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Acronyms

CASRN	Chemical Abstracts Service Registry Number
CBI	confidential business information
CEPA	Canadian Environmental Protection Act
CHPA	Canadian Hazardous Products Act
CMP	Chemicals Management Plan
DSL	Domestic Substances List
DSL IU	Inventory Update of the DSL
FA	Fisheries Act
FDA	Food and Drugs Act
GHS	Globally Harmonized System
GLP	Good Laboratory Practice
GPC	gel-permeation chromatography
GPE	Greatest Potential for Exposure
HAA	Health of Animals Act
iTH	Inherently Toxic to Humans
MIREC	Maternal Infant Research on Environmental Chemicals
MSDS	Material safety data sheet
NAC	National Advisory Committee
NDSL	Non-Domestic Substances List
NSFR	New Substances Fees Regulations
NSN	New Substances Notification
NSN	New Substance Notification
NSNR	New Substances Notification Regulations
NSP	New Substances Provisions
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PD	product development
PSL	Priority Substances List
RRR	Reduced Regulatory Requirement
SAGE	Science Advice for Government Effectiveness
SNAc	Significant New Activity
SNAN	SNAc Notice
TSMP	Toxic Substances Management Policy
UN	United Nation
WHMIS	Workplace Hazardous Material Information System

1. Introduction

This Draft final Report has been prepared by Milieu Ltd for the Brazilian Ministry of Environment with the aim of describing the Canadian model for chemicals management. As such the report provides detailed description of Canadian legislation and procedures for chemical risk assessment, managing the risks of chemicals, enforcing legislation, making information available to the public and involving stakeholders, as well as steps towards implementation of the UN Globally Harmonized System of Classification and Labelling of Chemicals.

The Government of Canada has implemented a high number of legislative acts and programmes dedicated to protecting human health and the natural environment from chemical risks. Its primary legal tool for assessing and managing chemical substances in the environment is the **Canadian Environmental Protection Act** of 1999 (CEPA), which is jointly administered by the Ministry of the Environment, hereafter know as **Environment Canada**, and the Ministry of Health, hereafter know as **Health Canada**. Under CEPA, Canada has set up procedures for the comprehensive science-based assessment of both existing substances, i.e. those substances considered known to the Canadian market, and new substances introduced to the Canadian market, through the **Existing Substances Program** and the **New Substances Program**. While the actual assessment of substances is undertaken by Environment Canada and Health Canada, CEPA gives these bodies powers to demand information from chemical suppliers and users, including requirements for testing.

Under the Existing Substances Program, Canada became the first country in the world to take a systematic look at existing substances when it began to categorizing the approximately 23,000 substances on Canada's **Domestic Substances List** (DSL), a list of chemicals known to be on the market in Canada. When the program was launched, the vast majority of these existing substances had never been examined for their environmental or health effects in Canada. These 23,000 substances have now undergone a categorisation process in order to identify those substances that required additional assessment, on the basis of risks to the environment or human health. Following a prioritisation process known as screening assessment, a large number of substances prioritised on the basis of their potential impacts have now been subject to assessment.

In addition, risk management measures for existing substances are foreseen under the Existing Substances Program. This includes the listing of substances found to be toxic in a **Toxic Substances List**, allowing the Government of Canada to then proceed with regulations, pollution prevention plans or environmental emergency plans for these substances. Risk management measures for toxic substances are developed through the **Toxics Management Process**, involving stakeholder

consultation and subject to a time limit. Substances that are persistent, bioaccumulative and toxic (PBT) are added to the **Virtual Elimination List**, with the aim of reducing releases to the environment of these substances to a level below which release can be accurately measured. Other measures include controls on exports of specific toxic substances, or the prohibition of certain toxic substances. Finally, substances produced or distributed in Canadian commerce are subject to the **Canadian Hazardous Products Act** (CHPA), which regulates the use of controlled substances primarily in consumer products. For controlled substances, suppliers must also comply with **Workplace Hazardous Material Information System** (WHMIS), a system similar in nature to the GHS.

Under the New Substance Program, new substances, i.e. substances that are those not listed on the DSL, undergo health and environmental risk assessments before importation into, or manufacture in, Canada. Under CEPA, any "person" manufacturing a new substance in or importing a new substance into Canada must provide a **New Substance Notification** (NSN) package to the New Substances Program. A NSN package must contain administrative and technical information, a fee (if applicable), and must conform to data requirements and timing according the substance category. The substance category depends on a range of factors, including the type of substance (e.g. chemicals and polymers), the tonnage that will be imported or manufactured, the intended use of the substance (e.g. research and development) and the circumstances associated with its introduction. In addition, the Program distinguishes between entirely new substances, and new substances that are accepted as being in commercial use internationally, with the latter listed on the **Non-Domestic Substances List** (NDSL). Substances on NDSL must also be notified, but are subject to lesser information requirements. For new substances not on the NDSL produced or on the market at 1 tonne + and for NDSL substances at 10 tonne +, test results are required, with increased requirements for non NDSL substances at 10 tonnes+.

Specific risk management measures are foreseen for controlling the risk associated with new substances in a pro-active manner. These include the use of **Significant New Activity Notices** to keep track of and control new and expanding activities with new substances, and the enactment of **Ministerial Conditions** requiring the implementation of risk management measures for specific new substances.

CEPA also includes provisions for the enforcement of requirements regarding chemical risk management, as well as relevant provisions on research and monitoring, information gathering, public participation and stakeholder participation.

In 2006, Canada launched the **Chemicals Management Plan** (CMP), with the aim of protecting human health and the environment by systematically assessing chemicals used in Canada and implementing a number of initiatives to manage the risks of chemicals. Since then, chemicals management measures have been conducted under the framework of the CMP. Implementation of the CMP is on-going; with Phase I now complete and work on Phase II begun.

In this introduction, we start by describing the roles of these key bodies in administering chemicals management legislation in section 1.1, including Environment Canada, Health Canada and the National Advisory Committee. Section 1.2 provides an overview of CEPA, including a more detailed introduction to the Existing Substance Program and the New Substance Program. Section 1.3 described the CMP in more detail, including a discussion of the main initiatives and approaches undertaken thus far and planned for the coming years. Finally, in section 1.4 we introduce some of the key policies that serve to frame chemicals legislation in Canada.

1.1. Chemicals Management Infrastructures

Environment Canada and Health Canada are responsible for proposing and implementing chemicals management legislation in Canada, with support for a National Advisory Committee. Health Canada and Environment Canada jointly launched the 2006 Chemicals Management Plan. These bodies and their responsibilities are briefly described below.

1.1.1. Environment Canada

Environment Canada was first created in 1971 and works to protect and conserve Canada's air, water, wildlife and spaces. Environment Canada is a science-based department, providing the science and technology information needed to make informed decisions about the environment. In addition, Environment Canada operates 15 research institutes and laboratories, as well as 32 water survey offices. Environment Canada is jointly responsible for administration of chemicals management legislation in Canada, with a focus of questions related to ecotoxicity and environmental impacts.

The Existing Substances Division at Environment Canada works to establish whether or not specific substances may threaten human health or the environment and should be considered for risk management. Assessment of New Substances is undertaken by the New Substances Division at Environment Canada. This division is also responsible for receiving New Substance Notifications from industry.

1.1.2. Health Canada

Health Canada is the Federal department responsible for helping Canadians maintain and improve their health. With regards to chemicals, Health Canada is involved in efforts to reduce the risks to human health through a range of tools, from providing information about proper use and disposal, to regulations that restrict or even ban use. Health Canada provides a wealth of materials to the public and for the operators of private activities on how to protect human health from chemical risks. Health Canada also conducts biomonitoring in order to generate data that can serve as an indicator and quantitative measure of exposure to chemicals in the environment, in order to increase understanding of exposure and provide information to inform the management of the health risks posed by chemicals.

The Existing Substances Division at Health Canada is responsible for the assessment of potential risks to human health posed by existing substances in Canada. The New Substances Assessment and Control Bureau at Health Canada assesses the potential human health risks to the general population associated with new chemical substances, pre-production or pre-import.

1.1.3. National Advisory Committee

In Canada, municipal, provincial, territorial and federal governments all play a role in managing chemical substances. CEPA established a National Advisory Committee (NAC) composed of one representative for each of the federal Ministers of the Environment and Health, representatives from each province and territory and six representatives of aboriginal governments drawn from across Canada. An aboriginal government means a governing body that, through an agreement with the Government of Canada, is authorized to enact laws respecting the protection of the environment or the registration of vehicles or engines.

The Committee advises the Ministers on actions taken under the Act, which enables national, cooperative action and avoids duplication in regulatory activity among governments. The Committee also serves as the single window into provincial and territorial governments and representatives of aboriginal governments on offers to consult. The duties of the NAC include advising the federal Ministers of the Environment and Health on:

- proposed regulations for toxic substances;
- proposed regulations on environmental emergencies;
- a cooperative, coordinated approach to the management of toxic substances; and
- any other matter of mutual interest.

1.2. The Canadian Environmental Protection Act, 1999

The Canadian Environmental Protection Act, 1999 (CEPA 1999) is the main legislative tool for preventing pollution and protecting the Canadian environment. CEPA in implemented by Health Canada and Environment Canada, which are required to ensure that a number of key principles in CEPA are upheld. These include ensuring that:

- there is public participation, openness and transparency in decision making and that there are mechanisms available for supporting these goals;
- there is commitment to promotion of human health and implementation of pollution prevention, as national goals;
- the Government of Canada is able to fulfill its international obligations with respect to the environment;
- the precautionary principle is implemented;
- the polluter pays principle is implemented;
- the importance of an ecosystem approach is recognized;
- the risk of toxic substances is recognized as a matter of national concern that transcends geographic boundaries;
- a consistent process for collaboration with other jurisdictions results in effective and integrated approaches, policies and programs to manage the risks to human health and the environment posed by the threats of toxic substances; and
- action is taken to apply all aspects of the program in a fair, predictable, transparent and consistent manner.

With regards to chemical risk assessment, Part 4 on Existing Substances and Part 5 on the New Substances Notification Regulations provide the legislative framework for the assessment and management of chemical substances. The legal framework aims to ensure the protection of the environment and of the health of Canadians from harmful substances and other pollutants. These programs are briefly introduced below.

1.2.1. Existing Substances Program

The Existing Substances Program implements the risk assessment of existing substances under CEPA. Specifically, the program identifies, prioritizes, and assesses substances that have been or are currently used in Canada as commercial substances or products, or are released into the Canadian environment on their own or as effluents, mixtures or contaminants and that pose risks to the health of Canadians and the environment. Risk managers within Environment Canada and Health Canada use

the results generated by risk assessments to develop suitable responses under CEPA to manage the risks posed by substances that are considered toxic.

Under the Human Health Existing Substances Program, the **Existing Substances Division** of Health Canada categorizes chemicals on the basis of toxicity, conducts screening assessments and priority substances assessments for human health. The **Environment Existing Substances Division** at Environment Canada categorises chemicals on the basis of ecotoxicity and assesses environmental risk. Health Canada and Environment Canada provide a scientifically rigorous, open and transparent process for assessing the risks posed by existing substances in Canada. They also provide information that supports actions on chemical substances that ultimately protect human health and the environment.

Existing substances include those on the Domestic Substances List (DSL). The DSL is a compilation of about 23,000 substances used, imported or manufactured in Canada for commercial purposes between January 1, 1984, and December 31, 1986, at a quantity of greater than 100 kg per year. Substances that are not listed on the DSL are considered to be new to Canada.

Part 4 of CEPA provides the framework for the identification, prioritization and assessment of existing substances and for the control or management of those considered to pose a risk. This framework is broad, open, transparent and evidence-based, taking into account aspects (i.e., exposure and effects) of a substance related to the potential risk it may pose, and it builds upon work done in other jurisdictions.

The principal phases of identification and assessment of priorities for risk management of existing substances specified under CEPA are categorization and screening assessment. The first step, **categorisation**, is now complete and determined which existing substances met the criteria of being potentially harmful to the environment or human health, in order to prioritise them for assessment. Prioritised substances were broken down into 12 batches, with the assessment of Batch 12 currently on-going.

Screening assessment aims to determine whether a substance meets the definition of toxic under CEPA. This then provides for the addition of the substance to Schedule 1 (the List of Toxic Substances) of the Act and for a review of further options for controlling risks to human health and/or the environment.

The Existing Substances Program is also involved in other federal, intergovernmental and international assessment initiatives including the Toxic Substances Management Policy (TSMP), and

the chemicals program of the Organization for Economic Cooperation and Development (OECD). The Existing Substances Program is discussed in detail under section 2.

1.2.2. New Substances Program

Canada has been screening and assessing new substances placed on the market since 1994. The New Substances Program is responsible for administering the New Substances Notification Regulations (Chemicals and Polymers) [NSNR (Chemicals and Polymers)] and the New Substances Notification Regulations (Organisms) [NSNR (Organisms)] of CEPA. Collectively known as the Regulations they are an integral part of Canada's national pollution prevention strategy. As part of the "cradle to grave" management approach for toxic substances laid out in CEPA, the Regulations were created to ensure that no new substances (chemicals, polymers or animate products of biotechnology) are introduced into the Canadian marketplace before an assessment of whether they are potentially toxic has been completed, and any appropriate or required control measures have been taken.

The New Substances Program consists of officials from both Environment Canada and Health Canada. The New Chemical Substances Sections of the New Substances Assessment and Control Bureau at Health Canada assesses the potential human health risks to the general population associated with new chemical substances, pre-production or pre-import. Under the Environment New Substances Program, the New Substances Division of Environment Canada assesses the potential environmental risks associated with new chemical substances.

Under the Program, Any company or individual who plans to import or manufacture a substance subject to notification under the Regulations must provide Environment Canada with a New Substances Notification (NSN) package containing all information prescribed in the Regulations prior to import or manufacture. The type of information required and the timing of the notification depends on such factors as the type of substance (hazard), the quantity that will be imported or manufactured, the intended use of the substance and the circumstances associated with its introduction (exposure). The New Substance Program is described in detail under section 3 of this report.

1.3. The Chemicals Management Plan

Launched in 2006, the Chemicals Management Plan (CMP) aims to protect human health and the environment by systematically assessing chemicals used in Canada, and by implementing a number of initiatives to manage the risks of chemicals. Jointly managed by Environment Canada and Health Canada, CMP is an integrated program that addresses environmental and health risks and ensures the

integration of current federal chemicals regimes for pesticides, cosmetics, foods and environmental risks posed by pharmaceuticals and personal care products.

Aspects of the Existing Substances Program involving the risk assessment of existing substances in Canada are managed under the framework of the CMP from 2006 onwards. Key elements of the CMP are presented in box 1 below.

Box 1: Key elements of Canada's Chemicals Management Plan

Class Assessment Approach for Aromatic Azo- and Benzidine-based Substances: Action on approximately 350 substances using a chemical class assessment approach, including aromatic azo- and benzidine-based substances that may degrade to produce certain aromatic amines or benzidines, and the corresponding aromatic amines or benzidines produced.

Regulations and enforcement: Immediate action on five substance categories confirmed to be harmful to the environment and to human health in the long run, moving toward prohibiting most uses, involving establishment of the Virtual Elimination List (see section 4.2) and revision of the Prohibition of Certain Toxic Substances

The Challenge: Categorization of substances on the DSL identified 200 chemical substances that are potentially harmful to human health or the environment that represent the highest priorities for risk assessment and appropriate controls. Canada is using existing tools and regulations to challenge industry to provide new information about how it is managing these 200 chemical substances. Substances have undergone screening assessment in 12 batches, with 11 batches now complete. Consultations on batch 12 are being finalized (see section 3.6).

Restrictions on re-introduction and new uses: This has been achieved through the CEPA provision on Significant New Activities, considered under section 5.3.1 of this report on the risk management of new chemicals.

