Within REACH: An Agenda for Improving the *Canadian Environmental Protection Act*, 1999

Prepared for
Canadian Environmental Network Toxics Caucus

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Prepared by:
Anne Wordsworth
Hugh Benevides
Paul Muldoon
Fe de Leon

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130 SPADINA AVE • SUITE 301 • TORONTO • ON. • M5V 2L4
TEL: 416/960-2284 • FAX: 416/960-9392 • www.cela.ca

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1.0 EXECUTIVE SUMMARY

In October of 2003, the European Commission released a proposed regulation which in effect would establish a new chemicals policy for the European Community. This initiative, entitled REACH (the Registration, Evaluation, Authorisation and Restriction of Chemicals), is a radical departure from the conventional approach to managing chemicals. Building on principles developed by member countries like Sweden, the European Union has designed a legislative framework that aspires to remedy the failures of current chemicals management regimes.

The Canadian government is currently poised to review its primary legislation on toxic substances, the *Canadian Environmental Protection Act*, 1999 (CEPA). According to CEPA, control measures on substances are required if a substance is found to be toxic as defined by the law.[1] The five year Parliamentary review on CEPA is scheduled to begin in the spring of 2005.[2]

The purpose of this report can be stated as follows:

- Review the current REACH proposal as outlined by the European Commission;
- Compare the key components of REACH with the present chemicals management framework under CEPA, with the identification of any gaps; and
- Propose recommendations where REACH components could or should be incorporated into, or harmonized with, CEPA.

The following list of recommendations have been proposed for strengthening the Canadian approach in managing toxic substances under CEPA.

1. CEPA should be amended to create a formal registration process, for substances already in use in Canada, like that in REACH. The registration process should require mandatory submission of data on the properties of substances.

2. Industries should be required to provide comprehensive information on substances they are manufacturing or importing into Canada, including chemical safety reports.

3. Timelines should be imposed on the required submission of data.

4. A separate chemicals secretariat with a mandate to provide oversight and co-ordination functions should be considered in Canada.

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[1] Under Section 64 of the CEPA, a substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions that:
(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitutes or may constitute a danger to the environment on which it depends; or
(c) constitutes or may constitute a danger in Canada to human life or health

[2] Subsection 343 (1) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires that "the administration of this Act shall, every five years after the coming into force of this Act, stand referred to such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established for that purpose."

5. This Agency should be funded by fees paid by industry for the registration of chemicals and other services.

6. Following the REACH approach, the distinction between new and existing substances should be eliminated within the CEPA approach.

7. An expanded Domestic Substances List should include all new and existing chemicals. The requirements for providing data to the government should be reviewed and revised to provide a more co-ordinated, less disjointed approach to registration or notification of substances. As with REACH, the requirements for data should be stricter for chemicals that are used in larger volumes and for chemicals with hazardous properties such as carcinogenicity.

8. The registry of information on chemicals should be transparent and available for public review.

9. Amendments to CEPA should ensure that industry provides adequate data for all new and existing chemicals in order to assist the government in making a determination of toxicity based on their inherent properties.

10. Unlike the REACH approach for registration, CEPA should retain its provisions to apply to animate or inanimate organisms (products of biotechnology). These provisions should also be retained for polymers, which may be included in REACH in the future.

11. Unlike REACH, CEPA should retain reporting thresholds, as low as 20 kilograms, currently required for some substances under the *New Substances Notification Regulations* but increase reporting requirements. This threshold should apply to all substances, existing and new.

12. CEPA should be strengthened to require importers of articles containing hazardous substances to submit chemical safety reports on their products.

13. CEPA should assert its authority to regulate toxic substances in products.

14. CEPA should impose stricter and shorter timelines, particularly at the evaluation/ assessment stage.

15. CEPA should extend the DSL categorization of existing substances to make it as broad in scope as the REACH program, in order to capture the following:

- substances that are known or suspected carcinogens, mutagens or reproductive toxins;
- substances that affect endocrine systems;
- substances that affect developmental functions; and
- substances that cause serious and irreversible effects to humans or the environment, equivalent to these other hazards.

The required health endpoints (in both qualitative and quantitative data) should be articulated in CEPA.

16. CEPA should make Section 71 a mandatory requirement for the categorization and assessment activities. Furthermore, Section 71 should include a timeframe for completing and submitting the information required by government to complete its assessment of substances.

17. CEPA should be strengthened to include a process of authorisations or approvals for CEPA-toxic substances. These authorisations should be time-limited.

18. Inherent toxicity under CEPA should be articulated to include substances that will be considered hazardous under REACH, those that are:

- carcinogenic;
- mutagenic;
- toxic to reproduction;
- persistent; bioaccumulative;
- very persistent; very bioaccumulative;
- endocrine disruptors; and
- substances identified as having serious and irreversible effects on humans or the environment equivalent to these other effects.

19. CEPA should include requirements for substitution of any chemical found to be “toxic”. This provision can be required under the pollution prevention planning requirements for CEPA "toxic" substances.

20. All substances that are found to be CEPA-toxic should be added to the National Pollutant Release Inventory to track the effectiveness of control programs to reduce them.

21. CEPA should be amended to prescribe deadlines for implementation of virtual elimination of toxic substances.

22. CEPA should be amended so that addition of a substance to the List of Toxic Substances is a decision of the CEPA Ministers, not a Cabinet decision.

23. The level of quantification should be removed as a condition of virtual elimination under CEPA.

2.0 INTRODUCTION

The development and use of synthetic chemicals has brought many benefits to our daily lives. However, the bulk of these chemicals have been introduced into the market with little or no knowledge of their effects on human health or the environment. It is estimated that even for those chemicals used in the highest volumes, it is possible to

make a limited assessment of risk for only about 15 per cent of them.[3] Some of these chemicals have turned out to be toxic, and their unanticipated impacts have done considerable harm.

Scientists have reported chemicals collecting in the environment and in humans -- brominated flame retardants in breast milk, multiple pesticides in body fat, teflon-related materials in drinking water and sexual changes in fish and wildlife brought on by exposure to chemicals. These reports are evidence that chemicals are marketed and used without enough understanding or consideration of how they will be dispersed in the environment.

To address these problems, legislation for managing toxic chemicals has been introduced in every country in Europe and North America, and, in both Canada and Europe, these laws have undergone periodic revision.

The Canadian government is currently poised to review its primary legislation on toxic substances, the *Canadian Environmental Protection Act*, 1999 (CEPA). According to CEPA, control measures on substances are required if a substance is found to be toxic as defined by the law.[4] The five year Parliamentary review on CEPA is scheduled to begin in the spring of 2005.[5]

Environmental organizations are interested in examining policy and legislative innovations in other jurisdictions for the purposes of understanding the "state-of-the-art" thinking of approaches to toxic chemicals management.

One such innovation is a regulation currently under consideration by the members of the European Union (EU). The European Union has also recently re-evaluated its legislation and its approach to chemicals management, and found that legislative changes were necessary to protect both the environment and human health.

In October of 2003, the European Commission released a proposed regulation which in effect would establish a new chemicals policy for the European Community. This initiative, entitled REACH (the Registration, Evaluation, Authorisation and Restriction of Chemicals), is a radical departure from the conventional approach to managing chemicals. Building on principles developed by member countries like Sweden, the EU has designed a legislative framework that aspires to remedy the failures of current chemicals management regimes.

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[3] Kemi, "Summary, A Non-Toxic Environment – The Generation Objective", Sweden, p. 5

[4] Under Section 64 of the CEPA, a substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions that:
(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitutes or may constitute a danger to the environment on which it depends; or
(c) constitutes or may constitute a danger in Canada to human life or health

[5] Subsection 343 (1) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires that "the administration of this Act shall, every five years after the coming into force of this Act, stand referred to such committee of the House of Commons, of the Senate or of both Houses of Parliament as may be designated or established for that purpose."

