts, stakeholders, or the public using a variety of mechanisms, such as publishing information on draft assessments for public comment in the *NICNAS Bulletin*.<sup>59</sup> According to program officials, industry members also have the opportunity to provide voluntary information prior to, during, or after the assessment process, and working closely with other international regulatory agencies has also contributed significantly to the effectiveness of the program. Officials also obtain input from standing committees composed of representatives from industry, community organizations, other government entities, and experts. Specifically, according to program officials, the program seeks input from the NICNAS Strategic Consultative Committee, which comprises representatives of industry and community organizations. In addition, program officials told us that consultations may also be undertaken with other stakeholders, such as academics and government risk management agencies.

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<sup>58</sup>According to an Environmental Protection Agency (EPA) website, action plans summarize available hazard, exposure, and use information on chemicals; outline the risks that each chemical may present; and identify the specific steps the agency is taking to address those concerns. As of June 2015, EPA has action plans on the following ten chemicals or groups of chemicals: Benzidine Dyes; Bisphenol A (BPA), Hexabromocyclododecane (HBCD); Methylene Diphenyl Diisocyanate (MDI); Nonylphenol and Nonylphenol Ethoxylates; Perfluorinated chemicals (PFC); Penta, octa, and decabromodiphenyl ethers (PBDEs) in products; Phthalates; Short-chain chlorinated paraffins; and Toluene Diisocyanate (TDI). Environmental Protection Agency, *Existing Chemicals Action Plans*, accessed July 23, 2015, <http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html>.

<sup>59</sup>According to the NICNAS website, the *NICNAS Bulletin* includes non-statutory notices relevant to the administration of the National Industrial Chemicals Notification and Assessment Scheme. The *NICNAS Bulletin* is published on the first Tuesday of every month and may include information published on the NICNAS website in the month preceding its publication. National Industrial Chemicals Notification and Assessment Scheme, *The NICNAS Bulletin*, accessed September 15, 2015, <http://www.nicnas.gov.au/communications/publications/the-nicnas-bulletin>.

### 3. WHO's IARC Monographs Programme, as Outlined in the Program's Preamble<sup>60</sup>

To guide its work, the IARC Monographs Programme uses a published Preamble document that serves as a statement of scientific principles and general operating procedures. An IARC official also told us that the Preamble establishes transparent, standard procedures for selecting and reviewing evidence and making a final evaluation.

#### Main Determination Made by Each Program's Assessments

WHO's IARC Monographs Programme makes determinations about the likelihood that selected agents—defined as specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposures, cultural or behavioral practices, biological organisms and physical agents—cause cancer in humans using five categories ranging from “the agent is carcinogenic to humans” to “the agent is probably not carcinogenic to humans.”<sup>61</sup> The Preamble states that a cancer ‘hazard’ is an agent that is capable of causing cancer under some circumstances, while a cancer ‘risk’ is an estimate of the carcinogenic effects expected from exposure to a cancer hazard. The Preamble goes on to state that the IARC Monographs Programme evaluates cancer hazards, even when risks are very low at current exposure levels, because new uses or unforeseen exposures could engender risks that are significantly higher. According to the program preamble, assessments are used by national and international authorities to conduct further assessment or decide among alternative options for public health decisions, among other things. Because assessments from the IARC Monographs Programme represent only one part of the information on which public health decisions may be based, and public health options may vary from one situation to another and from country to country, assessments do not include specific risk management recommendations, which are the responsibility of individual governments or other international organizations.

#### Criteria for Choosing What to Assess

According to the program's Preamble document, the IARC Monographs Programme uses two criteria to prioritize chemicals and other agents for assessment: (1) evidence of human exposure and (2) some evidence or suspicion of carcinogenicity. The program periodically convenes an advisory group to recommend topics for assessment. Advisory group documentation stated that the program convenes such advisory groups to ensure that IARC assessments reflect the current state of priorities for public health. The advisory group met in April 2014 and recommended 24 types of chemicals and other agents as high priorities for review. The advisory group also recommended 20 chemicals and other agents as medium priorities for review.