Rapid screening of lower risk chemical substances: Based on the results from the categorization of substances on the DSL, 1066 substances were identified for application of a rapid screening approach. These substances included those that met categorization criteria as being inherently toxic (ecological) and either persistent or bioaccumulative (but not both), in addition to being in commerce in low quantities (maximum use in Canada of 1000 kg per year based on 1986 data) and are therefore expected to be of lower concern. Sixty-one substances initially included in the approach have been withdrawn for a variety of reasons. The rapid screening approach has now been applied to 1005 substances believed to be of low concern. None of the substances met categorization criteria for human health.

Accelerated re-evaluation of older pesticides: Re-evaluation of the remaining 200 older pesticides, targeted for completion by 2009, to determine if these pesticides meet today's health and environmental standards. Acceleration of the review and registration of new and reduced-risk pesticides, to potentially replace older pesticides removed from the market following a re-evaluation decision.

Mandatory ingredient labeling of cosmetics: On November 16, 2006, the Government of Canada brought into force amended Cosmetic Regulations requiring ingredient labelling on all cosmetic products.

Regulations to address environmental risks posed by pharmaceuticals and personal care products: The Government of Canada intends to work closely with stakeholders to complete the health and environmental assessments of more than 9,000 substances used in products regulated under the Food & Drugs Act. In addition the Government of Canada will work with stakeholders to promote best practices for the proper disposal of Food & Drugs Act products, such as pharmaceuticals and personal care products, to reduce the burden on the environment.

Enhanced management of environmental contaminants in food: Canada intends to strengthen the regulation of contaminants under the Food and Drug Regulations. Actions will be taken to identify and reduce these contaminants in the food supply and to minimize potential health impacts on Canadians. Consumers will be provided with up-to-date food safety information to help them make healthy food choices for themselves and their families.

Monitoring, surveillance and research: Building a build a monitoring and surveillance regime to track exposure to toxic substances.

Good stewardship of chemical substances: Involves assessing all of the existing substances that have been identified through categorization of the DSL via successive rounds of assessment and, where necessary, regulatory action. Additional activities include working with key sectors to develop and codify comprehensive sound management practices; ensuring that information about chemical substances, their hazards and also practices for their safe management is available to Canadians; improving product labelling programs; and enhancing the monitoring of consumer products.

There are three overall objectives of the Plan. Firstly, CMP challenges industry and other stakeholders to take immediate action on chemicals of high concern, in particular through the provision of information on chemicals through mandatory survey to feed into substance assessment under the Existing Substances Program. Secondly, CMP involves a range of other regulatory activities targeted at food, cosmetics, drugs or biological drugs and pesticides that are not detailed within this report. Thirdly, CMP aims to generate new investment in research and monitoring in order to learn more about the effects of chemical exposure on human health and the environment, as well as to provide the necessary means to measure the success of actions to control or reduce risks.

Of particular importance is the Challenge, involving the assessment of existing substances that were categorized as being high priority for risk assessment. In addition, there are a number of other initiatives that are important, including the Petroleum Sector Stream Approach and the Polymers Approach. These elements are briefly outlined below, before reviewing Phase 2 of the CMP and introducing the CMP Stakeholder Advisory Council.

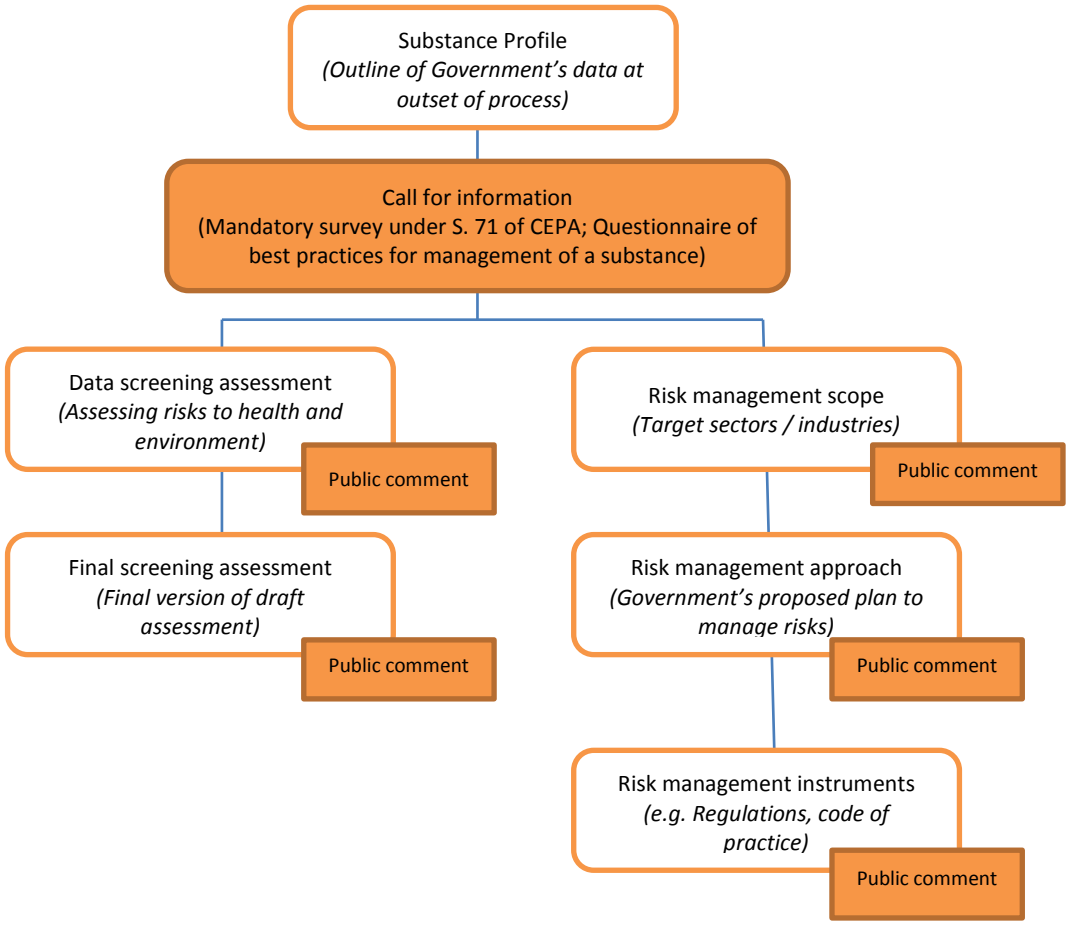
1.3.1. The Challenge

A key element in CMP is the collection of information on the properties and uses of the approximately 200 chemical substances identified through the categorization process as high priorities for action. This information will be used to make decisions regarding the best approach to protect Canadians and their environment from risks these substances might pose. This initiative is known as the CMP Challenge, with substances included in the challenge listed on the website of Environment Canada. Substances have undergone screening assessment in 12 batches, with 11 batches now complete. Consultations on batch 12 are being finalized (see section 2.5).

Environment Canada used the mandatory information gathering provisions of section 71 of CEPA to gather information deemed required for improved decision-making, including the use of Mandatory Survey Notices. Industry and interested stakeholders have also been invited to submit additional information that may be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship.

This information is used to feed into evidence-based decisions when assessing risks to human health and the environment, and developing measures to reduce these risks. Figure 1 outlines the process that is followed for each Challenge chemical.

Figure 1: The Challenge Process



Source: Chemical Substances website

1.3.2. The Substance Grouping Initiative

Under the Substance Grouping Initiative, Canada plans to assess and manage, where appropriate, the potential health and ecological risks associated with nine groupings of substances. The initiative includes the following substance groupings:

- Aromatic azo- and benzidine-based substances
- Boron-containing substances
- Internationally classified substances
- Certain organic flame retardants
- Cobalt-containing substances
- Methylenediphenyl diisocyanates and diamines (MDI/MDA)
- Phthalates
- Selenium-containing substances

- Substituted diphenylamines

Stakeholders are invited to indicate their interest in being engaged in discussions on one or more of these substance groupings by completing a Stakeholder Identification Form.

These substance groupings have been selected for further action based on the categorization exercise completed in 2006 and new information received as part of the first phase of the CMP. The groupings were identified based on structural or functional similarities and were assembled based on considerations related to assessment efficiencies, management efficiencies, the ability to support informed substitution decisions, timing of international actions and stakeholder engagement.

Timelines are being tailored to the needs of individual groupings, allowing for consideration of stakeholder engagement as well as risk assessment and risk management requirements. The proposed timeframes of key phases for each grouping and the launch month of initial stakeholder surveys are provided on the website of Environment Canada, and stretch from 2011 to 2016.

1.3.3. Petroleum Sector Stream Approach

The Petroleum Sector Stream Approach includes 164 substances identified as priorities for action through the categorization process and that were set aside to be addressed in a sectoral approach. A large portion of high priority petroleum substances are used or manufactured during petroleum refining or bitumen / heavy crude oil upgrading activities.

Initial information gathering has allowed the 164 Petroleum Sector Stream Approach Substances to be complied under 5 streams based on their production and uses:

- Stream 0- substances not produced by the petroleum sector and/or not in commerce;
- Stream 1- site-restricted substances, which are substances that are not expected to be transported off refinery, upgrader or natural gas processing facility sites;
- Stream 2- industry-restricted substances, which are substances that may leave a petroleum-sector facility and be transported to other industrial facilities (for example, for use as a feedstock, fuel or blending component), but that do not reach the public market in the form originally acquired;
- Stream 3- substances that are primarily used by industries and consumers as fuels;
- Stream 4- substances that may be present in products available to the consumer.

Environment Canada and Health Canada have developed a plan that includes information gathering, assessment of the substances, and development of risk management instruments, if required. There are 164 high-priority substances being assessed via this approach and of the 70 assessed to date, 40 will likely be concluded "toxic" in the final assessment and will likely be proposed for addition to the Toxic Substances List.

1.3.4. Polymers Approach

As a part of the Chemicals Management Plan, the Government of Canada plans to assess and manage, where appropriate, the potential health and ecological risks associated with certain polymers. These polymers were identified as priorities for further action during the categorization exercise of the DSL in 2006.

The Government of Canada has developed a proposed polymer approach to address these polymers. A tiered approach is proposed, taking into account the data requirements in the New Substances Program and the timing of upcoming information gathering initiatives. It is anticipated that this initiative will take place over multiple years, with high level information gathering and its analysis currently on-going, to be followed by the start of polymer specific surveys in 2014/2015. Further consultations on additional elements of the initiative are anticipated to occur throughout the process.

1.3.5. Phase 2 of the Chemicals Management Plan

In 2011, Canada launched the second phase of the CMP. Under this phase, Environment Canada and Health Canada will continue to work with all stakeholders for effectiveness and efficiency, invest in research and monitoring, work with international partners, and make information on chemicals publicly available. The next phase of the Plan will focus on:

- Further improving product safety in Canada;
- Completing assessments of 500 substances across nine categories including phthalates, primarily used in plastics; and,
- Investing in additional research for substances like Bisphenol A, flame retardants, substances that affect hormone function and substances that affect the environment.

Approximately 1,000 additional substances will also be addressed in the next five years through other initiatives, including rapid screening of substances which pose little or no risk.

1.3.6. Chemicals Management Plan Stakeholder Advisory Council

Under CMP, the Government of Canada has worked closely with health and environmental groups, consumer groups and industry to set clear priorities for the assessment and management of hundreds of chemicals. In doing so, the CMP Stakeholder Advisory Council was created. The Chemicals Management Plan Stakeholder Advisory Council is a multi-stakeholder group that contributes to the implementation of the Chemicals Management Plan (CMP). The purpose of the Council is to provide stakeholders the opportunity to offer advice and input to Government on the implementation of the CMP, and to foster dialogue on issues pertaining to the CMP between stakeholders and government, and among different stakeholder groups. Issues may include risk assessment, risk management, risk communications, monitoring, research, indicators of success, chemical policy, and other cross-cutting, integrated activities across the CMP.

The group holds a minimum of two meetings per year. Its current mandate is from April 2011 until March 31, 2016. Members represent National Aboriginal organizations, Consumer groups, Environment Non-Government Organizations, Health Non-Government Organizations and Industry (including associations, producers, users with a specific focus on downstream industry).

1.4. Approach to Chemicals Management

Program activities are guided by a variety of Government guidelines and policy documents, in particular Canada's Toxic Substances Management Policy, Science Advice for Government Effectiveness (SAGE) and Framework for the Application of Precaution in Science-based Decision Making about Risk. The manner in which these policy documents frame chemicals management in Canada is described below.

1.4.1. Toxic Substances Management Policy

The Toxic Substances Management Policy, introduced at federal level in 1995, takes a preventive and precautionary approach to dealing with substances that enter the environment and that could harm the environment or human health. It provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with the objectives of the policy. Some elements of the policy have been integrated into law through CEPA. The key management objectives of the policy are:

- the virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative (referred to as Track 1 substances); and
- management of other toxic substances and substances of concern throughout their entire life cycles, to prevent or minimize their release into the environment (referred to as Track 2 substances).

Consistent with this policy, risk managers at Health Canada and Environment Canada use the information provided by risk assessments to develop appropriate approaches to manage the risks posed by toxic substances. Through its risk assessment activities, the Existing Substances Program provides a key mechanism for identifying candidate substances for risk management, and feeds information into decision making by risk managers.

Toxic substances that are both persistent and bioaccumulative have been recognized as requiring special attention, as reflected in both domestic and international regulatory and policy frameworks. Once in the environment, it may be difficult or impossible to manage these substances or remediate past contamination. In addition, remote and cold regions, such as the Canadian Arctic, can act as global sinks for some of these compounds, making it important for Canada to act both domestically and internationally. Although it may not be possible to accurately predict all of the effects of these substances on the environment, the potential exists for these substances to cause long-term impacts. The use of a preventive approach in assessment of these substances is particularly important to ensure that harm to the environment and its biological diversity does not occur.

Box 2: Toxic substance definition under section 64 of CEPA 1999

"... a substance that is entering or may enter the environment in a quantity or concentration or under conditions that

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

Substances that meet the criteria set out under section 64 of CEPA (in box 2 above) are considered for risk management measures such as regulations, guidelines or codes of practice, to control any aspect of their life cycle, from the research and development stage through manufacture, use, storage, transport and ultimate disposal. More information on Risk Management can be found on the Management of Toxic Substances web section. Furthermore, when a substance meets the criteria set out under section 64 and is persistent, bioaccumulative and results primarily from human activity, it is proposed for virtual elimination under CEPA 1999.

1.4.2. Role of Science in Decision Making

A report on Science Advice for Government Effectiveness (SAGE) was developed by the Council of Science and Technology Advisors in May 1999 in response to the request by the Cabinet Committee on Economic Union to examine how the government could improve its use of science advice in reaching decisions and its explanations about how those decisions are reached. The report identifies key principles, including:

- Early Issue Identification;
- Inclusiveness;
- Sound Science and Science Advice;
- Uncertainty and Risk;
- Transparency and Openness; and
- Review.

The SAGE report provided the basis for the development of a government-wide set of principles and guidelines for the effective use of science in making policy and regulatory decisions, captured in the Government of Canada paper entitled "A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making" (Government of Canada, 2000). The principles and guidelines in the report address how science advice should be sought and applied to enhance the ability of government decision makers to make informed decisions. While some of these are suitably applied only at higher levels of the organization or at later stages of the toxics management process, many of them are directly applicable within the Existing Substances Program. Environment Canada's "Science Advice for Government Effectiveness: Recommendations for Implementing the SAGE Principles" and Health Canada's "Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks" demonstrate the Government of Canada's dedication to implementation of the SAGE principles.

1.4.3. Precaution in Science-based Decision Making

The Federal Government has developed a document entitled "A Framework for the Application of Precaution in Science-based Decision Making about Risk". This paper addresses the application of precaution in its various forms - "precaution", "the Precautionary Principle" or "the precautionary approach" - all of which have three basic components: the need for a decision; a risk of serious or irreversible harm; and a lack of full scientific certainty.

As stated in the document, the application of precaution primarily affects the development of options and the decision phases within science-based risk management, is clearly linked to scientific analysis, and cannot be applied without an appropriate assessment of scientific factors and consequent risks. A key role of developing ecological and human health risk assessments is to provide the necessary evaluation of science and potential risks to support the use of precaution in the ultimate decision making process, at which point factors such as social and ethical values and political and economic considerations will also be taken into account.