In the proposed REACH Regulation, the emphasis is on collecting data that will contribute to a better understanding of the hazards and risks that chemicals may pose throughout the supply chain, and regulating those chemicals that are of the highest concern.

It is important to note that, although the Regulation is still proposed rather than final, it is expected that it will become law within the next three years, perhaps with some changes. The proposed regulation has been passed to the European Parliament and the European Council for further discussion.

3.0 PURPOSE OF REPORT

The purpose of this report can be stated as follows:

- Review the current REACH proposal as outlined by the European Commission;
- Compare the key components of REACH with the present chemicals management framework under CEPA, with the identification of any gaps; and
- Propose recommendations where REACH components could or should be incorporated into, or harmonized with, CEPA.

Table 2 at the end of the report provides an overview of relevant sections in CEPA and the proposed REACH Regulations on selected issues relevant to assessing and managing toxic substances.

It is worth noting that the recommendations presented in the body of the report do not represent the complete set of the recommendations necessary to improve CEPA.

4.0 BACKGROUND TO THE *CANADIAN ENVIRONMENTAL PROTECTION ACT*

The *Environmental Contaminants Act*,[6] enacted in the mid-1970s, was designed to identify and manage toxic chemicals. That law became Part II of the original *Canadian Environmental Protection Act* (CEPA 1988). CEPA 1988 was replaced by CEPA 1999. Much of CEPA's toxic substance management scheme can now be found in Part 5, "Controlling Toxic Substances".

Planning for the Parliamentary review of CEPA is underway, and a range of concerns have been raised by review participants and stakeholders. Thus far, there is no publicly-available, comprehensive assessment of the effectiveness of CEPA.

Environment Canada and Health Canada have identified issues that the Parliamentary Committee might consider for the purposes of changing the legislation. Some of the risk assessment and management issues they have suggested include: streamlining the regulatory process to allow fewer interventions by Cabinet concerning a single substance, the possibility of eliminating a requirement for setting a 'level of quantification" for specific substances, and the debate around the advantages of

[6] S.C. 1974-75, c. 72

voluntary and regulatory instruments. They are also concerned about the inability of the Minister of Environment to prevent new substances that have not been assessed from entering the market. These issues are outlined in Appendix I.

Canada's Commissioner of the Environment and Sustainable Development (Office of the Auditor General) reviewed the federal toxics management regime in both 1999 and 2002, although these audits did not focus solely on CEPA.

In her 2002 Report to the House of Commons, she wrote that since her predecessor's 1999 audit, the federal government's "ability to detect, understand, and prevent the harmful effects of toxic substances is still limited. The processes we observed seem to defy timely, decisive, and precautionary action".[7]

Environmental organizations have also been concerned about the limitations of the federal chemicals management regime, as set out by CEPA. The concerns include:

- the failure to implement a precautionary approach;
- the failure to regulate or eliminate harmful substances in everyday articles and products;
- the lack of data on existing and new chemicals;
- the lack of onus on industry to provide information on chemicals;
- the categorization of the Domestic Substances List that does not explicitly take into account hazardous properties such as carcinogenicity or endocrine disruption for all chemicals; and,
- for chemicals identified as toxic, the lack of effective control measures.

The Canadian approach, in general, has fallen short in adequately protecting human health and the environment, especially with respect to substances found in consumer products. The upcoming review of CEPA provides an opportunity to reflect on the current gaps in the framework.

5.0 BACKGROUND TO REACH

Under legislation in Europe, Canada and the United States, similar regimes were established for managing toxic chemicals, by:

- setting up processes to screen new chemicals before they come onto the market;
- identifying the chemicals already in use;
- setting priorities for evaluating chemicals that might pose the greatest risks;
- assessing these chemicals of concern through a risk assessment process; and,
- limiting or banning the use of chemicals that prove to be unacceptably hazardous to human health and the environment.

[7] "Chapter 1: Toxic Substances Revisited" in (2002) Report of the Commissioner of the Environment and Sustainable Development to the House of Commons, at p. 1

In Europe, concern has been steadily increasing that these practices are inadequate for protecting human health and the environment. In the explanatory memorandum to the proposed REACH regulation, the current chemicals legislation in Europe was described in this way:

"There is generally a lack of publicly available knowledge about the properties and uses of existing substances. The risk assessment process is slow and resource intensive and does not allow the system to work efficiently and effectively. The allocation of responsibilities is inappropriate because the public authorities are responsible for the assessment instead of the enterprises that produce, import or use them."[8]

In response to these problems, the European Commission has spent several years developing innovative legislation that would replace existing directives and transform the way in which chemicals are managed in Europe.

A White Paper on a "Strategy for a Future Chemicals Policy," released in February 2001, presented the position of the European Commission and unveiled the proposed chemicals policy. After a full discussion at the public, Member State, and the Parliamentary levels, there was a widespread agreement on the need for reform. Industry, environment, consumer organizations and government all supported the direction of the proposed changes. European industry welcomed the new policy orientation that gave them greater responsibility for the safety of their chemicals.[9]

The White Paper has been followed by a draft regulation known as REACH -- the Registration, Evaluation, Authorisation and Restrictions of Chemicals. The proposed Regulation was issued on October 29, 2003. The Regulation addressed many of the issues raised after the publication of the White Paper. Cefic (the European Chemical Industry Council) supports the political objectives of REACH – protecting human health and the environment, and ensuring the competitiveness of industry –while still seeking to ensure the workability of the regulation.[10]

The proposed REACH Regulation builds on and replaces three European Directives and one Regulation that have been developed to manage chemicals in the European Union since the 1960s. These include the Dangerous Substances Directive (67/548/EEC), the Dangerous Preparations Directive (88/379/EEC), the Existing Substances Regulation (EEC 793/93) and the Limitations Directive (76/769/EEC). The first two relate to the classification, packaging and labeling of substances and preparations. The Existing Substances Regulation applies to the evaluation and control of the risks from existing substances, and the Limitations Directive restricts certain dangerous substances and preparations.

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[8] Commission of the European Communities, "Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals, Brussels, 29 October 2003, p. 5

[9] Ibid., p. 6

[10] Cefic (working groups of the European chemical industry association), "Cefic Communication on Commission's Proposal for Regulation on Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH)", Appendix 2, December 4 2003, p. 7

In order to implement REACH, the European Union will establish the European Chemicals Agency. This Agency will be responsible for coordinating the information and carrying out the tasks required by the regulation.

In developing REACH, the European Union has tried to incorporate some elements of precaution into the regulation by requiring that chemicals of high concern have authorisations before they are used. However, decisions to authorise chemicals may still be subject to risk-based assessments. Another condition in the authorisation process -- that substitutes be considered -- is also a way in which the idea of precaution is reflected in REACH.

The main features of REACH -- the registration process, the evaluations, the authorisations and restrictions -- will be discussed in the following sections of the report and contrasted with the way in which the same tasks are currently handled under CEPA. For additional details on specific requirements and obligations on managing toxic substances under REACH and CEPA, please refer to Table 2 at the end of the report.

The processes that are described under REACH are, of course, part of a proposed framework that has not yet been implemented. CEPA is at a different stage in its history, having already been in place and implemented in a changing form for almost 20 years. With this difference in mind, the following sections outline the stages of chemicals management, and provide a general overview of the similarities and differences between the Canadian and emerging European approaches.

It is also important to note that both REACH and CEPA generally cover chemicals that are not captured by other existing legislation in their respective jurisdictions governing pesticides, food additives and colourings, and cosmetics. Appendix II outlines a chart summarizing the main elements and requirements of the proposed REACH Regulation.