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<sup>60</sup>World Health Organization, International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble* (Lyon France, 2006), accessed November 4, 2014, <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

<sup>61</sup>The other determinations include, “the agent is probably carcinogenic to humans,” “the agent is possibly carcinogenic to humans,” and, “the agent is not classifiable as to its carcinogenicity to humans.”

## Involvement by External Experts, Stakeholders, or the Public

To involve experts, stakeholders, and the public, the program uses a variety of strategies. To involve experts outside of those serving as working group members, officials invite what they call “specialists”—experts who are deemed to have critical knowledge and experience but have a real or apparent conflict of interests—to participate in working group meetings. Invited specialists are asked to contribute their knowledge and experience during discussions, and may also contribute text on noninfluential issues in a monograph’s section on exposure. Invited specialists do not chair meetings or draft text that pertains to the description or interpretation of cancer data; or participate in making final evaluation decisions. To involve interested stakeholders, program policy allows representatives of national and international health agencies to attend meetings. In addition, according to a program official, individuals wishing to be observers may request to attend meetings, and the program invites a limited number of such observers who have relevant scientific credentials. Observers are invited with attention given to achieving a balance of observers from constituencies with differing perspectives. According to a program official, neither representatives nor observers draft any text for a monograph or participate in evaluation decisions. Also according to a program official, the program involves the public by soliciting public nominations for chemicals or other agents to assess. The program does not solicit public input on draft assessments.

### **4. WHO’s IPCS**

#### Main Determination Made by Each Program’s Assessments

According to program guidelines, WHO’s IPCS makes determinations about the health impacts of chemicals by a process of assessment that aims to provide a consensus scientific description of the risks of chemical exposure. To do this, authors usually base their work on an existing national, regional, or international review, or a review in preparation to provide a concise summary of the information considered critical for risk characterization. Alternatively, a full assessment may be written by an expert. Assessments include “sample” risk characterizations that, according to program guidance, are intended to provide examples of how risks of certain populations might be characterized, based upon the toxicological and exposure information presented in the assessment. Sample risk characterizations do not necessarily represent all possible exposure situations, but they are provided as example and guidance only. As with WHO’s IARC Monographs Programme, a program official told us that assessments from the IPCS do not provide specific risk management recommendations, but may inform further assessment or risk management measures made by WHO member governments or others.

#### Criteria for Choosing What to Assess

According to program officials, due to resource limitations, the program currently reviews chemicals primarily to satisfy obligations under international conventions, such as the

Stockholm Convention.<sup>62</sup> For example, in 2011, the program published an assessment on the human health effects of dichlorodiphenyltrichloroethane (DDT) with specific advice to the

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<sup>62</sup>The Stockholm Convention on Persistent Organic Pollutants, 2256 UNTS 119, is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have harmful impacts on human health or on the environment. United Nations Environment Programme, Stockholm Convention on Persistent Organic Pollutants, Overview, accessed August, 23, 2015, <http://chm.pops.int/TheConvention/Overview/tabid/3351/Default.aspx>.

Conference of the Parties to the Stockholm Convention about the use of DDT in controlling mosquitoes that spread malaria.<sup>63</sup> According to its annual activity report, the program reviews the literature annually to consider whether the assessment should be revisited. To date, according to this report, these literature reviews have not suggested that a revision is needed.<sup>64</sup> Prior to its current resource limitations, program guidelines state that the program used specific criteria to prioritize chemicals for assessment, such as (1) probability of exposure and/or, (2) significant toxicity. Additional criteria included whether a chemical: (3) was of transboundary concern, (4) was of concern to a range of countries (developed, developing, and those with economies in transition) for possible risk management, (5) had significant international trade, (6) had a high production volume, or (7) had a dispersive use. Special emphasis was placed on avoiding duplication of effort by WHO and other international organizations.

### Involvement by Experts, Stakeholders or the Public

To involve experts, program guidelines state that the program works with a primary author on a first draft, which is often based on an existing national, regional, or international review. This primary author usually prepares a first draft based on these reviews, or on a review in preparation using a standard outline created by IPCS to encourage consistency in form. The draft is then reviewed first by IPCS officials to ensure that it meets specified criteria. Following that, the draft undergoes an international peer review by scientists chosen for the panel. Primary authors are required to take peer reviewers' comments into account and revise their draft, as appropriate.