The "precautionary principle" is entrenched in CEPA 1999. In the preamble, CEPA 1999 recognizes that the "Government of Canada is committed to implementing the precautionary principle. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. In addition, section 76.1 of CEPA 1999 specifically directs the Ministers to apply a weight-of-evidence approach and the precautionary principle when conducting and interpreting the results of assessments of existing substances. General principles to guide application of the precautionary principle to decision making are presented in box 3 below.

Box 3: General principles of precautionary decision making

- The application of precaution is a legitimate and distinctive decision-making approach, notably within risk management.
- It is legitimate that decisions be guided by society's chosen level of protection against risk.
- In risk management, sound scientific information and its evaluation must be the basis for the decision to apply precaution and the measure selected in applying precaution; the scientific information base and responsibility for producing it may shift as knowledge evolves.
- Mechanisms should exist for re-evaluating the basis for decision and for providing a transparent process for further consideration, recognizing that in some cases re-evaluation may not be practical or productive.
- A high degree of transparency, clear accountability and meaningful public involvement are appropriate

2. Existing Substances Program

As discussed above, CEPA includes specific requirements regarding the assessment and management of substances currently existing in commerce or being released to the environment in Canada in Part 5, Sections 64 to 79 and Sections 90 to 99. Environment Canada and Health Canada jointly administer this part of the Act.

The three principal phases of the identification and assessment of priorities for risk management of existing substances specified under are categorization, screening assessment and in-depth Priority Substances List (PSL) assessment. One objective of the latter two phases, namely screening and full assessment, is to determine whether a substance is CEPA-toxic as defined in Section 64 of CEPA, which may then set the stage for addition of the substance to Schedule 1 (the List of Toxic Substances) of the Act and for reviewing options for controlling risks to human health and/or the environment.

In sections 2.1 to 2.8 below we described the roles of Environment Canada and Health Canada, the scope of substances included, as listed in the Domestic Substance List (DSL), and outline the approaches and procedures for substances risk assessment. We conclude by considering the requirements for implementing risk management measures in section 2.9.

2.1. Roles of Health Canada and Environment Canada

2.1.1. Environment Canada

The Existing Substances Division at Environment Canada performs the activities outlined in box 4, in order to establish whether or not specific substances on the DSL may threaten human health or the environment and should be considered for risk management.

Box 4: Roles of Existing Substances Division at Environment Canada

- Identifies substances for risk assessment -- Candidates are identified through seven mechanisms (feeders): 1) categorization of the Domestic Substances List (DSL), 2) industry-supplied information, 3) provincial or international decisions prohibiting or restricting substances, CEPA 1999), 4) public nominations to the Priority Substances List, 5) assessment of "new" substances similar to existing substances, 6) emerging science and monitoring, and 7) international assessment or data collection.
- Collects and manages data -- To support the identification of substances justifying risk assessment and risk management activities, ESD generates and collects scientific and technical information on the properties and amounts, concentrations, or nature of entry of any given substance in the Canadian environment, and monitors activities taking place elsewhere. Information or activities from the public domain, other federal departments, provinces and territories, other countries, industry, and science research programs is compiled, organized, and tracked.
- Sets priorities for assessments -- Once candidate substances have been identified, ESD focuses its resources on those most urgently needing assessment. This ensures an effective and efficient assessment process, and provides the risk management program with the means to effectively manage priorities.
- Conducts risk assessments -- When substances have been identified and priorities established, ESD reviews information and proposes decisions on substances in the Canadian environment. This involves problem formulation, entry assessment, exposure assessment, effects assessment, and risk characterization. ESD invites external scientific and technical experts from various groups to participate in the risk assessment process.
- Coordinates and integrates information -- ESD consults, liaises, and coordinates with provincial, territorial, and aboriginal governments, other federal departments and programs, stakeholders, international organizations, and other countries.
- Ensures communications -- ESD is committed to a well-understood, open and accountable process. This ensures that concerns of all Canadians are heard and ESD is abreast of emerging issues to make its endeavours and decisions intelligible to the public.

2.1.2. Health Canada

Health Canada is responsible for the assessment of potential risks to human health posed by existing substances in Canada. The Existing Substances Division conducts this work within Health Canada. As part of Health Canada's activities on existing substances, a human health screening assessment may be conducted on a substance identified from the categorization of the DSL, on a substance meeting criteria outlined under Section 75 of CEPA on actions taken by another Government, on a public nomination to the CEPA Priority Substances List, and on any other substance for which a human health screening assessment is desirable.

2.2. Risk Assessment under the Existing Substances Program

Risk assessments conducted under the Existing Substances Program may be conducted under one of the following procedures, including:

- Screening Assessments of substances that have been identified through the categorization of substances on the DSL, with the framework of the CMP “Challenge”;

- Priority Substances List Assessments;
- Reviews of decisions of other jurisdictions specifically prohibiting or substantially restricting substances; or
- Other assessments with the aim of making recommendations with respect to substances, including measures to control their presence in the environment.

Substances identified as priorities for risk assessments undergo a process which compares the effects of substances on humans or the environment to the potential for exposure. Assessments aim to determine if a substance meets the criteria set out under section 64 of CEPA, that is whether or not a substance *"is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity; constitutes or may constitute a danger to the environment on which life depends; or constitutes or may constitute a danger in Canada to human life or health"*.

Determining whether a substance meets the criteria set out under section 64 is therefore a function of its release into the environment, the resulting concentrations in environmental media and/or the potential for exposure in humans, and its inherent toxicity. Risk assessments are objective and science based, and not influenced by socio-economic considerations. The conclusion of the assessment is based on the application of the precautionary principle and a weight of evidence approach. Reports of risk assessments of existing substances completed under the Existing Substances Program are available on the website of Environment Canada.

Assessment of substances involves reviewing and characterizing information collected, and integrating this information on exposure and effects by considering the weight of evidence to reach a conclusion regarding the potential for risk to humans or the environment. The Existing Substances Program uses all scientifically robust information available at the time of the assessment to make conclusions on risk using a weight-of-evidence approach. Detailed information on the various aspects of the assessment process, including technical guidance on methods used to conduct assessments, may be found in Existing Substances Program guidance documents.

2.2.1. Principles and Approaches for Risk Assessment

Timely delivery of a credible risk assessment outcome is determined both by the administrative procedures that are followed and by the robustness of the science that forms the basis of the assessment. The Existing Substances Program applied a number of principles and approaches that have been derived from overarching guidelines and policies, such as those previously mentioned

(particularly the SAGE and the Precautionary Principle). These principles and approaches are presented in box 5 below.

Box 5: Principles and approaches for risk assessment

- **Predictability:** In order to foster consistency and predictability of the assessment process, the approaches taken to identify and analyze information and to characterize entry, exposure, effects and risks will be documented in publicly available guidance documents.
- **Innovation:** Approaches to risk assessment are constantly changing as science evolves. In addition, risk assessors may often face situations where assessments must be conducted for substances for which there is limited information relating to their properties, release, exposure or effects. The Existing Substances Program will use the latest tools and approaches, potentially in conjunction with domestic or international partners, to produce faster, more efficient, and technically solid assessments.
- **Openness and inclusiveness:** A key to achieving timely and credible assessment outcomes is stakeholder engagement. Ongoing consultations with interested parties at specific stages in the assessment process will demonstrate the Program's commitment to openness and inclusiveness. Furthermore, publicly available documents describe various aspects of the Program, including its policies, processes, and the technical approaches used in conducting assessments.
- **Information management:** In order to conduct rigorous assessments, the Existing Substances Program requires a wide range of substance-specific data including chemical and physical properties, quantities manufactured, quantities used and imported in Canada, its movement and persistence in the environment, effects on humans, effects on animals and plants, concentrations in the environment, and the results of long-term and short-term exposure to the chemical substance. The Existing Substances Program collects this information in a variety of ways, including literature searches and modelling exercises, and may generate this information by conducting or supporting research and, testing and conducting surveys. Also, stakeholders are expected to participate actively in providing the program with input at the outset of an assessment. All information will be rigorously analysed in order to ensure that the information used in the assessment is scientifically sound.
- **Use of sound science:** Approaches used by the Existing Substances Program to carry out risk assessments will be consistent with those used in regulatory assessments internationally. Methods presented in technical guidance documents are thoroughly reviewed and discussed. In assessing specific substances, external expertise will be sought, when appropriate, in conducting the assessments. In addition, draft assessments will be subjected to an external science review step, involving appropriate experts from government, academia, industry, or non-governmental organizations, notably targeting input on critical technical issues. Peer review may include multiple steps depending on the issues at hand.
- **Transparency:** Maintaining transparency is a key to credible assessment and management of the risks of substances. The Existing Substances Program recognizes that clear communication of uncertainties is an important part of achieving transparency. To satisfy the need for transparency, as well as to support sound assessment and risk management decisions, uncertainties as well as the approaches or assumptions made in dealing with those uncertainties will be recognized explicitly in any assessment.
- **Use of a weight-of-evidence approach and precautionary principle:** Section 76.1 of CEPA 1999 states that when conducting and interpreting the results of an assessment, a weight-of-evidence approach and the precautionary principle shall be applied. Under the Existing Substances Program, a weight-of-evidence approach and the precautionary principle will be used throughout the risk assessment and management process. Precaution in an assessment will usually be manifested through conservative assumptions or by considering the thoroughness, consistency, concordance, plausibility and other factors affecting the robustness of independent experimental observations.
- **Accountability:** The Existing Substances Program recognizes that assessment activities may require engagement from various stakeholders. However, the Program retains ultimate accountability for timely delivery of its publicly stated assessment objectives, and its performance will be measured on that basis.

2.2.2. Identifying Substances for Risk Assessment

Candidates for risk assessment under the Existing Substances Program are identified through seven main mechanisms (or "feeders") of equal importance:

- **Categorization of the DSL**: resulting in the identification of approximately 200 chemical substances through the categorization process as high priorities for action. These substances were divided into batches 1-12 for sequential screening assessment under the CMP Challenge. Eleven batches have been assessed and assessment of batch 12 is on-going.

- **Industry information:** Sections 70 and 71 of CEPA are information gathering provisions. 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. Section 71 allows Environment Canada 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. Environment Canada may request existing information or to require sampling, testing and the generation of new data.

- **Information exchange and review of decisions of other jurisdictions:** Section 75 of CEPA requires Environment Canada, to the extent possible, to cooperate and develop procedures for exchanging information on substances with other governments in Canada and OECD member states. Also, decisions made by these other jurisdictions to prohibit or substantially restrict substances for environmental or health reasons are to be reviewed to determine whether the substances are "toxic" or capable of becoming "toxic".

- **Nominations to the Priority Substances List (PSL):** Section 76 of CEPA 1999 requires the Environment Canada and Health Canada to establish and maintain the Priority Substances List (PSL), which specifies substances to which priority should be given in assessing whether they are toxic or capable of becoming toxic. Any person may request that a substance be added to the PSL. Environment Canada and Health Canada determine whether nominated substances should be prioritized for assessment and added to the PSL.

- **New substances notifications:** The CEPA 1999 approach to the control of new substances is both proactive and preventative, employing a pre-import or pre-manufacture notification and assessment process. When this process identifies a new substance that may pose a risk to health or

the environment, the Act empowers Environment Canada to intervene prior to or during the earliest stages of its introduction into Canada. The New Substances Program provides advance warning as well as knowledge of commercial chemicals that may be of concern. It also allows the Existing Substances Program to identify substances or classes of chemicals on the DSL that may have chemical properties similar to those managed under the New Substances Program.

- **Emerging science and monitoring:** The tracking of information from emerging science and monitoring studies allows the government to identify and respond to emerging concerns. Canada is working closely with government research institutes and Canadian universities, through informal working relationships, workshops and conferences, to keep abreast of new science and environmental monitoring information that give rise to concerns.

- **International assessment or data collection:** Many international programs deal with the risk assessment or risk management of industrial chemicals and identify substances for which some action should be considered. These programs also promote the mutual acceptance, and shared use of data, and the development of harmonized policies for managing risks to human health and the environment. Canada actively participates in the OECD Chemicals Programme and has established a strong relationship with the U.S. Environmental Protection Agency's Existing Chemicals Program to exchange information on substances of concern.

2.2.3. Other Triggers for Risk Assessment

Other assessments may be triggered by information provided by other programs, industry and scientific research. CEPA require persons to submit information on substances where a significant new activity for a substance has been identified. A significant new activity (see section 3.3.1) is an alternative use of the substance or other activity that results or may result in:

- a significantly greater quantity or concentration of the substance in the environment; or
- a significantly different manner or circumstances of exposure of the environment to the substance.

Significant new activities can apply to existing substances on the Domestic Substances List or new substances. The government assesses the new information on the substance to determine if it is toxic in relation to the significant new activity. CEPA requires that persons who obtain new information on a substance that indicates it might be toxic must submit this information to the government.

2.3. Existing Substances on the Domestic Substances List

The Domestic Substances List (DSL) includes substances that, from 1st January 1984 to 31st December 1986, were in commercial use, were used in manufacturing, were manufactured in or imported into Canada in quantities of ≥100 kg per year. CEPA defines a substance as any distinguishable kind of organic or inorganic matter, whether animate or inanimate, that is can be released as a single substance, an effluent, emission, waste or a mixture into the Canadian environment. Substances not on this list are considered to be new to Canada and must be assessed under the New Substances Program. DSL currently contains approximately 23,000 substances from the original list along with an additional 1,954 substances that have been added to the list following assessments of new substances.

As such, in 2006 there were about 23,000 substances on the list that could be manufactured in, imported into, or used in Canada on a commercial scale, but that had not been assessed for the risks they pose to the environment or human health. CEPA requires that all 23,000 of these un-assessed existing substances be sorted or "categorized" to determine which need further attention. The approach to categorising substances for assessment is described in section 2.5 below.

2.3.1. Domestic Substances List Update

The DSL was first compiled in the early 1990s to identify substances that were in commerce in Canada between 1984 and 1986. At the time of compilation, basic information such as substance quantities, uses and industry sectors involved were collected. The DSL information is now dated and may no longer represent current commercial activity in Canada. Updates do not include all substances on the DSL, but focus on subsets of substances based on priorities identified through the CMP. The work to update the DSL, undertaken under the Chemicals Management Plan (CMP), is separated into Phases, shown below. Phase 1 is now complete and work is underway on Phase 2.

- Phase 2 - 2012 Section 71 Notice (Mandatory Survey)
- Phase 1 - 2009 Inventory Update Information Summary - Chemicals
    - 2009 Section 71 Notice (Mandatory Survey) - Chemicals
    - 2009 Section 71 Notice (Mandatory Survey) - Micro-organisms

Under Phase 1, a Notice was issued in 2009 to collect data using a mandatory survey from those that manufactured or imported chemical substances, whether alone, in a mixture, in a product, or in a manufactured item during the 2008 calendar year. This Notice applied to approximately 500 chemicals, complementing the information collected or generated as part of the DSL categorization

process, in order to inform prioritization of these substances and subsequent risk assessment and risk management activities. An Update of Approximately 500 inanimate substances (chemicals) on the DSL (Information Summary) is available.