6.0 EXAMINING INTERNATIONAL APPROACHES TO MANAGING TOXIC SUBSTANCES: A LOOK AT THE PROPOSED REACH REGULATION AND THE CEPA APPROACH

6.1 A Comparison of the Registration of Chemicals under REACH and the Notification of Chemicals under CEPA

6.1.1 REACH's Registration compared to CEPA's Notification Requirements for Chemicals Already in Use

Governments have been struggling with assessing chemicals that are already on the market which may pose a hazard and for which little information exists. A huge backlog of substances, representing the vast majority of chemicals in use, has never been properly evaluated.

Legislation governing toxic chemicals has set up screening mechanisms to try and retrospectively assess the chemicals already in use, but government agencies have

been overwhelmed by the work involved in the thorough assessment and screening of thousands of substances. Consequently, governments have only been able to complete comprehensive risk assessments for a small number of substances.

More than 100,000 chemicals were on the European market in 1981. An estimated 99 per cent of these chemicals by volume remain largely untested and unregulated.

Europe's Approach on Registration Requirements for Substances Already in Use under REACH

In recognition of these limitations, REACH proposes a dramatic shift in the burden of responsibility for the identification of chemicals and their risks from government agencies to industry. Under REACH, a system of registration will be introduced. It will require all manufacturers and importers of substances in quantities greater than one tonne or more per year to register these substances. For the first time, extensive new information on the properties and risks of chemicals on the market will become available.

Included in the registration material will be information on the risk management measures that will be taken by the companies, and in the case of substances that are used in greater volumes, chemical safety assessments will be required. The number of chemicals that will be registered under REACH is estimated to be 30,000.

Information Requirements: Registration will mean that manufacturers and importers will have to submit a technical dossier to a newly created European Chemicals Agency within a certain time frame. The technical dossier will include the identity of the substance, information on the manufacturing and uses of the substance, classification and labelling, guidance on safe use, proposals for testing if further testing is needed, and other information as required. Standard information requirements for substances of 1 tonne or more include toxicological information such as flammability, corrosivity, mutagenicity testing and aquatic toxicity.

For substances that are imported or manufactured in greater volumes -- quantities of 10 tonnes or more per year, companies must also submit, as part of their registration, chemical safety reports, based on chemical safety assessments. The chemical safety report will include: human health hazard assessments,[11] human health hazard assessments of physicochemical properties, environmental hazard assessment, as well as an assessment of the persistence, bioaccumulative and toxic properties of the chemical. For substances manufactured or imported in quantities of 100 tonnes or more, the range and number of studies required is even more extensive. The chemical safety report will also consist of the risk management measures that are to be developed or put in place.

[11] Toxicological information on carcinogenicity, mutagenicity, and toxicity for reproduction, repeated dose toxicity, degradation and studies of its fate and behaviour in the environment will be part of these assessments (p. 9-10, Annex I, General Provisions for Assessing Substances and Preparing Chemical Safety Reports)

Downstream Users: Traditionally, information on the use and risks of hazardous chemicals by industries that are not the primary manufacturer or importer has been difficult to obtain. Those industries that use the chemicals but do not manufacture them or import them into Europe – "downstream users" – do not have the same responsibilities for registering that are imposed on manufacturers and suppliers.

REACH will require downstream users to ensure that the chemical safety assessments prepared by their suppliers include descriptions of the way in which they use the registered chemicals and the risks involved. If they are using the chemicals in a way that is not described in the manufacturers' assessments, they are obliged to notify the manufacturer so that such new uses are included in the chemical safety assessment. Alternatively, if they choose not to advise the manufacturer of the new use, they must notify the European Chemicals Agency and prepare their own chemical safety report.

This provision of REACH ensures that chemicals are used safely by all industries – manufacturers, importers and downstream users -- and ensures that any unforeseen uses of the chemical are known, either to the supplier or to the Agency. There are plans to develop guidelines that will make this process manageable, particularly for small and medium-sized companies.

REACH also provides for a pre-registration phase so that industries using the same substances can find each other and share information. This will enable them to share the costs of testing and registering chemicals, and reduce the duplication of animal tests.

Timelines: The ambitious goal of REACH is to collect information on all substances in use in Europe within 11 years. To accomplish this, REACH will impose a deadline for registrations allowing for a phased in approach that makes it possible to handle such a significant amount of data.

Under REACH, the substances that are the most heavily used and the most potentially hazardous must be registered first. This means that within 3 years all substances that are manufactured or imported in quantities of more than 1,000 tonnes per year, or substances that are considered to be carcinogens, mutagens or toxic to reproduction in categories 1 and 2, must be registered. Within 6 years all substances manufactured or imported in quantities of 100 tonnes or more per year must be registered, and within 11 years all substances manufactured or imported in quantities of one tonne or more per year must be registered. This staged implementation affords a timely and efficient process to establish the necessary basis for chemicals management.

If a substance is not registered or its registration is incomplete by the deadlines, companies will not be allowed to manufacture or import it. However, there are some chemicals that are not subject to the registration requirements of REACH. Polymers, for example, will not be subject to registration initially because of the potentially large number of registrations that would be required. The European Commission is considering how polymers might be addressed by REACH in the future. In addition, most intermediate chemicals and chemicals being used in research and development are not subject to the registration requirements.

The REACH regulation and its implementation by the European Chemicals Agency will be financed through registration fees paid by industry.

Canada's Approach for Notification of Substances Already in Use under CEPA

CEPA also includes procedures for addressing the backlog of chemicals already in use in 1986, and some substances put into commerce since then. All chemicals that were imported, used or manufactured in Canada have been compiled in the Domestic Substances List (DSL) by Health Canada and Environment Canada.

CEPA should be strengthened in order to compel manufacturers, users and importers of substances to submit more detailed information about substances, as in the REACH Registration process. Such a change is an appropriate way of shifting part of the burden on information about substances from public bodies to the industries that profit from those substances.

Information Requirements: The information gathered for the Domestic Substances List consists of all chemicals manufactured in or imported into Canada in quantities of not less than 100 kilograms in any one calendar year between January 1, 1984 and December 31, 1986.[12] Chemicals found on the Domestic Substances List include polymers and mixtures.

There were two types of forms [13]designed by Environment Canada to compile the Domestic Substances list. Generally, the forms require the reporting of only very basic information.[14] Foreign suppliers who were required to report chemicals used a different

[12] Exclusions of following substances to the DSL:

- substances reported under Pest Control Products Act, the Food and Drugs Act and the Atomic Energy Control Act (this covers registered active ingredients for pesticides, radioactive substances prescribed within the Atomic Energy Control Act and pharmaceuticals cosmetics, foods and food additives);
- substances not exceeding 100 kilograms that are used for research and development;
- substances in article (defined "as a manufactured item that is formed into a specified 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"; and
- substances occurring in nature

[13] Environment Canada, Canadian Environmental Protection Act Reporting for the Domestic Substances List, July 1989.

Report Form A was used to report substances with a CAS Registry Number and non confidential identities. Report Form B was used to report a substance either lacking a CAS Registry Number and/or having been identified as confidential.

[14] Information requirements include: the Chemical Abstracts Service or CAS number; the name of the substance; molecular formula and structure (Report Form B only); designation of confidentiality (Report Form B only); company name, site of headquarters and of manufacture; contact information; type of activity (manufacture or import); amount initially manufactured, imported in commerce; codes assigned for quantity range [Quantity ranges outlined for the Report Forms: under 100 kilograms, 100-1,000 kilograms, 1000-10,000 kilograms, etc.]; and codes assigned for particular use of the chemical [two digit codes are assigned to various use categories]

form to maintain a level of confidentiality of information for specific substances, such as mixtures.