- For one type of IPCS assessment called a Concise International Chemical Assessment Document (CICAD), the resulting second draft then moves to a second reviewing board—called the Final Review Board—with a role of, among other things, (1) ensuring that each assessment has been subjected to an appropriate and thorough peer review and (2) providing guidance on how to resolve any remaining issues that an author may not have adequately addressed. A program official told us that the Final Review Board will meet for 2 to 3 days to review and finalize the assessment.
- For types of IPCS assessments not considered by a Final Review Board, which may include IPCS' Environmental Health Criteria (EHC) documents, an official told us that WHO convenes a meeting of invited experts to consider peer review comments and agree on the final version of the assessment.

Assessments are also subject to approval by WHO senior management but are published on the basis of being the opinion of a group of experts rather than as the official policy of the organization.

According to a program official, to involve stakeholders and the public, program officials accept nominations on which chemicals to assess from anyone. In addition, they solicit stakeholder and public comments on draft assessments through publication on the program's website and through e-mail to those on the program's mailing list. Recent assessments received between 15 and 30 such comments, usually submitted by academics, industry stakeholders, and

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<sup>63</sup>World Health Organization, International Programme on Chemical Safety, Environmental Health Criteria 241, *DDT in Indoor Residual Spraying: Human Health Aspects* (Geneva Switzerland, 2011), accessed June 25, 2015, [http://whqlibdoc.who.int/publications/2011/9789241572415\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2011/9789241572415_eng.pdf?ua=1).

<sup>64</sup>World Health Organization, *WHO Chemical Safety – Activity Report 2014*, accessed February 3, 2015, [http://www.who.int/ipcs/about\\_ipcs/activity\\_report\\_2014.pdf?ua=1](http://www.who.int/ipcs/about_ipcs/activity_report_2014.pdf?ua=1).

nongovernmental organizations. For applicable assessments, the Final Review Board is responsible for considering these comments as they deliberate.

## Enclosure III: Selected Risk Management Measures for Chemicals Identified as Toxic Under CEPA 1999

In deciding which risk management measures to use to prevent and control risk associated with chemicals or substances identified as toxic under the *Canadian Environmental Protection Act, 1999* (CEPA 1999),<sup>65</sup> Canadian government officials told us that when they examine risk management measures, they consider potential effectiveness of a potential measure, along with whether it is proportional to the risks posed by any given chemical or substance. In addition, Canadian officials told us that they consider international agreements and their obligations under those agreements when deciding which risk management measures to pursue.

According to Canada's guide to CEPA 1999, risk management measures for chemicals on CEPA 1999's List of Toxic Substances are developed through a process that aims to involve stakeholders.<sup>66</sup> When selecting a specific risk management strategy for a chemical determined to be toxic under CEPA 1999, the government outlines the proposed approach for managing the risks to the environment and human health using risk assessments and other information to help determine which measure or measures would best address those risks. Initially, all available risk management measures are considered, including regulatory provisions of other governments and voluntary approaches. These may also include risk management measures that are already in place such as pollution prevention plans, administrative agreements, and Significant New Activity Notices.<sup>67</sup> Risk management measures may focus on any aspect of the chemical or other substance's life cycle—from the research and development stage through manufacture, use, storage, transportation, and ultimate disposal.

This enclosure focuses on four types of risk management measures used by Canada to address the risks posed by chemicals and other substances determined to be toxic. For each type of measure, this enclosure includes one example of how that measure addressed a chemical or other substance determined to be toxic under CEPA 1999.

### **Regulations**

Canada has promulgated regulations on chemicals and other substances that impose restrictions on a chemical-related activity, or set limits on the concentrations of a chemical, or other substance that can be used, released to the environment, or be present in a product.<sup>68</sup> According to an Environment Canada website, as of September 2015, there were 55 regulations

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<sup>65</sup>*Canadian Environmental Protection Act, 1999*, S.C. 1999, c. 3, as amended (Can.) [hereinafter CEPA 1999].