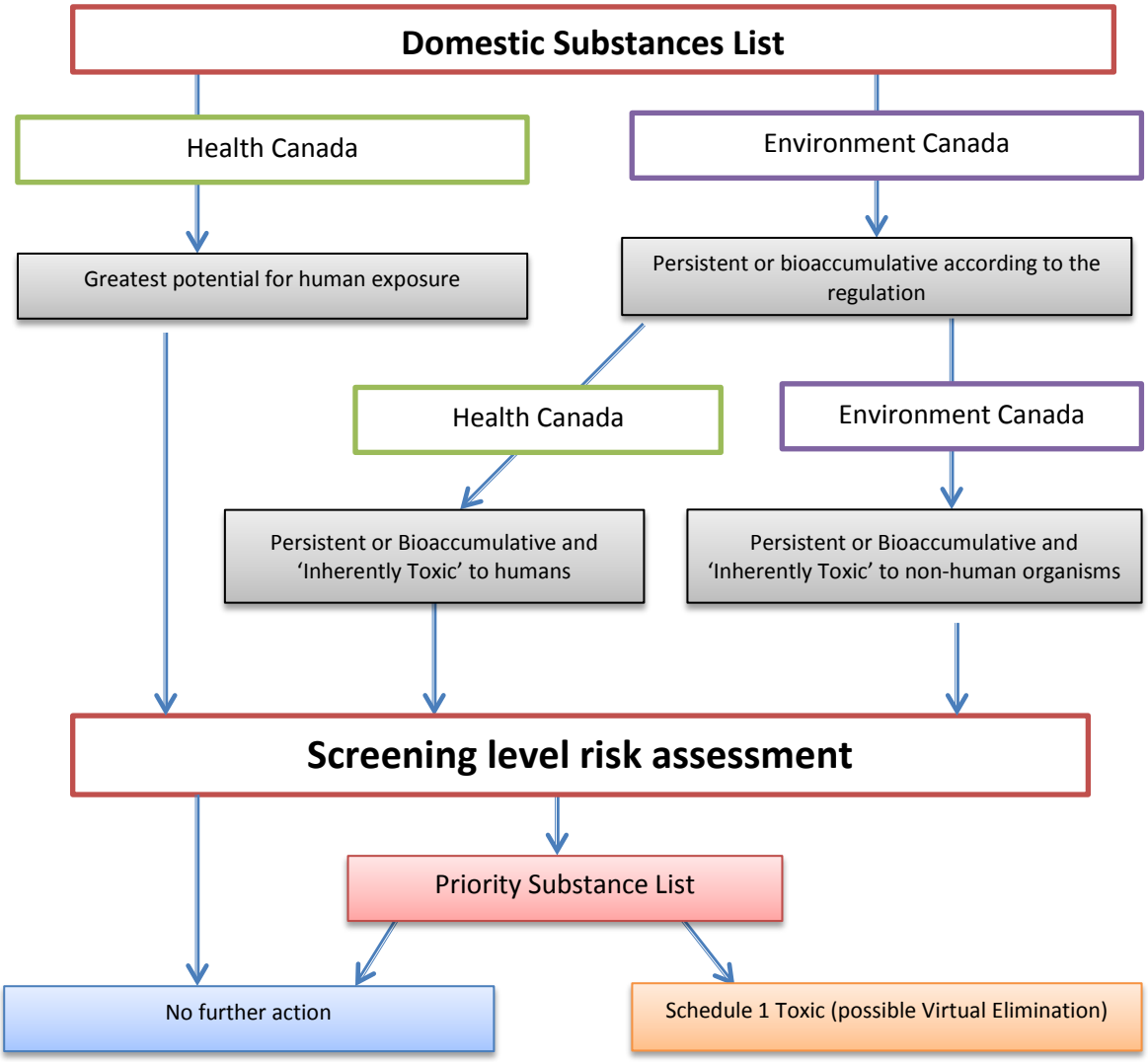
Building on Phase 1, an inventory update of the use and volume information on the remaining priority substances identified through categorization is required in the second phase of the CMP. In December 2012, a Notice was issued in the Canada Gazette, Part I: Vol. 146, No. 48 - December 1, 2012 under CEPA section 71. This Notice applies to approximately 2,700 Substances. Every person to whom this Notice applies is required to comply with the Notice by September 4, 2013.

In addition, persons who do not meet the reporting requirements of the Notice, but who have a current or future interest in any of the substances listed in the Notice, are encouraged to identify themselves as a stakeholder for the substance by completing the voluntary Declaration of Stakeholder Interest. Organizations that may be interested in submitting additional information include those that manufacture, import, export or use a substance, whether alone, in a mixture, in a product or in a manufactured item.

2.4. Categorization and Screening of Existing Substances

In September 2006, Environment Canada and Health Canada completed the categorization of all 23,000 existing substances on the basis of scientific evaluation. The resulting information is now being used to focus on those chemical substances of highest priority. Figure 1 below shows the key steps in categorization and the subsequent screening of substances.

Figure 2: Categorization and Screening Process



Source: Existing Substances Program website

Categorization was essentially an initial priority setting mechanism, which involved the systematic review of all DSL substances. Using information from Canadian industry, academic research and other countries, Government of Canada scientists worked with partners in applying a set of rigorous tools to the 23,000 chemical substances on the DSL. They were categorized to identify those that were:

- **inherently toxic** to humans or to the environment and that might be **persistent** (take a very long time to break down), and/or **bioaccumulative** (collect in living organisms and end up in the food chain)
- substances to which people might have **greatest potential for exposure**.

These categories are outlined briefly below.

2.4.1. Persistence, Bioaccumulation and Inherently Toxic to the Environment

Environment Canada was responsible for identifying and assessing the environmental risks of chemical substances that were suspected to be:

- **Persistent (P)**: chemical substances that take a very long time to break down in the environment - sometimes many years. These substances can affect the environment for a long period of time. Because they last for so long, they can travel long distances and pollute a much wider area than those substances that break down quickly; or
- **Bioaccumulative (B)**: chemical substances that can be stored in the organs, fat cells or blood of living organisms and remain for a long time. Over time, concentrations can build up and reach very high levels, and can also be transferred up the food chain; or
- **Inherently Toxic to the Environment (iTE):** chemical substances that are known or suspected, to have a harmful effect on wildlife.

Further details on the criteria and methods for prioritizing substances is available on the Environment Canada website.

2.4.2. Greatest Potential for Human Exposure and Inherently Toxic to Humans

Health Canada was responsible for identifying substances that have the Greatest Potential for Exposure or are Inherently Toxic to Humans. These two criteria are described as follows:

- **Greatest Potential for Exposure (GPE)**: when assessing human exposure to chemical substances, scientists look at more than persistence and bioaccumulation. Some shorter-lived substances might affect humans just as often as persistent ones. To get the complete picture, scientists look at how a substance is used. On the DSL, Health Canada identified those chemical substances suspected to be the ones that people are most likely exposed to.
- **Inherently Toxic to Humans (iTH)**: these are chemical substances that are known or suspected of having harmful effects on humans. Substances were examined for a number of human health effects, including cancer, birth defects and damage to genetic material.

Chemical substances that can potentially affect human health were prioritized for attention by the Government of Canada in order to address the risks of those substances suspected of presenting the highest hazard and greatest potential for exposure. Further information is available on the website of Health Canada.

2.4.3. The Results of Categorization

Following categorization, approximately 4,300 substances were identified as conforming to the characteristics of being inherently toxic to humans or non-humans (iT) and persistent (P) and/or bioaccumulative (B) according to the Persistence and Bioaccumulation Regulations, and those presenting the greatest potential for human exposure. Of these, 500 were considered high priorities, 2,600 were considered medium priorities, and 1,200 were considered low priorities for action. In many cases, more information is required to determine if these substances pose a risk to human health and/or the environment. Roughly 19,000 chemicals do not need further action at this time. Having these characteristics indicated that "the Government should assess the risks that may be associated with their continued use in Canada". This assessment is now taking place under the Chemicals Management Program (CMP), launched in 2006. These substances were divided into batches 1-12 for sequential screening assessment under the CMP "Challenge". Eleven batches have been assessed and assessment of batch 12 is on-going.

Categorization created a database of information on existing chemicals that will feed into decision-making on chemicals for years to come. Information from categorization is publically available to everyone in Canada, including those who need to assess risks and make decisions about managing and using chemical substances. The results of categorization can be accessed using an online search engine for the DSL. Lists of DSL substances that do not meet the categorization criteria and that do meet the categorization criteria can be downloaded, with the latter broken down by specific category (i.e. iT, PBT, BT, PT, health criteria). There is also a list of additional substances that did not meet the strict criteria of the categorization exercise, but do require further attention from a human health perspective.

2.5. Screening Assessment

The chemical substances identified as meeting the categorization criteria and needing a more thorough examination were then sorted through a screening assessment to identify those of the greatest potential for concern. A screening assessment (SA) involves a more in-depth analysis of a substance to determine whether the substance is "toxic" or capable of becoming "toxic" as defined in CEPA. As such, screen assessment involved a health screening assessment conducted by the Existing Substances Division of health Canada, and an environmental screening assessment conducted by the Existing Substances Division of Environment Canada.

This work is being undertaken in batches and is taking place within the framework of the CMP "Challenge". Eleven batches have been assessed thus far with the assessment of batch 12 on-going. Environment Canada maintains a List of Substances included in the Challenge, with files downloadable in Excel and Word.

2.5.1. Health Screening Assessment

Health screening assessments involve a focused comparison of critical data on exposure and effect i.e., those that have direct impact on either estimates of exposure of the general population in Canada or the measure of dose-response with which estimates of exposure are compared. Critical data are identified based on a comprehensive search and peer review of available data. These assessments involve an iterative approach where, in the first instance, upper bounding estimates of exposure are compared with lowest reported effect levels. The extent of assessment is limited to that necessary to determine that a substance is not a priority for risk management. For substances where margins of exposure are small, or for which it is assumed that there is some probability of harm at all levels of exposure for critical effects, comparisons of exposure and effects are refined increasingly taking into account weight of evidence for hazard and mode of action, as necessary, to permit meaningful conclusion and provision of advice for next stages. Data which would permit more definitive conclusion are also identified.

Following their assessment, Health Canada releases a draft State of the Science Report provides early access to the human health science for the substance. A State of the Science Report on an existing substance presents the technical/scientific basis for the corresponding human health screening assessment.

Depending on the content of the draft State of the Science Report, Health Canada may invite submission of information from relevant industry representatives regarding their existing or planned control measures for the substance(s) addressed in the Report. Health Canada and/or Environment Canada may also initiate consultations with industry representatives concerning such measures. State of the Science Reports are available online.

2.5.2. Environmental Screening Assessment

This determination of toxic to the environment consists of integrating the assessment of known or potential exposure of a substance with known or potential adverse effects on the environment (ecotoxicity). The exposure or potential for exposure of a substance depends on the amount of

substance released into the environment and its fate. The exposure assessment therefore consists of evaluating any known environmental concentrations of a substance, as well as predicting environmental concentrations of a substance from releases resulting from its production, processing, uses and disposal, and its environmental fate evaluated on the basis of intrinsic physical/chemical properties, environmental mobility, and its persistence.

The quality and detail of information available to conduct the SA influences the methods used. Information is be sought out from a variety of sources, including published scientific journals and databases, international reports, computer modelling estimates, and as necessary, through direct contact with industry. Notices under Section 71 of CEPA can be issued to companies obliging them to provide the requested information if available. Failure to do so may result in legal repercussions.

As a learning exercise, a Pilot Project for screening assessments was initiated by Environment Canada and Health Canada in 2001. This Pilot Project initially identified 123 substances which were expected to meet the categorization criteria of 1) being persistent and/or bioaccumulative and inherently toxic to human and non-human organisms and/or 2) having a high potential for exposure to Canadians. The objectives of the Pilot Project were to refine both process and scientific aspects of the Existing Substances Program. Specifically, the objectives were to refine the screening assessment process; develop and adopt tools and approaches for screening assessments; develop approaches for setting priorities for screening assessments; and engage stakeholders on new approaches for screening assessments and priority-setting. As a result of the September 2006 categorization decisions, of the list of 123 substances in the Pilot Project, 91 met the categorization criteria, 5 had uncertain categorization outcomes and 27 did not meet the criteria.

2.5.3. Publication of Screening Assessment in the Canada Gazette

A CEPA draft summary screening assessment and its associated conclusion and/or measure proposed are published in the Canada Gazette for public comment. A CEPA summary screening assessment usually consists of both the environmental and human health components. When notice of a proposed conclusion and/or measure is published in the Canada Gazette, any person may provide to the individual identified therein, written comments on the proposed conclusion and/or measure, as well as on the scientific considerations upon which they are based.

Following this comment period, the draft State of the Science Report may be revised as considered appropriate, and the CEPA final summary screening assessment and conclusions and/or proposed measure will be published in the Canada Gazette.

2.5.4. Outcome of the Screening Assessment

A screening assessment results in one of the following outcomes as prescribed in CEPA under Section 77(2):

- no further action is taken at this time in respect of the substance, if the SA indicates that the substance does not pose a risk to the environment or human health;
- the substance is added to the CEPA Priority Substances List in order to assess more comprehensively the risks associated with the release of the substance, if the substance is not already on the List; or
- it is recommended that the substance be added to the List of Toxic Substances in Schedule 1 of CEPA, substances on Schedule 1 can be considered for regulatory or other controls.

2.5.5. Rapid Screen Assessment

Within the context of the CMP and based on the categorization of DSL substances, 1,066 substances were identified for application of a Rapid Screening Approach. These substances included those that met categorization criteria as being inherently toxic (ecological) and either persistent or bioaccumulative (but not both), in addition to being in commerce in low quantities (maximum use in Canada of 1000 kg per year based on 1986 data) and are therefore expected to be of lower concern. Sixty-one substances initially included in the approach have been withdrawn for a variety of reasons. The rapid screening approach has now been applied to 1,005 substances believed to be of low concern. None of the substances met categorization criteria for human health.

In April 2013, the Final screening assessment of substances of low concern was released and the related Notice was published in the Canada Gazette, Part I: Vol. 147, No. 17 - April 20, 2013. The final screening assessment concluded that 533 of the 1005 substances of low concern do not meet the criteria as set out in CEPA section 64. The remaining 472 of the 1,005 substances which underwent rapid screening have been identified as requiring further screening assessment in order to evaluate their potential to cause harm. These substances will be addressed with other substances moving forward in the Chemicals Management Plan.

2.6. Priority Substances List Assessments

CEPA requires Environment Canada and Health Canada to establish a Priority Substances List (PSL) that identifies substances to be assessed on a priority basis to determine whether they pose a

significant risk to the health of Canadians or to the environment. In addition, any person may request that a substance be added to the PSL. Assessments of substances placed on the PSL are the shared responsibility of Environment Canada and Health Canada and involve an in-depth assessment of the potential risk associated with a substance.

2.6.1. Priority Substance List

CEPA requires the Ministers of the Environment and of Health to establish a Priority Substances List (PSL) that identifies substances to be assessed on a priority basis to determine whether they are toxic (as defined under CEPA Section 64) and pose a risk to the health of Canadians or to the environment. Assessments of substances placed on the PSL are the shared responsibility of Environment Canada and Health Canada. A Priority Substance may be a chemical, a group or class of chemicals, effluents or wastes.

The main objective of the Priority Substances Assessment Program is to ensure that accurate and scientifically valid assessments of the PSL substances are completed. Thus far, two lists of Priority Substances have been evaluated, PSL1 and PSL2. Assessments of the first 44 substances placed on the list (PSL1) were completed by February 1994. Following the recommendations of a multi-stakeholder Expert Advisory Panel, 25 substances were added to the list (PSL2), published in 1995. PSL2 including single chemicals as well as mixtures and effluents and assessment information is available online.

Environment Canada provides a website, Status of Prioritized Substances, documenting the status of each substance identified as a priority for further action during the categorization process. This list builds upon those that were posted on the CEPA Registry following the completion of categorization. It focuses on the priorities to be addressed, denotes under which initiative these priorities are being addressed, and includes new priorities identified since 2006. The list is not static, but rather as various initiatives under the CMP unfold, or information changes, it is updated.

2.6.2. Priority Substance List Assessment

Assessments of substances placed on the PSL are the shared responsibility of Environment Canada and Health Canada. The assessment and management of priority substances occurs in two distinct phases. Scientists must first determine whether a substance is “toxic” as defined under Section 64 of CEPA. For substances determined to be “toxic”, management options are identified and implemented,

in consultation with stakeholders to reduce or eliminate the risks the substances pose to human health or the environment.

Ecological risk assessment is performed by Environment Canada's Existing Substances Division, while human health risk assessment is conducted by the Existing Substances Division of Health Canada. The phases of the ecological risk assessment process are described below and were developed through experience gained in assessing and managing the first PSL substances and through consultations with interested parties.