Timelines: In an effort to establish the Domestic Substances List, the information compiled only refers to substances manufactured, imported or in use in Canada between 1984 and 1986. Any substance not on this List is considered "new" to Canada and therefore is subject to notification requirements under the *New Substances Notification Regulations*, described in the following section of this report. Finally, the Domestic Substances List is updated regularly to reflect changes from the decisions made under the *New Substances Notification Regulation*s

The Domestic Substances List includes about 23,000 chemicals, which are being categorized according to their characteristics of persistence, bioaccumulation and inherent toxicity, or for their potential for exposure to Canadians. This categorization must be completed by 2006 by Health Canada and Environment Canada, as required by the Act.

Substances that are found to be of concern, as a result of categorization, will be subjected to a further screening level risk assessment to determine their toxicity, and, if required, they will be fully assessed under the more comprehensive process set up for substances assigned to the Priority Substances List.

Commentary

One of the most important improvements in the REACH system over those currently in place in Europe and Canada is the introduction of registration. This system has the significant advantage of transferring the responsibility for identifying chemicals currently in use and managing their risks from government authorities back to the industries that create and supply them. The resources available to industry and their inherent knowledge of the chemicals they use makes it far more efficient for them to generate this information, than it is for government agencies with limited funding and resources.

The European approach through REACH accounts for downstream uses of chemicals and ensures that the uses of all substances are captured in its registration process. Furthermore, REACH will also impose fees for registration to help fund the work of the European Chemicals Agency. This provision will transfer some responsibility for the burden of the costs of managing chemicals in Europe from the government to industry.

Within 11 years, REACH will create a bank of vital information on chemicals that governments have been struggling to collect over the last two decades – for example, what makes chemicals harmful and what might make them safer. And it aims to make much of that information available to the public so that the people who are exposed to these chemicals are able to make informed choices.

In Canada, generally the onus is on the government to establish the safety or risks related to specific chemicals. A compilation of the Domestic Substances List was undertaken mainly to create an inventory of substances used, manufactured or imported in Canada, not to determine what substances were harmful to human health and the

environment. Prior to CEPA 1999, the Domestic Substances List was used to identify the substances for the Priority Substances List. However, the function of the list shifted under CEPA 1999, becoming the basis for the categorization of all substances. This effort was the first step towards the identification of substances of concern. This process is discussed in section 6.2 of this report.

Another difference in the Canadian approach is the quality of data compiled under the Domestic Substances List. Despite having a reporting threshold of 100 kilograms for substances listed in the Domestic Substances List, the qualitative and quantitative data collected for the Domestic Substances List are too limited to make a clear determination of risk to human health and environment. The government must rely on its own assessment process to make the determination, and subsequently, to manage substances. Under REACH, the registration process for substances meeting a quantity threshold of one tonne or more requires that industry provide some toxicological information such as flammability, corrosivity, mutagenicity and aquatic toxicity. See Table 1 in this section.

For those substances not listed on the Domestic Substances List, substances are considered new and require different information under the *New Substances Notification Regulations*. The nature of the data required under this regulation will be discussed briefly in section 6.1.2.

Table 1: Summary of Approaches for Substances Already In Use

Canada	Europe	Comments
Domestic Substances List (DSL)	Proposed REACH Policy	
General Scope	**General Scope to Chemicals**	
Categorization Screening of the Domestic Substances List.	Registration, Evaluation and Authorization of Chemicals.	Canada does not have a registration or authorization process
Number of substances Addressed in Approach	**Number of substances Addressed in Proposed Approach**	
Current Inventory Approx. 24,000 substances, including polymers.	Current Inventory approx. 100,000 substances, excluding polymers.	Europe's proposed approach does not distinguish between existing and new substances.
Notification Process	**Registration**	
Categorization phase - substances qualify for further assessment if they are categorized "in" based on Persistence, Bioaccumulation and inherent Toxicity. Health Canada categorising "in" based on quantity/end-use/human exposure profile. 2000 to 4000 substances may be categorized as "in" Categorization end date - Sept. 2006	Substances qualify for registration if the quantity exceeds 1 tonne/annum. Only registered substances can be manufactured or imported. 30,000 substances expected to require registration. Registration starts in 2006 once the regulation is in force.	Canada's approach only applies to those substances on the DSL, while EU's approach captures all substances in commerce In Canada, new substances are considered and assessed under the New Substances Notification Regulations (NSN). This process requires the submission of information on substances, based on quantity and type of substances.
Assessments	**Evaluations**	
Screening phase starts - Oct. 2006 Substances categorized "in" subject to Screening Level Risk Assessment (SLRA). Companies will have to submit extensive toxicological and environmental data along with information on products, technical data, end-uses, concentrations, customer profiles etc.	Companies must submit tiered sets of data based on volumes > 1 tonnes/year - Annex V > 10 tonnes/year - Annex VI > 100 tonnes/year - Annex VII > 1000 tonnes/year - Annex VIII The data required is similar to that under the CEPA *New Substances Notification*	Canada assesses new and existing substances in different ways. Screening Level Risk Assessment and Full Risk Assessment may be applied to substances on the DSL. Substances not listed on the DSL will be required to submit limited information for consideration under the NSN Regulations. Under the NSN Regulations, the process for reviewing applications for substances may take as little as 5

	Regulations (NSN Regulations). The 1 tonne/year trigger requires Schedule II type data under NSN Regulations. Requirements escalate up to Schedule III and beyond.	days or as many as 120 days. Waivers and extensions for reviewing an application may be granted on a case by case basis. There is a lack of transparency in this process.
Based on the SLRA, substances will be: - subject to no further action - added to the Priority Substances list for further review. - Declared CEPA "toxic" Action to be taken can include: - no action; - condition of use; - subject to Significant New Activity Restrictions; - regulations or instruments; or - bans.	When a submission is filed with the central agency, registration is accepted or rejected (based on technical grounds of completeness). For volumes >10 tonnes/annum, companies must submit a "Chemical Safety Report" which must include risk assessment for all uses, and measures for risk management. Substances of special concern (carcinogens, PBT endocrine disruptors etc.) are prohibited unless specific uses are authorized. Approx. 2000 substances are estimated to require authorization.	Canada - The scope of data to be collected and reviewed in the SLRA is not explicit. Hazardous properties will be reviewed based on availability of data. Europe - information to determine hazardous properties Is required in Chemical Safety Report. The threshold for compiling this data should lowered.
Timeframe for SLRA	**Timeframe for registrations (depend on volume)**	
Schedule - SLRAs will be phased in depending on how many substances are categorized "in"	Schedule - The registration process must be completed for each substance within a transition time-frame: > 1000 tonnes/annum - 3 years > 100 tonnes/annum - 6 years > 1 tonne/annum - 11 years	Canada - No set timeframe for completing SLRA on any substances; nor are there criteria outlined to determine if substances undergo full risk assessment. Health Canada and Environment Canada have to set priorities to identify substances to undergo SLRA. Europe - timeframe for submitting information for a substance differs for facilities depending on volume.

Recommendations:

1. CEPA should be amended to create a formal registration process, for substances already in use in Canada, like that in REACH. The registration process should require mandatory submission of data on the properties of substances.

2. Industries should be required to provide comprehensive information on substances they are manufacturing or importing into Canada, including chemical safety reports.

3. Timelines should be imposed on the required submission of data.

4. A separate chemicals secretariat with a mandate to provide oversight and co-ordination functions should be considered in Canada.

5. This Agency should be funded by fees paid by industry for the registration of chemicals and other services.

6.1.2 Approaches to "New" Substances Coming on to the Market

In addition to addressing the backlog of chemicals already in use, governments have also tried to set up procedures to examine the new chemicals being brought on to the market.