<sup>66</sup>Environment Canada, *A Guide to Understanding the Canadian Environmental Protection Act, 1999* (Dec. 10, 2004), accessed July 27, 2015, [http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04\\_e.pdf](http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04_e.pdf).

<sup>67</sup>These include instruments under CEPA 1999, as well as other risk management measures that are outside of CEPA 1999, including the regulatory provisions of other governments and voluntary approaches.

<sup>68</sup>For example, Environment Canada, *Prohibition of Certain Toxic Substances Regulations, 2012* (SOR/2012-285) (Jan., 2, 2013), accessed August 6, 2015, <http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=207> and Environment Canada, *Marine Spark-Ignition Engine, Vessel and Off-Road Recreational Vehicle Emission Regulations* (SOR/2011-10) (Feb. 16, 2011), accessed August 6, 2015, <http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=109>.

associated with chemicals and other substances determined to be toxic under CEPA 1999 and its predecessor CEPA 1988.<sup>69</sup> They cover a wide range of activities, chemicals, and emissions.

One group of substances that is managed in Canada through regulations is volatile organic compounds (VOC). VOCs are chemicals that are emitted as gases from natural sources—such as trees—as well as from anthropogenic (human-caused) sources—such as motor vehicles, paints, solvents, fuels, and other products. VOCs are also primary precursors to the formation of ground level ozone and particulate matter, which are the main constituents of smog. In Canada, human health concerns related to VOC emissions stem from: the transportation sector; the use of consumer and commercial products that contain solvents; some commercial and industrial processes; and residential wood combustion.<sup>70</sup> To manage risks associated with this group of substances, Canada has developed risk management measures to address those concerns, including promulgating its VOC Concentration Limits for Architectural Coatings Regulations (the VOC regulation).<sup>71</sup>

According to an Environment Canada website, the purpose of the VOC regulation is to protect the environment and health of Canadians from the effects of air pollution by reducing VOC emissions.<sup>72</sup> A draft of the proposed VOC regulation was made available for public comment on April 26, 2008 and citizens were given the opportunity to file comments. In addition, the National Advisory Committee under CEPA 1999 was given the opportunity to provide its advice.<sup>73</sup> The VOC regulation indicates that, while substances regulated by other acts are excluded from the VOC regulation, it provides sufficient protection to the environment and health.

According to an Environment Canada website, the regulation sets a maximum VOC concentration limit in 53 categories of architectural coatings.<sup>74</sup> In addition, the regulation defines methods for determining VOC concentrations and other test methods, labelling requirements, and record keeping.

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<sup>69</sup>Environment Canada, *Regulations and Other Instruments*, accessed August 6, 2015, <http://ec.gc.ca/lcpe-cepa/eng/regulations/default.cfm?n=9E7794D4-1>.

<sup>70</sup>Environment Canada, *Volatile organic compounds that participate in atmospheric photochemical reactions*, accessed July 14, 2015, <http://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=98E80CC6-1&xml=075320D0-CF6E-4261-890E-90725A29E3C4>.

<sup>71</sup>The VOC regulation defines “architectural coating” as “a product to be applied onto or impregnated into a substrate, for use on traffic surfaces such as streets and highways, curbs, berms, driveways, parking lots, sidewalks and airport runways, or stationary structures, including temporary buildings and their appurtenances, whether installed or detached.” Environment Canada, *Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations* (SOR/2009-264) §1 (Sept. 30, 2009), accessed August 6, 2015, <http://www.ec.gc.ca/lcpe-cepa/eng/regulations/detailReg.cfm?intReg=117>.

<sup>72</sup>Environment Canada, *Frequently Asked Questions – Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations*, accessed July 17, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E335DDC8-1>.

<sup>73</sup>Section 6 of CEPA 1999 created the CEPA National Advisory Committee (NAC) for the purpose of enabling national action and avoiding duplication in regulatory activity among governments within Canada. According to the NAC webpage, the role of the Committee can be broadly defined as a platform for advising the Minister(s) of Canada and ensuring a full and open sharing of information between the federal, provincial, territorial, and aboriginal governments on all matters related to the protection of the environment and the management of toxic substances.

<sup>74</sup>Environment Canada, *Frequently Asked Questions – Volatile Organic Compound (VOC) Concentration Limits for Architectural Coatings Regulations*, accessed July 17, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E335DDC8-1>.