Ecological Risk Assessment Process

In terms of the allocation of responsibilities and participation, a **Lead** is chosen within Environment Canada for each substance. The lead will be responsible for delivery of the ecological risk assessment. Representatives from other federal government departments and other agencies, serve as a **Contact Group** to identify their departments' interests in specific substances, names of experts who may wish to contribute to the assessment and relevant information available in their departments. They will also provide feedback at critical steps. With the assistance of other government departments, environmental NGOs, industry, academia and other sources, the Lead will establishes **Environmental Resource Group**, a group of scientific and technical experts who will actively contribute to the assessment. A **Liaison Group** is established for groups or individuals who would like to receive online updates on the progress of the assessments, but may not have time or expertise to participate in a more involved fashion.

Problem formulation is the first stage in the assessment; its purpose is to establish the goals and focus of the assessment, and to identify any essential data gaps. Problem formulation is completed by Environment Canada with help from the Environmental Resource Group, Health Canada. Results of the problem formulation are broadly communicated on the updates website.

Data essential to complete the assessment are identified and a strategy for information gathering is developed. The mandate for requesting information from industry under CEPA will be used to obtain required existing or new information if voluntary or other means are not suitable. A draft ecological risk assessment is reviewed by the Environmental Resource Group, other government departments and by targeted experts. A public scrutiny stage near the end of the process allows stakeholders to provide supporting or conflicting scientific evidence. Finally, the department makes its recommendations to Environment Canada and Health Canada in the final Ecological Risk Assessment.

Health Risk Assessment

As under the screening assessment, health screening assessments involve a comparison of critical data on exposure and effect based on a comprehensive search and peer review of available data. Following their assessment, Health Canada releases a draft State of the Science Report provides early access to the human health science for the substance. A State of the Science Report on an existing substance presents the technical/scientific basis for the corresponding human health screening assessment.

Outcomes of Priority Substance List Assessment

Environment Canada and Health Canada jointly publish an assessment report including the conclusion with respect to CEPA "toxic", and a Canada Gazette Notice summarizing the report and announcing planned risk management measures. In addition, several documents, such as fact sheets and scientific journal articles, will be published or made available electronically. The outputs of the assessment of the PSL 1 and PSL2 are available online. Summaries of the public comments and their responses are also available from the website for each substance.

2.7. Review of Decisions of Other Jurisdictions

CEPA calls for exchanging information on substances with other levels of government in Canada, as well as with OECD member states. When Environment Canada receives information that another government has prohibited or substantially restricted a substance for environmental or health reasons, Environment Canada and Health Canada are obliged to review the decision. The review determines whether the substance is toxic or capable of becoming toxic in the Canadian environment. In this way, Canada benefits from a streamlined decision-making process through the sharing of scientific data, the capacity of other governments and efforts by others to develop risk management measures.

A substance is "CEPA-toxic equivalent" if it satisfies the definition of "CEPA-toxic" as a result of a systematic, risk-based assessment. Such assessments can include determinations made under other federal statutes, or can incorporate appropriate elements of assessments done by or for provinces or territories, international organizations or other appropriate scientific authorities.

2.8. Outcomes of a Risk Assessment

Once the Ministers have conducted a risk assessment of an existing substance under the Priority Substances List, a screening level risk assessment or a review of a decision by another jurisdiction, they must propose one of two measures:

1. They may recommend that the Governor in Council (the federal Cabinet) add the substance to the Schedule 1 List of Toxic Substances and, if applicable, to the Virtual Elimination List. They typically add the substance to Schedule 1 if they determine that the substance meets the criteria for "toxic" under the Act and that regulatory or pollution prevention or environmental emergency planning risk management measures should be taken under CEPA. These lists and associated risk management measures are discussed in section 3 below.

2. They may propose no further action under CEPA. They typically do this if they determine that the substance is not "toxic." They also may propose no further action under CEPA if they determine that the substance is toxic but that actions being taken or about to be taken under other federal acts or by provincial, territorial or Aboriginal governments are sufficient to manage the risks in a timely manner.

2.9. Risk Management Measures for Existing Substances

Examples of risk management measures under CEPA for existing substances include regulations, pollution prevention plans, environmental emergency plans, guidelines, codes of practice and administrative agreements. These measures may target any aspect of the substance's life cycle, from the research and development stage through manufacture, use, storage, transport and ultimate disposal. CEPA provides the authority for various risk management measures, or CEPA instruments, summarized in box 6 below.

Risk management measures for toxic substances are developed through the Toxics Management Process, discussed under section 2.9.3 below. For regulations, pollution prevention plans or environmental emergency plans the substance must be on the List of Toxic Substances (discussed in section 2.9.1 below) or in the case of environmental emergency plans be, at least, recommended for addition to the List. Substances proposed for virtual elimination of releases to the environment are added to the Virtual Elimination List (see section 2.9.2).

Box 6: Risk management measures foreseen for controlling chemicals "CEPA instruments"

- Regulations impose restrictions on an activity related to a substance, or set limits on the concentrations of a substance that can be used, released to the environment or be present in a product;
- Pollution prevention plans require the preparation and implementation of a plan outlining actions to prevent or minimize the creation or release of pollutants and waste;
- Environmental emergency plans require persons to prepare and implement a plan regarding the prevention of, preparedness for, response to, and recovery from an environmental emergency;
- Environmental quality objectives recommend qualitative or quantitative goals or purposes for pollution prevention or control of toxic substances. They often recommend ambient environmental quality targets or maximum acceptable levels.
- Environmental codes of practice recommend procedures, practices, or quantities of releases relating to facilities and activities during any phase of development of and operation involving a substance, and any subsequent monitoring activities.
- Environmental quality guidelines can be developed to recommend a concentration for toxic substances in surface water, agricultural water, soil, sediment, and human and animal tissue. Guidelines may also be developed to prevent, prepare for, or respond to an environmental emergency or to restore environmental quality.
- Environmental release guidelines include standards expressed as concentrations or quantities, for the release of substances into the environment from facilities or activities.
- Agreements respecting environmental data and research are usually cooperative arrangements with a provincial, territorial, aboriginal or foreign government or any person respecting the creation, operation, and maintenance of a system for monitoring environmental quality.
- Administrative agreements are usually work-sharing arrangements between the federal government and provincial, territorial, or aboriginal governments or aboriginal peoples respecting the administration of CEPA 1999.

2.9.1. Schedule 1: List of Toxic Substances

Substances that are determined to be "toxic" under CEPA- through a Priority Substances List assessment of the substance, a screening assessment, or the review of a decision by another jurisdiction - are recommended for addition to the List of Toxic Substances (Schedule 1). The Government can then to proceed with regulations, pollution prevention plans or environmental emergency plans for these substances. Preventive or control actions such as regulations, guidelines or codes of practice, are then considered for any aspect of the substance's life cycle from the research and development stage through manufacture, use, storage, transport and ultimate disposal or recycling.

The List of Toxic Substances currently contains 85 individual or families of substances, representing over 1000 discrete chemical substances. There are some 60 different tools in place to manage these. For instance, there are regulations for polychlorinated biphenyl (PCBs), guidelines for the release of ammonia dissolved in water, and a pollution prevention planning requirement for certain pollutants in wastewater effluents.

2.9.2. Virtual Elimination List

CEPA requires the virtual elimination of releases of substances that are persistent, bioaccumulative, toxic (PBT) and primarily the result of human activities. Virtual elimination is the reduction of releases to the environment of a substance to a level below which its release can be accurately measured. Section 65 of CEPA mandates Environment Canada and Health Canada 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.

2.9.3. Toxics Management Process

Risk management measures for toxic substances are developed through the Toxics Management Process, involving stakeholder consultation. Central to the toxics management process is the development of a **Risk Management Approach**, which outlines the proposed approach for managing the risks to the environment and human health for a particular toxic substance. The National Advisory Committee plays a key role in advising the federal government on activities and on cooperative, coordinated approaches to the management of toxic substances.

In developing the Risk Management Strategy, Environment Canada and Health Canada identify the sources that pose the greatest risk to the environment and human health, guided by the science in the risk assessment. A **Risk Management Objective** is then identified for these sources. This objective is usually based on results achieved from the best available processes, products, or techniques used by the sector or, in some cases, environmental quality objectives.

Once an objective has been set, the management measures that could achieve the risk management objective for each source are selected. The suite of tools can comprise a combination of measures representing the most feasible options for managing the substance. For a toxic substance that is subject to the time-clock provisions (see section 3.4), at least one of the risk management measures must be a CEPA instrument.

A **Risk Management Scope Document** is published online, summarizing the proposed risk management under consideration. Industry and other interested stakeholders are invited to submit comments on the risk management scope document during a 60-day comment period. Comments received on the risk management scope document are then taken into consideration in the

development of a **proposed Risk Management Approach Document,** also published online. A second consultation then involves a 60-day public comment period. These documents are accompanies by a Regulatory Impact Analysis Statement (RIAS). The RIAS provides information to Canadians and decision-makers on regulatory decisions and their impacts to protect and advance the public interest in health, safety and security, the quality of the environment, and the social and economic well-being of Canadians.

In response to this, a **draft instrument** is developed and subject to further consultations. On this basis, a **proposed instrument** is published, followed by further consultations, and publication of the **Final Instrument**.

Details and documents for chemicals recently added to Schedule 1 following screen assessment (Batch 11) for which regulatory actions are under developed are provide on the website of Environment Canada.

2.9.4. CEPA Time-Clock Provisions

For a substance proposed for addition to the List of Toxic Substances under a formal CEPA assessment, a **proposed regulation or instrument establishing "preventive or control actions"** for managing the substance must be developed with 24 months. The proposal is published in the *Canada Gazette*, Part I, for a 60-day comment period. Once proposed, the Ministers have a further 18 months to finalize the regulation or instrument. The Gazette notices are also published on the CEPA Environmental Registry website. The time clock provisions apply to substances added to the List of Toxic Substances on the basis of formal CEPA assessments, i.e. through assessments other than Priority Substances List assessment, a screening assessment, or the review of a decision by another jurisdiction.

For a risk management instrument to satisfy CEPA requirements, it must pass the "legal test" of establishing preventive or control actions that reduce or eliminate the risks to the environment or human health. Each instrument is assessed on a case-by-case basis to determine whether this requirement is met.

Within the Toxics Management Process, the government may hold preliminary consultations with the most affected stakeholders during the development of the risk management strategy. There are formal opportunities for public participation during the risk management stage. During the 60-day comment

period, interested parties can provide comments on the proposed regulation or instrument, or file a notice of objection requesting that a **Board of Review** be established.

A Board of Review enquires into the nature and extent of the danger posed by the substance that is the subject of the order or the proposed instrument or regulation. Depending on the nature of the comments received, the Minister of the Environment then determines if further discussions or a Board of Review are warranted.

After taking into account any information provided during this 60-day period, the Ministers publish the final instrument in the *Canada Gazette*, Part I or II depending on whether the measure consists of a regulation or other instrument, as well as on the CEPA Environmental Registry.

2.9.5. Exports of Substances

CEPA provides the authority to establish an Export Control List (Schedule 3) containing substances whose export is controlled because their use in Canada is prohibited or severely restricted or because Canada has accepted, through an international agreement (i.e. Rotterdam or Stockholm Conventions), to control their export. Prohibited substances can be exported only if they are to be destroyed or if the export is in compliance with regulations. Regulations can specify:

- prohibitions on export;
- conditions under which an export may be made;
- the type of information to be provided to the Minister with respect to the export; and
- the type of information to accompany an export and to be kept by the exporter.

Details concerning these exports are made public through the CEPA Environmental Registry website. These provisions of CEPA implement the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

2.9.6. Prohibition of Certain Toxic Substances

In January 2013, Environment Canada issued Regulations on the Prohibition of Certain Toxic Substances, 2012, repealing the 2005 Regulations. The 2012 Regulation are a multi-substance risk management instrument used to prohibit the manufacture, use, sale, offer for sale or import of certain toxic substances listed in Schedule 1 and 2 of these Regulations, as well as products containing these substances with a limited number of exemptions. The new legislation regulates twenty-six known toxic substances, thirteen more substances than were originally identified in the 2005 Regulations.

2.9.7. Canadian Hazardous Products Act

Chemical substances produced or distributed in Canadian commerce have been and continue to be subject to the Canadian Hazardous Products Act (CHPA). This law regulates prohibited, restricted, and controlled substances primarily in consumer products. For controlled substances, suppliers must comply with Workplace Hazardous Material Information System (WHMIS) regulations for labeling products, providing prescribed information on Material Safety Data Sheets, and providing proper notification and education of employees on the safe use of hazardous substances.

3. New Substance Program

The New Substances Program is responsible for administering the New Substances Notification Regulations (Chemicals and Polymers) [NSNR (Chemicals and Polymers)] and the New Substances Notification Regulations (Organisms) [NSNR (Organisms)] outlined under Part 5, Sections 80 to 89 of CEPA. As part of the "cradle to grave" management approach for toxic substances laid out in the CEPA, the Regulations were created to ensure that no new substances (chemicals, polymers or animate products of biotechnology) are introduced into the Canadian marketplace before an assessment of whether they are potentially toxic has been completed, and any appropriate or required control measures have been taken. Under the New Substance Notification regime, Environment Canada and Health Canada are required to assess substances that are not on the DSL in order to determine whether they should be subject to risk management measures.

Any company or individual who plans to import or manufacture a substance subject to notification under the Regulations must provide Environment Canada with a New Substance Notification (NSN) package containing all information prescribed in the Regulations prior to import or manufacture. New substances that are accepted as being in commercial use internationally are listed on the Non-Domestic Substances List. Substances on the Non-Domestic Substances List (NDSL) must also be notified, but are subject to lesser information requirements. As such, new substances cannot be manufactured or imported until:

- the Minister has been notified prior to manufacturing or importation of the substance;
- relevant information needed for an assessment of its potential toxicity has been provided to the Minister and the appropriate fee has been paid; and
- the period for assessing the information (as set out in regulations) has expired.

The Regulations subdivides all substances into three categories: chemicals, polymers, and biotechnology products. This report will focus on notification requirements for polymers and chemicals. To reflect their relative low toxicity, requirements for polymers often are more lenient.

Environment Canada previously had requirements for substances that were manufactured or imported in quantities greater than 20 kilograms (kg) in any calendar year between January1, 1987, and June 30, 1994. These transitional substances were subject to less burdensome data requirements, but the transitional provisions have officially expired.

Canada sets testing requirements for new substances according to several “Schedules”. The Schedule that is required depends on the type of substance involved, and the annual or cumulative amount of

substance intended to be manufactured in or imported into Canada. The practical effect for industry is that extensive production volume monitoring is necessary to predict reporting requirements so that data can be developed and submitted without interrupting sales. Accordingly, it is important that producers maintain accurate estimates of the annual and accumulated total amount of a new substance to be manufactured or imported.

3.1. Non-Domestic Substances List

The Non-Domestic Substances List (NDSL) is an inventory of substances that are not on the DSL but are accepted as being in commercial use internationally. The list is based on the United States Environmental Protection Agency's Toxic Substances Control Act (TSCA) Chemical Substances Inventory, and contains more than 58,000 entries. Substances that are not on the DSL but are listed on the NDSL are subject to reduced information requirements.

Since 1995 the NDSL has undergone annual revisions that have added or deleted substances incorporated into, or removed from, the TSCA Inventory five or more years before the date of the NDSL revision. Thus, the NDSL can be thought of as a list of substances not on the DSL and that "trails" the TSCA Inventory by approximately five years. Note, substances on the TSCA Inventory that have restrictions imposed on their manufacture or import under TSCA as a result of a risk assessment by the US EPA are not added to the NDSL.

3.2. Exemptions

To avoid duplication, substances regulated by other Canadian laws listed under Schedules 2 and 4 of CEPA are exempt from the NSN requirements. Federal Act listed in Schedule 2 or 4 of CEPA 1999, and that requires notice and assessment of potential risk to the environment and human health prior to import or manufacture is exempt from the NSNR. Substances imported or manufactured below the threshold quantities are also exempt from the NSNR. Other exemptions from NDSL requirements are presented in the box 7 below.