The first step taken by Canada and countries in Europe was to distinguish between the chemicals in use before the early 1980s and chemicals introduced after that. Chemicals introduced after 1981 in Europe and after 1986 in Canada are called "new" chemicals, while chemicals already on the market are referred to as "existing" chemicals.[17]

Europe's Approach to New Chemicals under REACH

In Europe, programs for handling new chemicals are currently governed by the Dangerous Substances Directive (Directive 67/548/EEC). This Directive requires new substances manufactured or imported in quantities of 10 kilograms or more to be tested and assessed for possible risks to human health and the environment before coming on the market. For higher volume chemicals, industries must provide more in-depth testing on long-term and chronic effects. Member States are responsible for reviewing new chemical dossiers and some have stricter review and data requirements than others. It is, however, not a comprehensive review of the risks.

REACH will eliminate the distinction between so-called "new" and "existing" chemicals. All chemicals, regardless of when they were introduced, will be registered. New chemicals approved in Europe before REACH is enacted will be automatically registered under REACH. Substances that are introduced once REACH becomes law

[17] CEPA uses the word "substance" rather than chemical; we use them interchangeably in this report

will be subject to the same registration requirements as all other substances. The idea is to stimulate development of safer chemicals by levelling the playing field.

Registration will require manufacturers and importers to obtain comprehensive information on their substances, including performing new tests where necessary to establish the safety of these chemicals, and submitting the data to the European Chemicals Agency. This information will be used by the industries to manage chemicals more safely, and by the Agency to decide which chemicals need further evaluation. The goal of registration is to ensure that information on chemical safety is generated by the manufacturers and importers prior to a government review.

Canada's Approach to New Chemicals under CEPA

In Canada, there are two ways in which new chemicals can find their way onto the Canadian market.

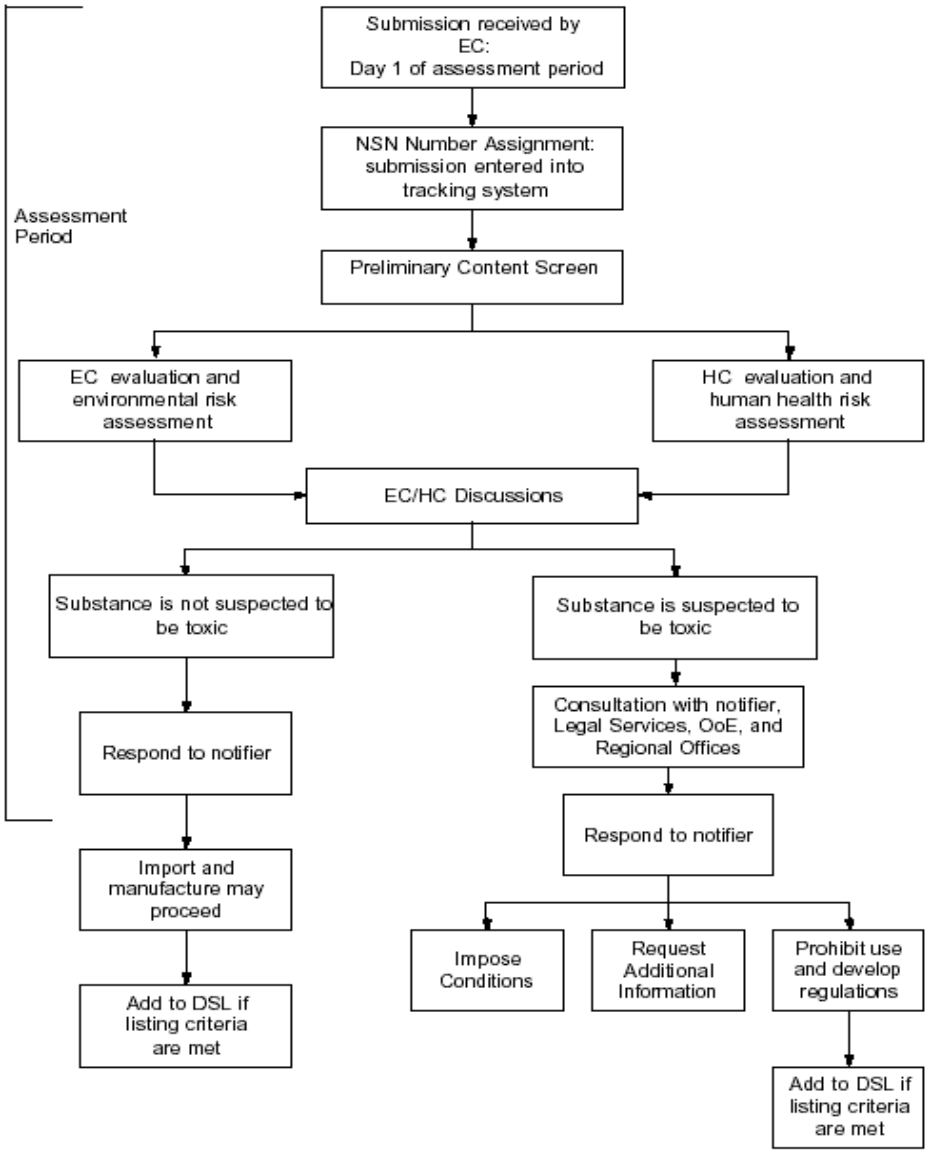
The main entry point for new substances on the Canadian market is the *New Substances Notification Regulations*. These regulations require notification and some testing information to be submitted by the manufacturer or importer. Notification requirements must be submitted for all substances that are not listed on the Domestic Substances List. For an overview of the New Substances Notification process refer to Figure 1.

The information requirements pertaining to new chemicals are complex, and do not necessarily include a comprehensive assessment of their safety. For example, the following information is required for substances that are manufactured or imported in one year and in small quantities between 20 and 1000 kilograms:

- the chemical name;
- the Chemical Abstracts Service (CAS) number;
- any trade names or synonyms of the chemical name;
- a material safety data sheet (MSDS), if one exists for the substance;
- “all information in respect of the substance that is relevant to identifying hazards to human health and the environment and that is in the person’s possession”;
- the intended uses of the substance; and
- contact information of any other government agencies in Canada or elsewhere that have been notified of the manufacture or import.[18]

[18] *New Substances Notification Regulations* (NSNR), SOR/94-260, Schedule I

Figure 1: Requirements for New Substances under the *New Substances Notification Regulations*



For a substance meeting the above data points, the Ministers of Health and Environment are effectively deemed to have assessed the required information submitted on the substance *just five days after the notification*. Longer assessment periods and more information requirements apply to substances meeting higher quantity thresholds. In effect, the substance is then presumed to be harmless and is allowed to enter into Canadian commerce.

The NSN covers new substances, polymers and products of biotechnology. Thresholds for submitting notification may differ slightly depending on whether the substance is a new chemical, a polymer or a biotech product. Different requirements and different

assessment periods apply depending on the volume of chemical being manufactured or imported.

A key provision in the *New Substances Notification Regulations* makes it possible for new substances to come onto the Canadian market without a complete evaluation. If the government's review of a new chemical is not completed within the specified timeframe, the government must allow the manufacturer or importer to bring it on to the market without a complete review. This is similar to schemes in the current U.S. and European legislation that rely on notification and allow substances on the market if a review is not done within a certain time frame. In Canada, the time frame allotted to the government for their reviews depends on the type of substance and the Schedules under which the substance is considered. Initial assessment periods for some substances can be as little as five days, and up to 120 days.

Should additional information be required for making a determination, an extension for review is granted. The length of the extension depends on the nature of the new substance, polymer or biotechnology product, as set out in the regulation's Schedules.

A second list, called the non-Domestic Substances List, offers another entry point for new chemicals entering the Canadian market.