## Pollution Prevention Plan Notices

CEPA 1999 authorizes the Canadian Minister of the Environment to issue notices requiring affected people (e.g., industrial facility operators) to prepare and implement pollution prevention plans for substances or group of substances specified on CEPA 1999's List of Toxic Substances. CEPA 1999 defines pollution prevention as "the use of processes, practices, materials, products, substances or energy that avoid or minimize the creation of pollutants and waste and reduce the overall risk to the environment or human health." Pollution prevention involves determining where waste is generated to identify how best to eliminate or reduce it at the source.

According to an Environment Canada website on pollution prevention plans, the notices are published in the *Canada Gazette* and do not provide details about them, but rather states that affected people may prepare a plan in the form that makes the most sense for their facility, as long as the plan meets specific requirements.<sup>75</sup> Those requirements can include that the plan addresses the specific "factors to consider" outlined in the notice and complies with the timelines established in the notice. In addition, the website has outlined ways for the plan to be most effective, including that it

- designate a senior manager who will be accountable for the plan;
- clearly state the risk management objectives for the plan;
- create a schedule for meeting the objectives of the plan; and
- create a plan for measuring, tracking and evaluating the success of the selected options and for implementing corrective and preventative measures, among others.<sup>76</sup>

According to an Environment Canada website on pollution prevention plans, as of September 2015, there were 13 published notices in the *Canada Gazette* requiring pollution prevention plans: (1) siloxane d4 in industrial effluent, (2) the resin and synthetic rubber manufacturing sector, (3) bisphenol A (BPA), (4) the polyurethane and other foam sector (except polystyrene), (5) mercury releases from dental amalgam waste, (6) mercury releases from mercury switches in end-of-life vehicles, (7) base metals smelters and refineries and zinc plants, (8) wood preservation facilities, (9) textile mills that use wet processing, (10) nonylphenol and its ethoxylates, (11) inorganic chloramines and chlorinated wastewater effluents, (12) dichloromethane, and (13) acrylonitrile.<sup>77</sup> Pollution prevention is about avoiding the creation of pollution and waste, rather than trying to clean it up or manage it after the fact. A pollution prevention website states that waste has traditionally been managed through treatment, recycling, control equipment, and landfilling—referred to in Canada as "end-of-pipe" processes. Pollution prevention involves determining where waste is generated to identify how best to eliminate or reduce it at the source.

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<sup>75</sup>Environment Canada, *Pollution Prevention (P2) Plans*, accessed June 29, 2015, <http://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=BC71EA4E-1>.

<sup>76</sup>Ibid.

<sup>77</sup>Environment Canada, *Pollution Prevention Planning Notices and Results*, accessed September 22, 2015, <http://www.ec.gc.ca/planp2-p2plan/default.asp?lang=En&n=BCAA1E50-1>.

Canada published a pollution prevention planning notice in the *Canada Gazette* in 2003 for acrylonitrile.<sup>78</sup> Acrylonitrile is a volatile, flammable, colorless liquid with a weakly pungent odor. According to an Environment Canada fact sheet, there are no known natural sources of acrylonitrile. It is not produced in Canada, and the majority of acrylonitrile is used in the chemical industry to produce synthetic rubbers and polymers. In 2008, according to Environment Canada, an estimated 5,900 metric tons of acrylonitrile was imported in Canada—all of which was imported from the United States.<sup>79</sup>

The notice required that any person who owned or operated a facility that manufactured synthetic rubber—where such manufacture and use of acrylonitrile that resulted in its release to the environment—to prepare and implement a pollution prevention plan.<sup>80</sup> One Canadian facility issued such a plan in 2004 that included four different pollution prevention techniques: (1) on-site recovery, reuse, and recycling; (2) equipment/process modifications; (3) spill and leak preventions; and (4) good operating practices. According to the *Final Report: Pollution Prevention Planning and Acrylonitrile*, implementation of the acrylonitrile pollution prevention plan helped the Canadian company significantly reduce releases of this chemical into the environment. In July 2009, the *Final Report* stated that the facility took actions to prevent pollution at the source, noting that the pollution prevention plan had been fully implemented.