Box 7: Exemptions from NSN Requirements

Certain types of substances do not require an NSN. These include:

- Any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined.
- Any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design.
- Any animate matter that is, or any complex mixtures of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity.
- Transient reaction intermediates that are not isolated and are not likely to be released into the environment.
- Impurities, contaminants and partially unreacted materials the formation of which is related to the preparation of a substance.
- Substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors
- Substances that are loaded on a carrier outside Canada and moved through Canada to a point outside Canada.

3.3. New Substances Notification

Under Section 81 of CEPA, any "person" manufacturing a new substance in or importing a new substance into Canada must provide an NSN package to the New Substances Program. This NSN package must contain all information specified in the Regulations. Notification is required if the substance proposed for manufacture or import is subject to sections 80–89 of the Act, namely:

- substances new to Canada (e.g. those not on the Domestic Substances List);
- substances undertaking a **Significant New Activity** that are listed on the DSL with an "S" flag[1];
- polymers being manufactured or imported that do not meet the conditions of a **Reduced Regulatory Requirement (RRR) Polymer** that are listed on the DSL with a "P" flag[2]; and
- substances regulated under any other Act of Parliament or regulations not listed on Schedule 2 to the Act (e.g. substances regulated under the Food and Drugs Act) and for which a) applies.

For a more detailed explanation on the substances that need to be notified, Environment Canada provides a website on determining the need to notify under the New Substance Notification Regulations.

[1] The "S" Flag indicates that the substance has a Significant New Activity (SNAc) Notice assigned to it.
[2] The "P" Flag indicates that it is a Reduced Regulatory Requirement (RRR) Polymer which is listed on the DSL.

3.3.1. Significant New Activity

CEPA includes several provisions dealing with S**ignificant New Activities** (SNAc) in relation to the use of a substance. A SNAc is an alternative use of a substance or other activity to that already notified that results or may result in:

- a significantly greater quantity or concentration of the substance in the environment; or
- a significantly different manner or circumstances of exposure to the substance.

If there is a suspicion that a SNAc may result in the substance becoming toxic, the substance can be subject to a **Significant New Activity Notice**. The Notice communicates the criteria under which the government must be re-notified. The government assesses the new information on the substance to determine if it is toxic in relation to the significant new activity. Significant new activities can apply to existing substances on the DSL or to new substances.

When a SNAc Notice is issued, a substance is added to the DSL with a “S” flag once it meets all eligibility criteria. In this case, importers, manufacturers and users must submit the information specified within the SNAc notice if they wish to manufacture, import or use the substance outside the scope of activities specified in the SNAc notice. When a SNAc Notice is issued but the substance is not added to the DSL because it does not meet the eligibility criteria, all importers/manufacturers must comply with the NSN requirements by submitting the appropriate prescribed requirements. When information is submitted in compliance of a SNAc notice, Environment Canada and Health Canada must assess it within the time period specified in the SNAc Notice.

Environment Canada provides a website with a comprehensive listing of all substances subject to SNAc Notice.

3.3.2. Reduced Regulatory Requirement Polymer

The "P" Flag indicates that it is a Reduced Regulatory Requirement (RRR) Polymer which is listed on the DSL. A RRR polymer is:

(a) a polymer that is not one of the types listed in items 1 to 4 of Schedule 7 and that has a number average molecular weight greater than 10 000 daltons, with less than 2% of its components having molecular weights of less than 500 daltons and less than 5% of its components having molecular weights of less than 1 000 daltons;

(b) a polymer that is not one of the types listed in Schedule 7 and that has a number average molecular weight greater than 1 000 daltons and equal to or less than 10 000 daltons, with less than 10% of its

components having molecular weights of less than 500 daltons and less than 25% of its components having molecular weights of less than 1 000 daltons; or
(c) a polymer that is a polyester manufactured solely from reactants listed in Schedule 8, or an anhydrous form of those reactants, other than the reactants or their anhydrous forms that include both 1-butanol and fumaric or maleic acid.

Any substance listed on the DSL with a "P" Flag must be re-notified if a non-RRR version of the polymer is being proposed for manufacture or import. The non-RRR version is not considered to be listed on the DSL and is considered to be a new substance.

3.3.3. Notifier

If the notifier providing the NSN package is not a Canadian resident they must identify a Canadian resident who is authorized to act on their behalf as the “Canadian Agent”. All notices and correspondence from the NS program will be sent to the “Canadian Agent” who is required to keep the information and any supporting data for a period of five years.

NSNR provides for a rule of succession in the case of the transfer of certain rights regarding substances subject to notification. Successors are requested to sign a Certification Form prior to change of ownership if they wish to take advantage of the current notification status of a substance. This form indicates the transfer of rights or privileges, in relation to information provided for the substance, from the original notifier to the successor. The transfer of rights or privileges includes the responsibility of any risk management actions taken or SNAc Notices issued on the substance. This provision reduces duplication of work for industry as well as the NS program, since it allows successors to continue manufacturing or importing a new substance without having to “re-notify” and wait for the assessment period to expire.

3.3.4. Data Requirements under NSNR Schedules

A New Substances Notification (NSN) package must contain all required administrative and technical information prescribed in the Regulations, including the appropriate fee (if applicable), and must conform to the requirements for data and timing set in the relevant Schedule. As such, type of information required and the timing of the notification depend on such factors as the type of substance, the quantity that will be imported or manufactured, the intended use of the substance and the circumstances associated with its introduction.

The different Schedules are established by separating substances into categories and notification groups. Substances are first generically categorized by substance type (e.g. chemicals and polymers), and then each substance type is further separated into notification groups based on factors such as volume of manufacture or import or proposed use (e.g. research and development). The NSNR Schedules are presented in table 1 below.

Table 1: NSNR Schedules

SCHEDULE 1	Chemicals and biochemical that are research and development substances, contained site-limited intermediate substances or container export-only substances
SCHEDULE 2	Biochemical and polymers
SCHEDULE 3	Polymers and biopolymers that are research and development substances, contained site-limited intermediate substances or contained export-only substances
SCHEDULE 4	Other chemicals and biochemical not on the NDSL (100kg) or on the NDSL (1,000kg)
SCHEDULE 5	Other chemicals and biochemical not on the NDSL (1,000)kg) or on the NDSL (10,000kg)
SCHEDULE 6	Other chemicals and biochemical not on the NDSL (10,000kg)
SCHEDULE 7	Types of polymers
SCHEDULE 8	List of reactants and their CAS numbers
SCHEDULE 9	Reduced regulatory requirement polymers and other polymers and biopolymers (1000kg)
SCHEDULE 10	Other polymers and biopolymers on the NDSL or all of whose reactants are on the DSL or NDSL (10000kg)
SCHEDULE 11	Other polymers and biopolymers not on the NDSL (10000 kg)
SCHEDULE 12	Overview of information requirements

Threshold volumes must be calculated on a calendar year basis, and for mixtures relate to the net amount of new substance, not the quantity of formulation containing the chemical. For example, if 10,000 kilograms of “Formulation A” containing 13% of new “Chemical B” is imported during a calendar year, then the annual importation quantity of new “Chemical B” would be 1,300 kilograms. This system of notification groups allows the New Substances program to match information requirements with anticipated concerns about quantities and characteristics of specific groups of substances.

Schedule 1 concerns chemicals that are research and development substances, contained site-limited intermediate substances or container export-only substances at a tonnage of 1,000kg per year for an individual company, or a cumulative total of less than 5,000kg. Data requirements include chemicals name, CAS number, a Material Safety Data Sheet and exposure information, as well as a summary of all other information and test data that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical. Notifiers are not required to generate new test data. Similar requirements are set for polymers and biopolymers intended for research and development under Schedule 3.

Schedules 4 to 6 set data requirements for chemicals, with requirements increasing for the tonnage by tonnage bands that vary according to whether or not the substances are on the NDSL or not. Test requirements are set under Schedules 5 and 6. Details of data requirement under the different schedules are available on Canada's Justice Laws Website.

3.3.5. Request to Waive Data Requirements

Under subsection 81(8) of CEPA, a request to waive the requirement for any of the prescribed information may be made. The decision to grant an exemption will be made, on a case-by case basis, by officials within Environment Canada and Health Canada based on whether one or more of the criteria at paragraphs 81(8)(a)-(c) of CEPA are satisfied. The criteria include whether:

- in the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;
- a substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human life; and
- it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.

Exemptions requests must be submitted in writing as part of a notification package and should include a well-documented rationale to support the request.

3.3.6. Test Procedures

The conditions and test procedures used for the development and reporting of test data provided in NSNs must be consistent with the conditions and test procedures of the OECD "Guidelines for Testing of Chemicals" current at the time of testing. The appropriateness of the OECD method for the substance must be determined, and any necessary modification should be made (including the use of an alternative method) to ensure the acceptability of test data. Any deviations from the OECD guidelines should be clearly noted and explained. The laboratory practices used to develop test data for a new substance notification must be consistent with the "Principles of Good Laboratory Practice" (GLP) set out by the OECD.

3.3.7. Submission of the NSN Form

Submissions must be made on the NSN form, Form 04-2622E (04/2000). This form is divided into two sections: Part A addresses administrative information and substance identity, and Part B is for physiochemical and toxicity test results and associated technical information.

Where testing has been required, the package must include items such as full toxicity study reports, slice data associated with gel-permeation chromatography (GPC) analysis, descriptions of all study procedures (including procedures associated with molecular weight determinations), and waiver requests (including the justifications for such requests).

A complete NSN package must clearly substantiate confidential business information claims and chemical identity masking requests. Estimates of manufacture or import volumes for three years, use, disposal, and information on the mode of transportation, and a Canadian Material Safety Data Sheet must be provided. A submitter must also identify any other governments that have reviewed the substance.

3.3.8. New Substances Notification Assessment Periods

When Environment Canada receives a NSN Package from a company or individual proposing to import or manufacture a new substance, a joint assessment process is carried out with Health Canada to determine whether there is a potential for adverse effects of the substance on the environment and human health. Assessment periods range from 5 to 75 calendar days, depending on the type and amount of substance being manufactured or imported. NSN packages must be provided prior to the number of calendar days prescribed and in advance of the prescribed trigger quantity set out in the Schedules being exceeded. These are shown in Table 2.

Table 2: Schedule Numbers, Assessment Periods and Quantities Triggering NSN for Chemicals and Polymers

Schedule	Explanation	Time (days)	Annual quantities (kg)
Chemicals I	Special category[a] chemicals — NDSL[b] and not on NDSL 30 1,000 Update of information	30 30	1,000 10,000
4	Not on NDSL	5	100
4	NDSL	30	1000
5	Not on NDSL	60	1000
5	NDSL 60 10 000 NDSL — high release/exposure[c]	60 75	10,000 50,000
6	Not on NDSL	75	10,000
Polymers 3	Special 49category[a] polymers — NDSL and not on NDSL	30	10,000
9	All polymers	30	1,000
10	Non-RRR polymers[d] either on NDSL or all reactants on DSL/NDSL Non-RRR polymers[d] either on NDSL or all reactants on DSL/NDSL — high release/exposure[d]	60 60	10,000 50,000
11	Non-RRR polymers[d] not on NDSL and not all reactants on DSL/NDSL	60	10,000

a Special categories include research and development, contained site-limited intermediate and contained export-only substances
b NDSL – Non-domestic Substances List.
c There may be an additional assessment period for those substances that exceed 50 000 kg/year if they meet one of the following criteria: releases anticipated to exceed 3 kg/day into the aquatic environment after wastewater treatment; or significant public exposure
d Non-RRR polymers – Non-reduced Regulatory Requirement Polymers

3.3.9. New Substances Notification Fees

The New Substances Fees Regulation was developed to incorporate service fees to be provided with each NSN package submitted under the Regulations. The amount of fees required is dependent on the annual sales in Canada for the notifier, the specific Schedule being submitted and other services being requested (e.g. confidential search on the DSL or NDSL or masked name application). Additional information can also be found in the NSFR and the Regulations Amending the New Substances Fees Regulations.

Currently, fees do not apply to biochemicals, biopolymers, research and development substances and substances that are regulated under any other Act of Parliament. In addition, fees also do not apply to SNAc or to the submission of additional information required for special category Schedule 1 notifications (at 10,000 kg/yr).

3.3.10. Confidentiality

NSN submitters can claim certain information as confidential, but they must substantiate their request for confidentiality for each item that is claimed Confidential Business Information. The confidentiality privilege is satisfied by:
(1) identifying which particular information is confidential by entering the letter "C" on the NSN form in the spaces provided;
(2) providing the substantiation information prescribed in the Guidelines for the Notification and Testing of New Substances for each item claimed CBI; and
(3) signing the general CBI Certification Statement on the NSN form.

Canada's procedure for "protecting" a confidential chemical identity is generally to mask a single element in the fully specific chemical name. This leaves much of the chemical identity exposed to public view.

3.3.11. Research and Development

Canada views R&D as activities undertaken primarily to create or improve a product or process and determine its technical viability and performance properties. R&D activity includes systematic investigation or research by means of experimentation or analysis, other than test marketing.

No NSN is needed for R&D activity for a chemical substance if the quantity is limited to less than 1,000kg per year for an individual company, or a cumulative total of less than 5,000kg. Once this amount is exceeded, the chemical substance is subject to notification and regulation as a product development (PD) substance. A PD substance is an R&D chemical in the process of being evaluated before full commercialization in a single program that lasts two years or less (e.g., pilot plants, production trials, or customer trials other than test marketing), in order to modify the technical specifications of the R&D substance in response to performance requirements of potential customers. PD filings are reviewed within 21 days, but are valid for only two years. In addition, Environment Canada requires updates every six months.

For R&D polymers, a Schedule 11 is required once tonnage reaches 1,000kg per year, or a cumulative 5,000kg. When polymer R&D activity exceeds 10,000kg per year for a company, or a cumulative quantity of 50 000 kilograms, it is subject to notification and regulation as a PD substance. Schedule 11 requires information on the composition of the R&D polymer, an MSDS, and a brief statement describing the research activity that is being conducted.

3.4. Assessment of the NSN Package

The purpose of the assessment of the NSN package is to ensure that, either because of the inherent properties of the substance or because of measures taken to mitigate exposure to the substance, the use of the substance will not pose a significant risk to human health or the environment.