The non-Domestic Substances List is a list of chemicals that are not on the original Domestic Substances List. CEPA created the non-Domestic Substances List (nDSL) as a way of ensuring that new chemicals in use internationally could be assessed before entering the Canadian market. The non-Domestic Substances List is based generally on the list of new substances introduced under the U.S. *Toxic Substances Control Act*, for which some data have been collected and evaluated. Some data collected on these substances may be kept confidential even when listed on the non-Domestic Substances List.

According to Environment Canada, there are some 56,000 substances on the non-Domestic Substances List[19]. The Act requires that the non-Domestic Substances List be updated every five years. In principle, all chemicals listed on the non-Domestic Substances List can come onto the market after they have met the requirements of the *New Substances Notification Regulations.*

Industry has expressed concerns over the length of time it takes to add substances to the non-Domestic Substances List. The five year interval for updating the non-Domestic Substances List with substances found on the U.S. list has long been viewed as a barrier to their interests. After the manufacturers or importers have met the requirements of the *New Substances Notification Regulations* and been approved for use, they may be moved from the non-Domestic Substances List to the Domestic Substances List.

To reduce the time interval and ensure that the government and industry met their obligations under the Act, the Four Corners Arrangement was established between

[19] Personal communication with Environment Canada, New Substances Branch,on July 14, 2004

Environment Canada, Health Canada, the U.S. Environmental Protection Agency, the U.S. Chemicals Producers Association, the American Chemistry Council, and the Canadian Industry Coordinating Group. This Arrangement was created for the purposes of sharing data from the U.S. Toxic Substances Control Act, protecting confidential business information and allowing quicker access to the Canadian market. The Arrangement was first run as a pilot project in 1996 and formalized into an Agreement in 1998. It allows information to be considered by Health Canada and Environment Canada on substances used in the United States for addition to the non-Domestic Substances List without waiting for the five year interval.

The information gathered through this Arrangement is far less onerous than the information required in the notification process. A request that the Four Corners Arrangement apply must be submitted simultaneously with the notification package.

The addition of substances to the non-Domestic Substances List through this process is undertaken with a lack of public transparency and access. The confidentiality of information provided in a Four Corners submission is generally protected.

Commentary

In general, the laws for new chemicals in both jurisdictions impose notification requirements and the submission of information on classification and labelling to government agencies from the companies seeking to use them.

However, REACH will introduce a consistent approach for both new and existing substances. By making all substances part of the REACH registration program, a comprehensive package of information on the nature and hazards of any chemical already in use or coming into use will be required. The onus will be on the manufacturer or importer to provide the required data, understand the supply chain risks and show that the chemical can be used safely.

In addition, REACH offers a level of transparency that the current Canadian system does not. Non-confidential information, including the results of toxicological and ecotoxicological studies and guidance on safe use, will be available to the public. The European Commission is currently developing the framework for this data. The public will have an opportunity to know what substances have been registered, and can be assured that safety assessments have been done before a chemical comes on the market and for chemicals already in use.

In Canada, the burden of assessing the risk from the introduction of new chemicals into commercial use falls primarily on government agencies. Environment Canada and Health Canada are still responsible for proving that these chemicals pose a risk. In the case of the *New Substances Notification Regulations*, limited information is required.[20]

[20] Under the *New Substances Notification Regulations* (NSNR), SOP/94-260, Schedules I-XVIII provides specific details on the information that may be required by the government to assess substances including: mammalian toxicity test, mutagenicity data (in vitro/in vivo), skin irritation test, skin sensitization test, fish and daphnia acute toxicity test, etc. The volume and type of substance to be assessed will determine what NSNR Schedule applies.

Additionally, if the government cannot evaluate them in a timely manner, the chemicals must be allowed onto the market, regardless of their threat to the environment or to human health.

Recommendations:

6. Following the REACH approach, the distinction between new and existing substances should be eliminated within the CEPA approach.

7. An expanded Domestic Substances List should include all new and existing chemicals. The requirements for providing data to the government should be reviewed and revised to provide a more co-ordinated, less disjointed approach to registration or notification of substances. As with REACH, the requirements for data should be stricter for chemicals that are used in larger volumes and for chemicals with hazardous properties such as carcinogenicity.

8. The registry of information on chemicals should be transparent and available for public review.

9. Amendments to CEPA should ensure that industry provides adequate data for all new and existing chemicals in order to assist the government in making a determination of toxicity based on their inherent properties.

10. Unlike the REACH approach for registration, CEPA should retain its provisions to apply to animate or inanimate organisms (products of biotechnology). These provisions should also be retained for polymers, which may be included in REACH in the future.

11. Unlike REACH, CEPA should retain reporting thresholds, as low as 20 kilograms, currently required for some substances under the *New Substances Notification Regulations,* but increase reporting requirements. This threshold should apply to all substances, existing and new.

6.1.3 Substances in Articles

European Approach to Substances in Articles under REACH

Concerns have been expressed not only about toxic chemicals, but also about the hazards of such chemicals when they are contained in articles and products. Sweden and Denmark, in particular, have aggressively targeted certain substances in products, and enacted their own restrictions and bans on these substances. For example, in 2000 Denmark banned the use of phthalates in children's toys.

Under the proposed REACH regulation, it is assumed that most substances found in products will be registered if they are imported or manufactured for subsequent use in

products in large enough quantities to meet the REACH threshold. If restrictions on these substances exist, their use would not be allowed in products.

However, products that are wholly manufactured outside of Europe and imported may potentially contain hazardous substances that would not be covered by REACH. Pressure from northern European countries to address this possibility has led to some provisions in REACH intended to limit the risks from potentially hazardous substances in articles. Under REACH, producers or importers of articles that contain dangerous substances in quantities of one tonne or more per year must register these substances if they will be released from the article during normal use.

A lesser requirement will be imposed on manufacturers or importers of substances in articles where the substances meet the criteria for classification as dangerous, and can be released during normal conditions of use even though their release is not intended. This applies to products that are likely to leak dangerous substances, for example. In this case, companies are required only to notify the European Chemicals Agency. The Agency has the discretion to require producers and importers to register these substances if they are present in products in quantities of more than one tonne per year.

Importers of articles must also comply with all the authorisations, restrictions on specific hazardous substances identified in Annex XVI of REACH and the restrictions on persistent organic pollutants.

Although REACH introduces some limited requirements for substances in articles, the northern European countries have criticized REACH for the lack of information about the content of dangerous chemicals in articles even where there is no obvious potential for release.

Canada's Approach to Substances in Articles under CEPA

CEPA has the potential to address problematic substances in products under its broad regulatory powers. So far, however, it has only addressed these substances as individual chemicals. For example, under the *Prohibition of Certain Toxic Substances Regulations, 2003*, benzidine and hexachlorobenzene cannot be used, sold, offered for sale or imported. This includes the use of these substances in products. Other substances, such as lead in children's jewellery, have not been adequately controlled. Products containing hazardous substances continue to enter the Canadian market mainly because of the weaknesses of the Hazardous Products Act.[21]

Commentary

The REACH approach to substances in articles and products appears to be stronger than the approach taken in CEPA. However, doubts about its ability to ensure the safety of products have been communicated by various stakeholders to the European

[21] Kathleen Cooper et. al.., Environmental Standard Setting and Children's Health, A Report by the Children's Health Project, a joint effort of the Canadian Enviormental Law Association and the Ontario College of Family Physicians Environmental Health Committee, 2000

Commission. In Europe some restrictions on hazardous chemicals in articles have been implemented under the Limitations Directive, more than have been enacted in Canada. These will be carried over under REACH. Europe has also restricted the use of hazardous chemicals such as lead and cadmium in electric and electronics equipment under a recent European Directive.

In both REACH and CEPA, there is a need to address the potential hazards of substances in articles and products. At the very minimum, those products that are assembled in Europe will be captured by REACH.

Recommendations:

12. CEPA should be strengthened to require importers of articles containing hazardous substances to submit chemical safety reports on their products.