### **Administrative Agreements**

According to Environment Canada documents, including Canada's guide to CEPA 1999, administrative agreements are work-sharing arrangements between the Canadian federal government and its provincial, territorial, or aboriginal governments to streamline efforts in administering CEPA 1999 regulations.<sup>81</sup> The agreements usually cover topics such as inspections, monitoring, and reporting. A Canadian official told us that implementing administrative agreements do not meet CEPA 1999 deadlines for drafting and finalizing risk management instruments. As of September 2015, there were 2 administrative agreements.

According to an Environment Canada website on administrative agreements, the Canadian federal government currently has an agreement with Saskatchewan covering seven CEPA 1999 regulations.<sup>82</sup> According to the website, the agreement with Saskatchewan has been in force since September 15, 1994 and covers regulations related to the pulp and paper mill sector, ozone depleting substances and products, chlorobiphenyls, federal mobile polychlorinated biphenyl (PCB) treatment and destruction, and storage of PCB material. This working agreement between the Canadian federal government and the Provincial government of Saskatchewan

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<sup>78</sup>Environment Canada, *Final Report: Pollution Prevention Planning and Acrylonitrile*, accessed July 17, 2015, <http://www.ec.gc.ca/PLANP2-P2PLAN/58F5925A-30C9-411B-8C24-696BDBCCE60B/ACRYLONITRILE%20FINAL%20REPORT%20JULY%202009.PDF>.

<sup>79</sup>Environment Canada, *Acrylonitrile*, accessed July 20, 2015, <https://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=611706C9-1>.

<sup>80</sup>Environment Canada, *Final Report: Pollution Prevention Planning and Acrylonitrile*, accessed July 17, 2015, <http://www.ec.gc.ca/PLANP2-P2PLAN/58F5925A-30C9-411B-8C24-696BDBCCE60B/ACRYLONITRILE%20FINAL%20REPORT%20JULY%202009.PDF>.

<sup>81</sup>Environment Canada, *A Guide to Understanding the Canadian Environmental Protection Act, 1999* (Dec. 10 2004), accessed July 27, 2015, [http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04\\_e.pdf](http://www.ec.gc.ca/lcpe-cepa/E00B5BD8-13BC-4FBF-9B74-1013AD5FFC05/Guide04_e.pdf) and Environment Canada, *Administrative Agreements*, accessed June 17, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=9A610C9B-1>.

<sup>82</sup>Environment Canada, *Administrative Agreements*, accessed June 17, 2015, <http://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=9A610C9B-1>.

notes that both entities are committed to maximizing cooperation and coordination in their respective compliance and enforcement programs. Specifically, the Canada-Saskatchewan administrative agreement recognizes that sustainable development and social well-being depend upon the preservation of a high standard of environmental quality. To implement the administrative agreement, a management committee was established that is responsible for ensuring collaboration among activities including those related to monitoring, research, spills and releases, publications, and conferences.

### **Significant New Activity Provisions (Orders and Notices)**

According to an Environment Canada website, Significant New Activity provisions, when issued, trigger an obligation for a person to provide the Canadian federal government with information about a substance when proposing to use, import, or manufacture the substance for a significant new activity.<sup>83</sup> The website goes on to state that the government then assesses the substance for potential risks to human health, the environment, or both. Officials told us that a Significant New Activity provision is essentially an obligation to report an activity—of manufacture, import, or use—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, allowing for future management, as needed. In addition, if an individual or corporation wants to manufacture, import, or use the substance in a way that is captured by the Significant New Activity provision, Canada requires that specific additional information is provided by the individual or corporation; a risk assessment be performed; and, if necessary, risk management measures be implemented by the government prior to any new activity. Officials told us that they have used Significant New Activity provisions to address substances found to be toxic as part of their Chemicals Management Plan (used 28 times as part of the Chemicals Management Plan as of September 2015).<sup>84</sup> They stated that because current exposures were negligible or well managed for these substances and because there is a reasonable suspicion that new activities with respect to these substances may result in new or increased risks to the environment or human health, Canadian officials felt the best course of action was to require notification by the individual or corporation if its uses for those chemicals changed.