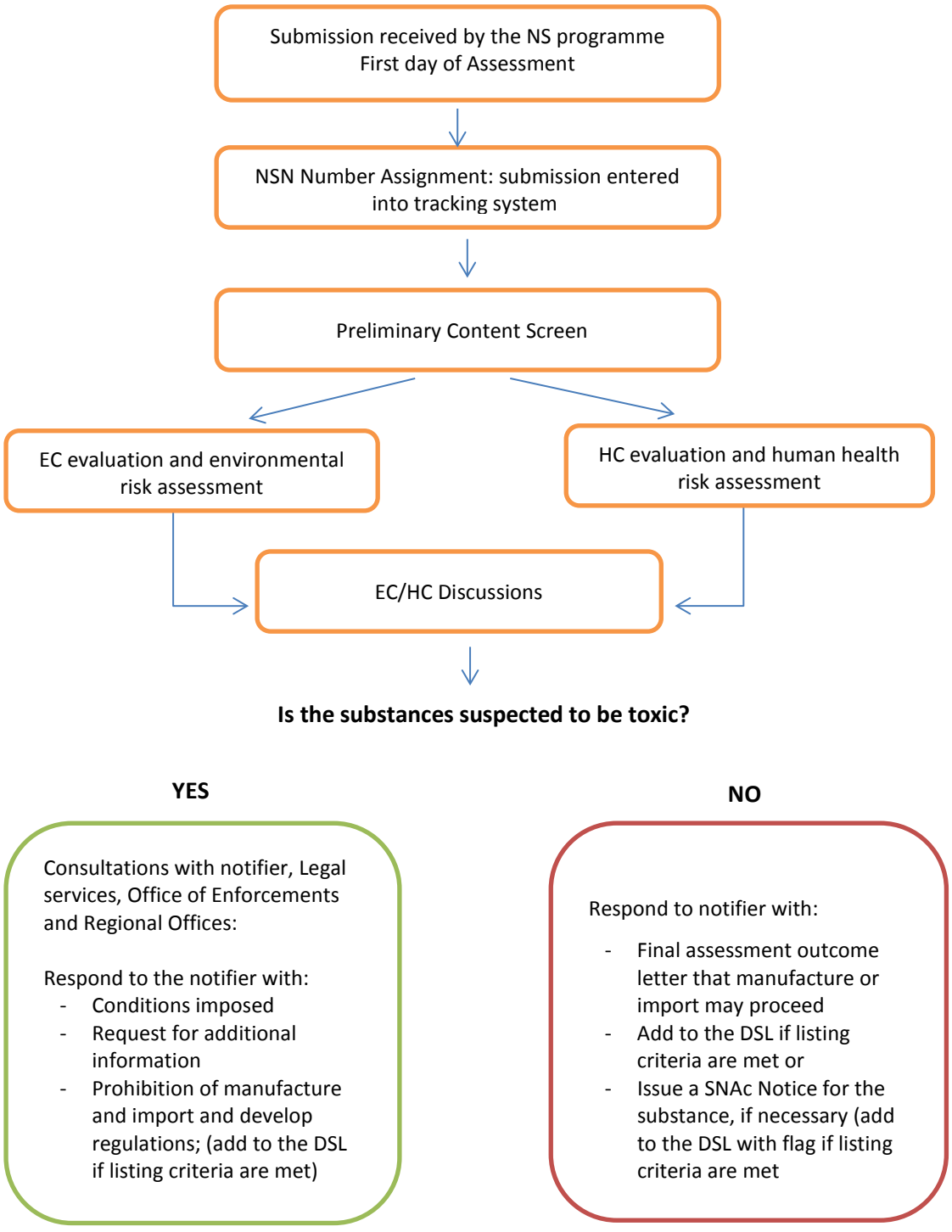
Figure 3 gives an overview of the assessment process from the day the NSN package is received by the New Substances program to the day the substance is added to the DSL or risk management measures are taken on the substance.

As a first step, evaluators within the New Substances program will assess the NSN package to determine the acceptability of:

- the substance identity and masked names;
- claims for Confidential Business Information;
- test protocols and procedures;
- test data;
- rationales for requests for waivers of information;
- rationales for use of alternative test protocols or surrogate information; and
- exposure information.

Deficiencies in the submitted information that cannot be easily resolved may result in the rejection of the NSN package and termination of the assessment period.

Figure 3: Overview of the New Substances Notification Assessment Process



EC: Environment Canada

HC: Health Canada

3.5. NSN Assessment

The purpose of the NSN assessment process is to determine whether or not the substance is, or is suspected of being, "toxic" or capable of becoming "toxic" as per any of the criteria set out in section 64 of CEPA. Environmental and human health assessments are conducted by Environment Canada and Health Canada respectively, using the information on chemical or biological properties, hazards, uses and exposure provided, and any other information that is available to the New Substances program, to determine whether the substance is suspected of being toxic or capable of being toxic. The assessment must be completed within the prescribed assessment period.

On their website Environment Canada provides an Overview of the Ecological Assessment of Substances under the Canadian Environmental Protection Act, while Health Canada provide details on the Determination of "Toxic" for the Purposes of the New Substances Provisions (chemicals and polymers) under the Canadian Environmental Protection Act - Human Health Considerations.

Determination of whether a substance is, or is suspected of being, toxic or capable of becoming toxic involves assessment of the potential for exposure of humans and components of the environment and of the adverse effects of the substance on humans or the environment (including other living organisms, interacting natural systems and the abiotic components of the environment). The assessment of adverse effects on humans and other living organisms considers endpoints such as lethality, mutagenicity, reproductive effects and organ toxicity, whereas adverse effects on the abiotic components of the environment include consequences such as depletion of the ozone layer, global warming and production of acid rain.

The potential for exposure to a substance depends on the quantity, rate, frequency and conditions of release of the substance into the environment at all points in its life cycle, as well as the mobility, environmental compartmentalization and persistence of the substance. The exposure assessment considers the use of the substance identified by the notifier, as well as other possible ways in which the substance might be used if it were listed on the DSL, without restrictions.

A substance may be "suspected" of being toxic if either the adverse effects of a substance or the potential exposure to a substance is of concern. For example, substances with considerable potential for exposure because of continuous release of high quantities or persistence in the environment may be suspected of being toxic, although there may be uncertainty regarding any biological or environmental hazard from the information available for the initial assessment. When an assessment

has led to a "suspicion of toxicity", CEPA has a unique provision, under subsection 84(1), which foresees specific risk management measures.

3.5.1. Request for Additional Information

When the New Substances Program requires additional information to be provided to determine whether the substance is toxic or capable of becoming toxic, a request for additional information with a prohibition of manufacture or import pending this testing may be imposed to mitigate any risk to human health or the environment. The person required to submit the information is prohibited from manufacturing or importing the substance unless the information is provided and the regular assessment period has expired or a period of 90 days after the additional information was provided has expired, whichever is later. Once the required additional information has been submitted, it will be assessed to determine if the substance is toxic or capable of becoming toxic and if it is appropriate to take alternative risk management measures.

3.5.2. NSN Assessment Outcomes

There are three possible outcomes of an assessment:

1. There is no suspicion of toxicity, and no action is taken;
2. There is no suspicion of toxicity for the current activities associated with the substance, and a SNAc Notice is published for the substance; or
3. There is a suspicion of toxicity, and risk management measures are imposed.

If the completed environmental and human health assessment reports on the notified substance determine that there is no suspicion that the substance is toxic or capable of becoming toxic, no action is taken. If no action is taken prior to the end of the assessment period, the notifier may, after the assessment period has expired, begin manufacturing or importing the substance in amounts exceeding the quantity that triggered the notification. A final assessment outcome letter will be sent to the notifier.

The notifier will be advised in writing, before the end of the assessment period or extended assessment period, if the New Substances Program suspects that the substance is toxic or capable of becoming toxic, and what action will be taken. In addition, the notifier will be advised before the end of the assessment period if the New Substances Program intends to develop a SNAc Notice in relation to the substance. Possible risk management options for new chemicals, including SNAc Notices, are considered under section 4.6 below.

3.5.3. Risk Assessment Summaries

Environment Canada and Health Canada are looking to increase the transparency of the New Substances Program by publishing summaries of environmental and human health risk assessment reports for new substances that are chemicals or polymers, beginning with a pilot phase. The substances covered by the pilot are chemicals and polymers which meet the following criteria:

- the risk assessment is completed and the notification(s) is(are) finalized;
- a SNAc Notice has been imposed; and
- the SNAcNotice was published in the *Canada Gazette* between August and December 2010.

Risk assessment summaries are published for the following three substances:

- Carbopolycyclic diol polymer with carbonic dichloride and substituted phenol ester;
- Aromatic isocyanate polymer, alkoxy-alkylamine blocked; and
- Poly(oxy-1,2-ethanediyl), alpha- monoalkyl ethers- omega-mono-(hydrogen maleate).

These summaries provide an overview of scientific information examined during the assessment period, and the conclusions and regulatory decisions that were made. The key elements found in the summaries include:

- the substance identity,
- its use,
- its hazard
- its exposure
- its environmental fate,
- the assessment of its ecological risk,
- the assessment of its human health risk, and
- the regulatory decisions

This evaluation does not include an assessment of the potential exposure and health risks specifically associated with occupational exposure, nor does it include any assessment for the substance which is already prescribed under the *Food and Drugs Act* or other federal legislation.

The New Substances Program has announced its intention to publish on a biannual basis risk assessment summaries of new substances for which:

- the risk assessment is completed and the notification(s) is(are) finalized;
- a restriction (e.g., ministerial condition, SNAc Notice) has been imposed; and
- the restriction was published in the Canada Gazette.

3.6. Risk Management of New Substances

Risk management procedures that are specific to new substances include the use of Significant New Activity Notices to keep track of and control new and expanding activities with new substances, and the enactment of Ministerial Conditions requiring the implementation of risk management measures for specific new substances. These two procedures are discussed below.

3.6.1. Significant New Activity Notice

A new substance assessment looks at the potential risks for the notified activities and any other possible activities involving the substance. If there is a suspicion that a significant new activity may result in the substance becoming "toxic", the Act allows the Minister to issue a SNAc Notice within 90 days after the end of the assessment period. A SNAc Notice is a notice describing, by inclusion or exclusion, a significant new activity that results or may result in:

- a significantly greater quantity or concentration of the substance in the environment; or
- a significantly different manner or circumstances of exposure to the substance.

A Comprehensive Listing of Substances that are Subject to a Significant New Activity Notices is published by Environment Canada. SNAc Notices oblige re-notification and assessment of prescribed additional information **prior to any of these parties undertaking a significant new activity** which is defined in the notice. The SNAc Notice defines:

- the substance (by specific substance name or masked name, if claimed confidential);
- the significant new activity, either by inclusion (*e.g.*, listing the new activity) or exclusion (*e.g.*, anything other than a certain activity);
- the information that must be notified;
- the timelines for providing the information; and
- the period for assessing the information.

When information is submitted in compliance with a SNAc Notice, it is called a Significant New Activity Notification (SNAN). The New Substances program must assess the SNAN within the time period specified by the SNAc Notice. From the assessment of this additional information, the SNAc Notice may be modified or rescinded, or other risk management measures can be imposed, if necessary. The original SNAc Notice stands unless a notice is published in the *Canada Gazette* to amend or rescind the SNAc Notice based on the additional information.

If a SNAc Notice has been issued for a new substance not yet on the DSL, the notifier still remains responsible for submitting:

- the subsequent Schedules of information under the Regulations, if necessary;
- the prescribed additional information in subsection 7(2), 7(3), 11(2) or 11(3) of the Regulations in the case of significant exposure or high release; and
- the appropriate notice to fulfill the DSL listing criteria.

The substance will not be eligible for listing on the DSL until all of the above-mentioned information has been received, accepted and assessed as "no suspicion of toxicity". Until the substance has been added to the DSL, no other notifier may manufacture or import the new substance for *any* activity prior to submitting an NSN package under the Regulations.

Once a new substance has been added to the DSL with an "S" flag, the SNAc Notice applies to all manufacturers, importers and users of that substance.

3.6.2. Ministerial Conditions

The risks of substances determined to be or suspected of being toxic or capable of becoming toxic may be managed through conditions or prohibitions imposed on their import or manufacture. The government can issue a Ministerial Condition in order to implement the following risk management measures for new substances that are toxic or suspected to be toxic:

- permit the manufacture or import of the substance subject to specified conditions or restrictions;
- prohibit the manufacture or import of the substance for a period not exceeding two years unless replaced by a regulation; or
- prohibit the manufacture or import of the substance until additional information or test results have been submitted and assessed.

Types of restrictions on the substance include, but are not limited to:

- maximum volume;
- the physical form (*e.g.*, must be imported as a plastic pellet);
- the use; or
- the disposal of the substance or containers that held the substance.

These measures are published as Ministerial Conditions and must be taken before the expiration of the assessment period. Notifiers will be advised, prior to the end of the assessment period, that there are

concerns with the substance. Usually the assessment period is extended, which provides time to prepare the risk management measure and obtain Ministerial approval. The notifier will be advised of the extension of the assessment period and proposed risk management measures prior to the end of the initial assessment period.

A notifier may submit additional information and request a re-evaluation of the decision made by the New Substances Program. The New Substances Program will review and consider this additional information and may amend or rescind the conditions. The conditions stand unless a notice is published in the Canada Gazette to amend or rescind the conditions based on the additional information.

Publication of Ministerial Conditions

Ministerial conditions are published in the Canada Gazette, Part I, after they have been issued to the notifier. When a condition or prohibition is issued or altered, the notice must be published in the *Canada Gazette*, Part I, describing the action and the substance to which it applies.

Obligation of the Notifier

The notifier and, if prescribed, the notifier's customers are obliged to abide by the conditions imposed on the substance in the Ministerial correspondence and keep records as indicated. Substances that have conditions imposed on thems are not eligible for addition to the DSL. Therefore, any new notifier who wishes to manufacture or import the same substance must submit an NSN package, as prescribed by the Regulations. This may result in the same or similar conditions being imposed.

4. **Enforcement**

CEPA provides the authority to carry out inspections and investigations, following the Compliance and Enforcement Policy. Enforcement officers have a wide range of powers to enforce the Act, including the right to:

- enter premises;
- examine any substance, product, fuel, cleaning product or water conditioner;
- open and examine the contents of any receptacle or package;
- examine any books, records, electronic data or other documents;
- take samples;
- seize evidence;
- conduct tests or take measurements;
- stop and detain conveyances such as a vehicle, ship or aircraft for the purpose of conducting an inspection; and
- use enforcement tools.

CEPA also allows for the designation of individuals as CEPA analysts, who will support the enforcement function. CEPA analysts can be chemists, biologists, engineers, forensic accountants or laboratory personnel. They are entitled to accompany enforcement officers on inspections and they have the power to enter premises, open receptacles, take samples, conduct tests and measurements, and require that documents and data be provided to them. These powers can only be exercised when accompanied by an enforcement officer.

The following enforcement tools can be used:

- warnings, when there is minimal or no threat to the environment or human life or health, to indicate the existence of an alleged violation, so that the alleged violator can take notice and return to compliance;
- directions to deal with or prevent illegal releases of regulated substances;
- tickets for offences under the Act where there is minimal or no threat to the environment or human life or health, such as the failure to submit a written report;
- Ministerial orders requiring remedial measures;
- detention orders for ships;
- environmental protection compliance orders to prevent or stop a violation;
- injunctions to stop or prevent a violation;
- prosecution under the authority of a Crown prosecutor; and

- environmental protection alternative measures, as an alternative to prosecution, to come to agreement on measures that the accused must take in order to restore compliance.

The maximum penalties include fines of up to $1 million a day for each day an offence continues, imprisonment for up to three years or both. CEPA includes mandatory sentencing criteria for consideration by the courts such as the cost to remedy the damage done to the environment. Violators may also have to pay for clean-up costs or forfeit any profits earned as a result of an offence. Corporate officials can be prosecuted if they authorize, accept or participate in any violation of CEPA or its regulations.

5. Information and Stakeholder Participation

CEPA contains a number of provisions relating to research and monitoring, information gathering and public reporting. In addition, CEPA foresees a high level of stakeholder participation in the design and implementation of legislation on chemicals. These aspects are briefly considered below.

5.1. Research and Monitoring

Environment Canada conducts research on the effects of pollution on environmental quality, the nature and dispersion of pollution on ecosystems, pollution prevention and the control and abatement of pollution. In addition, Environment Canada and Health Canada conduct research and studies specifically on hormone disrupting substances and measures to prevent or control the risks associated with these substances. Health Canada conducts research on the role of substances in illnesses or health problems.

Scientific research also supports the assessment of substances and whether and how to control such substances. Environment Canada and Health Canada participate in a multitude of cooperative projects with universities and research agencies in Canada and around the world to conduct research related to environmental sciences.

A key element of the Chemicals Management Plan is monitoring chemicals in both humans and the environment. Monitoring chemicals in air, water, wildlife and humans involves the regular collection of physical, chemical and biological data using standard methods and protocols. There are a variety of monitoring and research programs in place, such as the Canadian Health Measures Survey and the Maternal Infant Research on Environmental Chemicals (MIREC) study. The Chemicals Management Plan also includes observations of sensitive species through an ecological monitoring program that will also serve as an "early warning" system for harmful substances in the ecosystem and for concentrations of potentially harmful chemicals in various media such as air, water, soil or biota such as fish.