13. CEPA should assert its authority to regulate toxic substances in products.

6.2 Priority Setting, Evaluation and Assessments

The next step in the process of controlling hazardous chemicals is determining which ones pose the greatest risk. Once government agencies have sorted out which substances are in use and in what quantities, they must assess the chemicals for their toxic properties and their impacts on human health and the environment. Because of the thousands of chemicals in use, assessments of one chemical at a time present a formidable challenge to the goal of assessing all chemicals in use.

Moreover, it is in the interests of the industries who market and use them not to be forthcoming with the information on chemical risks. The onus is currently on governments to do the scientific studies and assemble evidence that specific chemicals are hazardous and should be banned or controlled.

Europe's Approach to Assessing Chemicals using Evaluations under REACH

After registrations have been submitted to the European Chemicals Agency, the second stage of the REACH process is the evaluation. Evaluations will be done after companies have submitted all the information required by the registration. Because the registration process obliges industries submit data for registration, the European Chemicals Agency will receive more detailed and explicit information on various chemicals, including chemical safety reports for those chemicals manufactured or imported in large volumes.

The registration information submitted by companies for registration will be reviewed from two different perspectives. The two different types of evaluations of registration information that will be performed under REACH are "dossier" evaluations and

"substance" evaluations. These will be done by the countries (referred to as Member States) in which the companies are located.

Member States will examine the registration data and conduct the dossier evaluation. The primary reason for this first review of the registration material is to avoid unnecessary animal testing.

When companies submit their registration data, not all the testing requirements will have been completed and they may have to fill in the gaps in toxicity information through animal testing. Manufacturers or importers that propose animal testing in their registrations may be required to share data with other companies that propose similar testing.

Concerns about animal testing have a higher profile and resonance in Europe than in Canada. One of the primary goals in revising the European chemicals legislation has been the promotion of non-animal testing.

The second type of evaluation that may be done is a substance evaluation. If the registration data and chemical safety reports suggest that the chemicals may present a hazard, evaluations of particular substances will be done by Member States. Substance evaluations are intended to clarify whether a suspicion of a risk to human health or the environment is justified.

The European Chemicals Agency will set the priorities for which substances are evaluated in order to determine which chemicals need to be more strictly controlled. The criteria will be risk-based and take into account the available information on hazard, tonnage and potential for exposure. The Member States will incorporate the Agency's priorities into their rolling plans for evaluations.

The Member States may also propose specific substances to evaluate, and in consultation with the European Chemicals Agency, decide which ones they will include in their plans. They are only allowed to choose a substance for evaluation and include it in their plans if they have reasons to suspect that a substance presents a risk.

Substances may present a risk if they have a "structural similarity to known substances of concern or with substances that are persistent and liable to bioaccumulate, that suggests that the substance under suspicion for one or more of its transformation products, has properties of concern or is persistent and liable to bioaccumulate. The suspicion may also arise from aggregated tonnage from the registrations submitted by several registrants".[22]

Member States also have the authority to require further information or testing from the industries, if it is necessary for their evaluations. There is a time limit of one year in which to finish this work.

[22] The REACH Proposal Process Description, June 2004

The purpose of these evaluations is to identify chemicals of high concern that pose a risk to human health and the environment, as well as to fill in remaining data gaps. These evaluations may lead to proposals to place controls on these chemicals – either through the authorisation process or through restricting their use (see the next sections).

Canada's Approach to Assessing Chemicals using Categorization, Prioritization and Assessment under CEPA

In Canada, there are three stages that determine whether a substance will be controlled by CEPA. Figure 2 and 3 are charts describing the stages for identifying and assessing substances already in use in Canada. First, there is the identification of substances of concern. Second, these substances are then subjected to either a screening level risk assessment or an in-depth risk assessment. Some substances may be screened first and then proceed to the more comprehensive risk assessment, which is described as the third stage.

Stage 1 – Triggers for Assessment

To identify chemicals as candidates for further screening or assessment, there are a number of triggers:

- The first way in which chemicals can be identified for further screening or assessment is through the Domestic Substances List categorization[23] process.

Categorization Process Requirements (s. 73): Health Canada and Environment Canada are required by section 73 to review the Domestic Substances List to determine which chemicals have the greatest potential for exposure for Canadians, or are persistent or may bioaccumulate, and are inherently toxic to humans or non-human organisms. Using these criteria, the chemicals on the Domestic Substances List are being categorized to determine which ones require either screening level risk assessments or more comprehensive risk assessments. The categorization process was a new obligation created under CEPA 1999 to address the large number of substances in Canadian commerce for which little or no data are available. This process must be completed by September 14, 2006. See Figure 2 for an overview of activities by Environment Canada and Health Canada on the categorization of the Domestic Substances List.

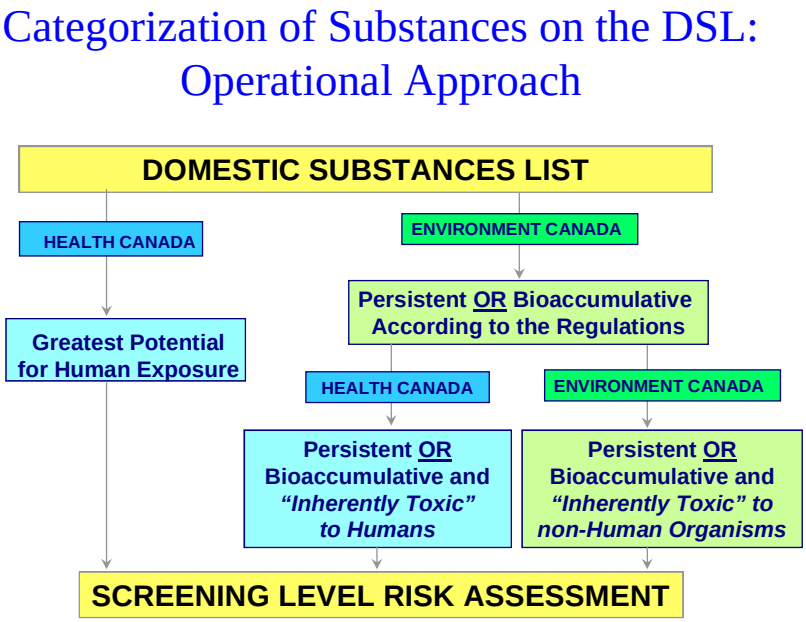
- The second way in which chemicals are identified as chemicals of concern is by being placed on the Priority Substances List.[24]

Development of the Priority Substances List: Two priority lists have been developed in Canada through multi-stakeholder consultations. From time to time, substances have been added to the priority substances lists (PSL) on an ongoing basis since 1988. A total of some 69 substances or classes of substances have been evaluated -- forty-four

[23] CEPA 1999, s. 73
[24] CEPA 1999, s. 76

through the first priority list, and twenty-five from the second priority list established in 1995.

Figure 2: Categorization of the Domestic Substances List[25]



- A third way is through public nomination to the Priority Substances List.

Public Nomination Process (section 76)*:* The public may nominate substances to be considered as priorities for assessment under a process described in CEPA 1999. The nominated substance would undergo a screening level risk assessment, and, at the discretion of the Minister of the Environment, be placed on the Priority Substances List. Once on this List, the substances will undergo a full risk assessment. Very few substances have been accepted for assessment through this pathway.

- A fourth way in which substances can become candidates for screening or assessment is by evaluating regulations from other jurisdictions that have enacted bans and severe restrictions.