According to a Canadian government website, Environment Canada and Health Canada are undertaking a review of Significant New Activity Orders and Notices currently in place under CEPA 1999<sup>85</sup> since publication of the first Significant New Activity provisions in 2001. This is because Canadian policies and procedures have changed, particularly with respect to the nature and scope of a Significant New Activity provision, as well as the criteria used to identify what a “significant new activity” entails. The website states that the review is being undertaken to ensure that Significant New Activity provisions are in step with current information, policies, and approaches. The resulting changes are expected to provide greater clarity of scope and improve ease of compliance by industry.<sup>86</sup>

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<sup>83</sup>Environment Canada, *The Significant New Activity Provisions under CEPA 1999*, accessed June 30, 2015, <http://www.ec.gc.ca/lcpe-cepa/default.asp?Lang=En&n=9EFCCB36-1>.

<sup>84</sup>Officials told us that Significant New Activity provisions are also used to address substances found to be nontoxic as part of the Chemicals Management Plan.

<sup>85</sup>Government of Canada, *Significant New Activity (SNAc) Orders and Notices*, accessed June 30, 2015, <http://chemicalsubstanceschimiques.gc.ca/plan/approach-approche/snac-nac/index-eng.php>.

<sup>86</sup>Ibid.

C.I. Pigment Red 104, also known as molybdate orange is an example of a chemical that Canada manages with a Significant New Activity provision.<sup>87</sup> This pigment is part of the chemical grouping UVCB substances (substances of Unknown or Variable Composition, Complex Reaction Products, or Biological Materials), which means that its chemical composition is not precisely known, among other things.<sup>88</sup> According to the *Canada Gazette*, C.I. Pigment Red 104 is used in plastic formulation for commercial applications and export; commercial, nonconsumer paints and coatings; and in a very limited number of commercial printing inks or coatings used for plastics and certain outdoor applications such as commercial identification decals. According to the *Canada Gazette*, this substance was reported to be manufactured in and imported into Canada in 2006.<sup>89</sup> According to the *Canada Gazette*, on January 31, 2009, a notice summarizing the scientific considerations of a final screening assessment for C.I. Pigment Red 104 was published in the *Canada Gazette*.<sup>90</sup> The final screening assessment report concluded that “C.I. Pigment Red 104 is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.”<sup>91</sup>

The Significant New Activity provision applicable to C.I. Pigment Red 104 refers to its use as a component of commercial printing inks, or as a component of decals in industrial or commercial applications, among other things. The *Canada Gazette* states that at least 180 days before the day on which the quantity of C.I. Pigment Red 104 exceeds 100 kilograms in any one calendar year, the Canadian government must be provided, among other things: (1) a description of the significant new activity in relation to the substance; (2) the anticipated annual quantity of the substance to be used for the significant new activity; and (3) if known, the three sites in Canada where the greatest quantity of the substance is anticipated to be used or processed and the estimated quantity by site.<sup>92</sup>

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<sup>87</sup>C.I. Pigment Red 104, or molybdate orange, contains lead compounds including lead chromate and lead molybdate.

<sup>88</sup>The composition of a UVCB could be unknown because the molecular structure or composition is unknown or because it is a complex mixture of different molecules. For example, C.I. Pigment Red 104 is a mixture of lead compounds such as lead chromate and lead molybdate. Other examples of UVCBs include fuel oil, beeswax, and soybean flour.

<sup>89</sup>*Canada Gazette*. Ottawa, July 18, 2012. SOR/2012-138 to 148 and SI/2012-49 to 54 and 56 to 57.

<sup>90</sup>*Ibid.*

<sup>91</sup>Environment Canada, *Proposed Risk Management Approach for C.I. Pigment Red 104*, accessed July 20, 2015, <http://ec.gc.ca/ese-ees/default.asp?lang=En&n=5EC834E2-1>.

<sup>92</sup>*Canada Gazette*. Ottawa, July 18, 2012. SOR/2012-138 to 148 and SI/2012-49 to 54 and 56 to 57.

## Enclosure IV

### **GAO Contact and Staff Acknowledgments**

#### **GAO Contact**

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