5.2. Information Gathering and Reporting

Environment Canada and Health Canada are required to distribute information to the public. Publishing information promotes public participation and gives Canadians access to environmental information that relates to their communities. Environment Canada is obliged to distribute information

on pollution prevention and periodic reports on the state of the environment, while Health Canada distributes available information about the effects of substances on human health. Canada provides information on its chemicals policies on a website entitled the Chemical Substances Portal.

5.3. Environment Registry

Environment Canada maintains the CEPA Environmental Registry. The Environmental Registry is available for Canadians to help them to understand how the federal government administers CEPA and to allow for participate in the consultation and decision making processes under the Act. Industry, environmental, labor, health and aboriginal groups and individuals are examples of those who are continually invited to participate in a wide variety of public consultations.

5.4. National Pollutant Release Inventory

CEPA also requires that the Minister maintain and publish a National Pollutant Release Inventory. This inventory (searchable by postal code or substance) provides Canadians with facility-specific information regarding on-site releases and off-site transfers of over 300 substances listed on the inventory. Companies that manufacture, process or otherwise use a listed substance at or above the reporting threshold must report their releases or transfers to Environment Canada annually.

5.5. Stakeholder Participation

The federal government recognizes that consulting with all types of stakeholders and cooperating with other jurisdictions are essential processes. Canada is committed to a clear, open and accountable assessment process.

The Existing Substances Program recognizes that efficiency and effectiveness in the delivery of program activities is in large part due to involvement of stakeholders at key milestones in the assessment process, especially during (i) assessment framework development, (ii) prioritization, (iii) scoping/problem formulation/issue identification, (iv) expert peer review, and (v) the public comment period. Stakeholders include representatives of industries and industry associations, non-governmental organizations, environmental and health groups, and labour and consumer organizations. The Existing Substances Program has identified roles and in some cases responsibilities for stakeholders. Some examples include:

- Sharing of data, information and expertise that is critical to ensuring that correct decisions are made;
- Reviewing the way in which information was used in making those decisions;
- Promoting effective communication between the different stakeholder communities;
- Facilitating coordination between the Government and specific industrial sectors during planning and assessment phases;
- Participating in discussions concerning modifications to the framework of the program or to development of new approaches to apply within the program;
- Bringing forward issues or identifying substances for consideration by the Government;
- Supporting general proactive good stewardship practices in the handling and management of chemicals.

When an assessment report has been drafted, and prior to its approval by senior managers, it is sent for science 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. Final copies of the assessment reports, as well as other communication material, are made readily available to interested stakeholders.

Engaging stakeholders and the public is central to the Chemicals Management Plan. Regular public information sessions and consultations are held on specific topics. In addition, the Chemicals Management Plan Stakeholder Advisory Council has been established to offer advice and input from industry, non-government organizations, labour and Aboriginal groups on the overall implementation of the Chemicals Management Plan. The Chemical Substances Web site provides information on all activities related to the Chemicals Management Plan. All significant documents and decisions are posted on this Web site for a 60-day public comment period. Canadians and organizations are encouraged to review the information and provide comments.

6. Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Implementation in Canada

Canada has long been a key driver in the development and adoption of Globally Harmonized System of Classification and Labeling of Chemicals (GHS) at the United Nations level. Indeed, Canada's Workplace Hazardous Materials Information System (WHMIS) with is one of the four major hazardous chemical standards upon which the United Nations GHS is based. However, the complexities of Canada's chemical hazard regulations has necessitated additional time to align the necessary stakeholders and to work through the maze of changes GHS adoption brings to chemical classification, labeling, and safety data sheets into line with GHS. As such, proposal to align the WHMIS with GHS is expected to be published in Canada Gazette I, in Spring 2013. The Policy and Programme Services Office at Health Canada's Product Safety Programme serves as the national coordinator for the implementation of GHS in Canada.

After the proposed changes are published in Canada Gazette I, the next step is to publish an enacted rule in Canada Gazette II – for which the most recently stated goal is spring 2014. Finally, the enacted regulations would need to be worked into regulations at the territory and province level, with an effective date for implementation expected to be June 1, 2015.

GHS adoption will have implications for the Hazardous Product Act, Controlled Products Regulations, consumer products, pesticides and other pest control products, and the transportation of dangerous goods. Canadian suppliers and employers are expected to get a phase-in period for compliance. Nevertheless, GHS alignment with WHMIS will bring a host of new challenges to suppliers, employers and workers that make, sell, or use controlled products. GHS will not replace WHMIS, but will dramatically alter three key areas, namely chemical classification, Safety Data Sheets and labels.

6.1. Chemical Classification

Under GHS, WHMIS will have new rules for chemical classification, and even some new hazard classes. Under GHS there will be 16 physical hazard classes and 10 health hazard classes. New classes include Explosives, Aspiration Hazard, and Specific Target Organ Toxicity (single exposure). A few classes like Biohazards, currently covered by WHMIS, are not part of GHS. However, Canada is not expected to drop such classes. Furthermore, it is possible Canada will adopt classes also not

covered in GHS, yet covered by occupational health and safety in Canada, such as combustible dust and simple asphyxiants.

6.2. Safety Data Sheets

Safety data sheets in the GHS format have 16 sections in a very strict order. Canada, which currently has a 9 heading MSDS requirement, has already made allowances for use of the 16 section GHS format in Canada. After GHS adoption, suppliers will be required to produce and distribute safety data sheets in the new 16 section format. Other requirements, such as having safety data sheets in both English and French are not expected to change.

Confidential Business Information is likely to remain largely the same, with suppliers needing to comply with Federal Hazardous Materials Information Review Act and Regulations. Disclosure to medical professionals and emergency personnel will also likely remain compulsory.

6.3. Labels

Some of the biggest changes to WHMIS will likely come in the form of GHS formatted labels. WHMIS labels after GHS are expected to have the following mandated elements:

- Product Identifier (hazardous ingredients may be required)
- Supplier Identifier (name, address, and telephone number)
- Hazard symbols/pictograms (square set at a point)
- Hazard Statements (with standardized warnings based upon chemical classification)
- Precautionary Statements (prevention, storage, disposal)
- Precautionary Statements (response)
- Signal Word (“Danger” or “Warning”)

There will be no change to the requirements for employers to include labels on containers into which controlled products have been transferred, on containers that have damaged or illegible supplier labels, and on those containers used for controlled products produced and used in-house.

In table 3, an overview of the GHS implementation phases in different sectors is presented.

Table 3: State of the art of the GHS implementation

Workplace	
Focal point:	Department of Health: National Officer of WHMIS (Workplace hazardous materials information system). Product Safety Programme
Main relevant legislation:	Hazardous Product Act and associated Controlled Products Regulations
Transport of dangerous goods	
Focal point:	Department of transport: Transport of Dangerous Goods Directorate
Main relevant legislation:	Transportation of Dangerous Goods Act, 1992 and Transportation of Dangerous Goods Regulations
GHS implementation status	**Implemented** Amendment 6 to the Canadian transportation of dangerous goods regulations entered into force on 20 February 2008, following its publication in Part II of the Canada Gazette. The regulations, as amended, are based on the 14th revised edition of the UN Model Regulations (except for the Dangerous Goods List, which will be updated to the 15th revised edition in Amendment 8). Detailed information about the regulatory proposals under development is available at Transport Canada website. For international transport of dangerous goods see Implementation through international legal instruments, recommendations, codes and guidelines
Consumer Products	
Focal point:	Department of Health: Consumer Product Safety Bureau, Product Safety Programme
Main relevant legislation:	Consumer Product Safety Act and associated Consumer Chemicals and Container Regulations, 2001
Pesticides	
Focal point:	Department of Health: Pest Management Regulatory Agency
Main relevant legislation:	Pest Control Products Act and associated regulations
GHS implementation milestones (workplace, consumer products and pesticides)	
2003:	Completion of the situation analysis (by sector) which compared existing hazard communication requirements to the GHS. Multi-stakeholder workshop to introduce and launch work on GHS
2004-2005:	Multi-stakeholder technical consultations (pest control products, workplace chemicals, consumer products). Objective: achieve harmonization between sectors (to the greatest extent possible) and between trading partners.
2006:	Publication of a document containing a summary of the results of the multi-stakeholder technical consultations (up to February 2006): "Comparison of Sector Interim Recommendations or Preferred Options".
2007:	Technical consultations and further development of Interim Recommendations
2008- 2009:	Completion of consultations; consultation on implementation phase-in options; consultations with trading partners; economic analysis (baseline study). Full economic analysis; development of final recommendations, decision making, draft regulations; regulatory process; phasing in implementation.
Spring 2013	Proposed amendments to the Regulations

Source: UNECE website

7. Advantages, Challenges and Disadvantages

7.1. Advantages

7.1.1. Industry's Role in Providing Data

Under the assessment of existing substances, CEPA Section 71 has been used extensively to oblige industry to submit certain information about substances being assessed to the government for the purpose of risk assessment, and risk management practices if applicable. Certain information gathering costs are therefore passed onto industry and this represents an advantage of the system for assessing existing substances. From industry's perspective, the requests for information on existing substances are targeted, rather than applying across the board to all substances, so reducing the overall burden on industry.

With regards to new substances, industry's obligations to provide data depend on substance type, tonnage thresholds, and categories of use. For chemicals not intended for research, testing is required at 1 tonne for non-NDSL substances and at 10 tonne + for NDSL substances. Thus the information requirements for new substances that are accepted as being in commercial use internationally are less stringent. Where the data provided is inadequate for effective risk assessment, Environment Canada and Health Canada can require the notifier to provide additional data. Again, this is done on a case by case basis, so reducing the overall administrative burden for industry.

7.1.2. Progress under the Chemicals Management Program

The CMP has been an important and valuable program, generating significant momentum in the assessment of existing substances. The Challenge in particular, has resulted in timely, systematic chemical assessments and risk management decisions. The use of screening assessment to assess substances in batches and prioritize substances for further assessment was effective, considering the number of substance assessments and the limited timeframe for such to occur. In addition, the application of a Rapid Screening Approach to substances of lower concern was fruitful in quickly processing over a thousand substances.

CMP also sparked additional assessment and risk management activity, including action on chemicals assessed via the Priority Substances List. However, progress has been slower under the Petroleum

Sector Stream Approach, where one-third of the high-priority substances identified through categorization were to be assessed.

7.1.3. Advantages of the New substances Program for Industry

The NSN has a number of features that reduce the burden on industry. Reduced requirements for substances destined for research and development aim to promote innovation for products and processes. In addition, the reduced requirements for new substances that are accepted as being in commercial use internationally, i.e. are listed on the Non-Domestic Substances List, reduce the administrative burden on industry. It does mean that Environment Canada and Health Canada will have less information with which to conduct their risk assessments, although they may be able to draw additional information from international databases, such as the REACH database and CLP Inventory managed by ECHA. Finally, a notification can be transferred to a successor, implying that notification must not be repeated.

7.1.4. Keeping Track of Significant New Activities

The SNAc procedures allow the Government of Canada to effectively track new activities and uses of new substances that might increase the impacts on the environment and/or on human health from those substances, by requiring notification of specified changes.

7.1.5. Stakeholder Participation

Stakeholder participation is likely to make the implementation of legislation more acceptable to both the regulated community and to other stakeholder, such as NGO, since it allows stakeholder to contribute to shaping process outcomes and generates ownership. In Canada, both the procedures for substance assessment and for subsequent risk management involve multiple opportunities for stakeholder participation. Effective participation is based on access to information throughout the various processes, with Canada making extensive use of online databases and webpages to inform stakeholders.

With regards to screening assessment, reports are made available to stakeholders and the public throughout the process, including through State of the Science Reports, and draft summary screening assessment and associated conclusions and/or measure proposed. These documents are revised according to comments received following public comment periods. Reports of risk assessments of existing substances completed under the Existing Substances Program are available on the website of

Environment Canada. With regards to risk assessment, uncertainties as well as the approaches or assumptions made in dealing with those uncertainties are recognised explicitly.

Under Priority Substance assessment, the Environmental Resource Group will include stakeholder from other government departments, environmental NGOs, industry, academia and other sources, who will actively contribute to the assessment, which is then subject to public comment periods. The outputs of the assessment of the PSL 1 and PSL2 are available online, with summaries of the public comments and their responses are also available from the website for each substance.

The Toxic Management Process involves a number of opportunities for stakeholder comment on proposed risk management procedures, with consultations on final proposals for legal instruments. For risk management under the CEPA time clock provisions, stakeholder may request that a Board of Review be established, to enquire into the nature and extent of the danger posed by the substance that is the subject of the order or the proposed instrument or regulation.

The New Substance Program provides limited opportunities for stakeholder involvement, besides the notifier. All SNAc Notices are published in the Canada Gazette and a list is provided online. Environment Canada and Health Canada are looking to increase the transparency of the New Substances Program by publishing summaries of environmental and human health risk assessment reports for new substances that are chemicals or polymers.

In addition, at a higher level, stakeholders are able to provide input through the Chemicals Management Plan Stakeholder Advisory Council on issues such as risk assessment, risk management, risk communications, monitoring, research, indicators of success, chemical policy, and other cross-cutting, integrated activities across the CMP.

7.2. Disadvantages and Challenges

7.2.1. Notices for Mandatory Surveys to Gather Information

While Environment Canada and Health Canada may request data and testing from industry, it is done on a substance by substance basis, with a Notice published in the Canada Gazette to establish each mandatory data gathering survey. This has implications in terms of costs to the Government and the time required to publish the Notice and allow the industry to respond.

7.2.2. Managing Data Limitations

The screening process under the Existing Substances Program may be slow to identify challenges such as chronic effects from existing chemicals, or substance for which data availability is limited.
For example, under the assessment of the Second Priority Substance List, due to limitations of the available data on effects of two of the PSL2 substances (aluminum salts and ethylene glycol), a definitive conclusion of toxic or not toxic with respect to human health could not be reached. Therefore, assessments of these two substances were suspended in order for Health Canada to collect data on toxicity to human health.

7.2.3. Costs of Risk Assessment Fall on Government

Environmental and human health assessments for new substances are conducted by Environment Canada and Health Canada respectively. As such, the Government of Canada takes on the costs of assessing the information on a substance and determining whether it is toxic or not. The government therefore maintains control over the process, but must also provide the resources for the assessment.

Finally, the risk assessment does not cover occupational exposure, implying that this element of exposure is not integrated into the risk management decisions.

8. **Conclusion**

Canada was the first country in the world to undertake a systematic examination of the un-assessed chemicals and other substances in use, prior to introduction of the evaluation of new substances. In Canada, this represented some 23 000 substances, and the first step, categorisation, was achieved by 2006.

Building on this success, the launch of the CMP in 2006 generated significant momentum in the assessment of existing substances, through screening assessment and the prioritisation of substances for in-depth assessment. The Challenge in particular, has resulted in timely, systematic chemical assessments and risk management decisions. The new approach introduced a systematic, outcome-oriented approach to chemicals management in Canada, with substances prioritized for assessment on the basis of risk. This provided a shift from a reactive and rigid process to a more flexible and timely one. In addition, implementation of the Existing Substances Program and the New Substances Program shifted the burden of data gathering from falling solely on government to a shared responsibility with industry. Nevertheless, the fact that substance assessment is performed by Environment Canada and Health Canada implies that the costs to Government of substance assessment remain considerable.

The implementation of risk management measures hinges on the identification of a substance as toxic according to CEPA. A range of risk management options are available to allow the Government of Canada to regulate or prohibit the use of toxic chemicals.

Canada places a particular emphasis on the importance of transparency and stakeholder participation in all stages of chemicals management, from assessment to the development of risk management options. This can be expected to improve compliance levels by industry and satisfaction amongst a range of stakeholder groups.

With regards to GHS, Canada faces some complexities in aligning the WHMIS with GHS, with a proposal expected to be published in Canada Gazette I, in Spring 2013.

In 2001, building on successes and lessons learned since 2006, the Government of Canada launched the next phase of the CMP in 2012. Canada has committed to continuing to work with industry to support stewardship and innovation, partner and engage with all stakeholders for effectiveness and efficiency, invest in research and monitoring, work with international partners, and make information on chemicals publicly available.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