Other Jurisdictions (section 75): Section 75 allows for the review of restrictions introduced in other jurisdictions, including Europe. It is possible that the evaluations that will be done under REACH will significantly increase the number of chemicals that need to be considered for controls[26]. If the European evaluations result in bans or severe restrictions, the Canadian government will have to review such decisions, using

[25] Presentation by Environnment Canada on January 28th, 2004
[26] John Buccini, "The Relevance of National and International Initiatives on Toxic Substances to the Managment of Hazardous Air Pollutants in Canada", prepared for The Hazardous Air Pollutants Working Group of the Canadian Council of Ministers of the Environment, March 30, 2002

information exchange procedures that CEPA requires be established. Unless the chemical is regulated by another federal Act, Canada will be obliged to make a determination whether the substance is CEPA-toxic. The government has not yet developed the information exchange system required by subsection 75 (2), and this section has not yet been implemented.

- *Other Triggers:* Although we do not have information on whether these triggers have been used, substances may also become candidates for fuller assessments:

  - through industry information;[27]

  - as a result of international assessment and data collection; and

  - through emerging scientific findings on substances.

Stage 2 - Screening Level Risk Assessment

After substances on the Domestic Substances List have been categorized, or otherwise identified as chemicals of concern, Health Canada and Environment Canada choose those that need a screening level risk assessment or a comprehensive risk assessment. The screening level risk assessment is intended to reduce the amount of time that it takes to decide whether a chemical is "toxic" and to avoid a longer risk assessment process.

Substances that have been identified through the categorization process as having the greatest potential for exposure or meeting the criteria for persistence or bioaccumulation and inherent toxicity are sent to the screening level risk assessment process. Chemicals identified through the other triggers could also be candidates.

The objective of the screening level risk assessments is to decide which chemicals are "toxic" or have the potential to become "toxic", as the term is defined by CEPA (referred to as "CEPA-toxic"). Based on the screening level risk assessments, chemicals are divided into three major groups:

- those for which no further action is needed because they are not considered toxic;
- those that are declared toxic and should, therefore, be proposed for addition to the List of Toxic Substances; and
- those that need more assessment to determine whether they are toxic or not. Substances that fall into the third category of needing more study will be slated for full risk assessment. They may be added to the Priority Substances List. Figure 3 provides an overview of actions that can be taken upon completion of the screening level risk assessment.

[27] Note: Where anyone dealing with a substance obtains information suggesting that the substance is toxic, s/he must, "without delay," provide that information to the Minister of the Environment. See CEPA, s. 70

Environment Canada and Health Canada are jointly responsible for conducting and completing screening level risk assessments of these chemicals. CEPA does not provide a timeline by which the screening level risk assessments are to be completed.

The federal Commissioner of the Environment and Sustainable Development described the experience with the process to date in this way: "the federal government is…required subsequently to assess or screen the substances identified through categorization and *this may take a few decades to complete*".[28]

In the five years since CEPA has been enacted, only the screening level risk assessment for brominated flame retardants (seven polybrominated diphenyl esters) has been publicly released. Currently, another 123 substances that are part of a pilot project are undergoing screening level risk assessments that began in 2002. The results of this pilot project will highlight some of the challenges of the screening level risk assessment process.

Members of the environmental community have expressed concern that the current categorization of all 23,000 chemicals on the Domestic Substances List may result in substances of concern not being captured for screening level risk assessments.[29] For example, Health Canada is required to determine the greatest potential for exposure for every substance on the Domestic Substances List, but Health Canada will only be reviewing a partial list of relevant substances for inherent toxicity to humans. Environment Canada first reviews the complete list for substances that are persistent or bioaccumulative but not inherently toxic to non-human organisms. Health Canada is limited to reviewing only those chemicals that have already met the criteria set by Environment Canada. Furthermore, the criteria set out in CEPA do not explicitly include carcinogenicity, mutagenicity or endocrine disruptors, as they do in REACH.

In addition, the obligations set out in CEPA do not provide a process for those Domestic Substances List substances that meet the criteria for persistence and bioaccumulation, but not inherent toxicity, characteristics that may be useful in identifying persistent organic pollutants. Such substances are the focus of the Stockholm Convention on Persistent Organic Pollutants.[30] This approach is unlike REACH, which identifies a list of hazardous properties including persistence, bioaccumulation and toxic, to identify substances that require authorisation (see section on authorisation). Persistent organic pollutants under the Stockholm Convention will be restricted under REACH.

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[28] "Chapter 1: Toxic Substances Revisited" in (2002) Report of the Commissioner of the Environment and Sustainable Development to the House of Commons, at paragraph 1.23 (emphasis added)

[29] More details on issues related to categorization, refer to Comments on Environment Canada's "Guidance for Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List: Determining Persistence, Bioaccumulation Potential and Inherent Toxicity to Non-Human Organisms, prepared by CELA, World Wildlife Fund Canada and Canadian Association of Physicians for the Environment, November 7, 2003

[30] The Stockholm Convention on Persistent Organic Pollutants has provisions to nominate additional POPs for action under the Convention. The POPs Review Committee established under the Stockholm Convention is responsible for considering POPs nominations.

The government departments must release the results of screening level risk assessments in a draft assessment report for a public comment period of 60 days. However, CEPA does not set out a timeframe for finalizing the assessment reports.

Stage 3 – Full Risk Assessment

Some substances may be selected from the categorization and screening process to undergo a full risk assessment to determine whether they are toxic and need to be controlled. The full risk assessment has also been used for those substances on the Priority Substances List.

The full risk assessment may take up to five years to complete.

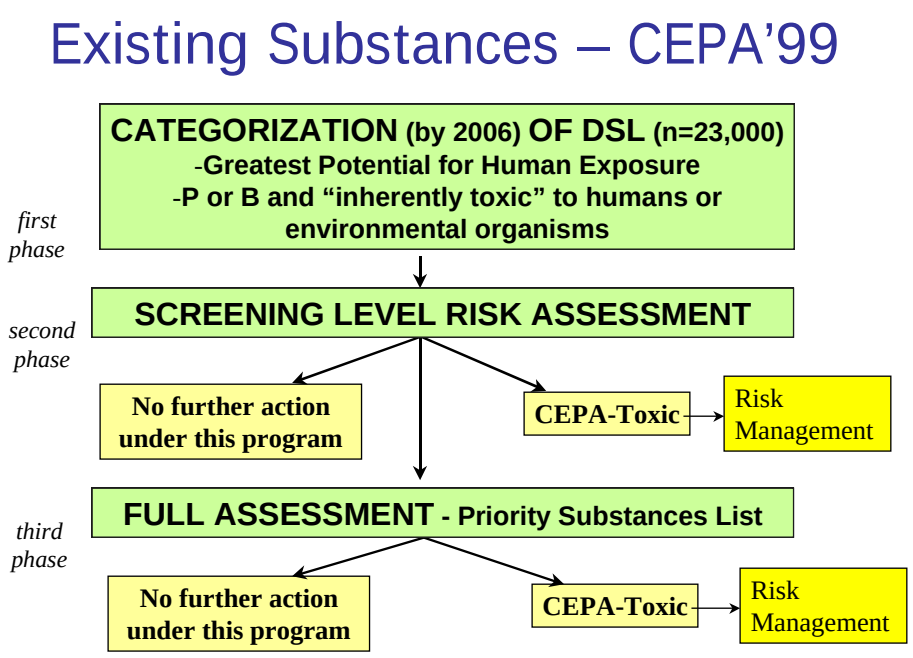
To allow for the determination of toxicity to be made, data collection is comprehensive and additional tests can be conducted. Under CEPA 1999, the government has the authority to require the companies to submit information on specific chemicals. This requirement has been triggered mainly for those substances sent on for full assessment.

When the risk assessment is completed, the results are released as a draft assessment report through the *Canada Gazette Notice* for a 60 day comment period. The draft assessment may designate the substance as "CEPA-toxic" and include a recommendation that the substance be placed on the List of Toxic Substances.

The length of time to finalize an assessment report is undefined in CEPA. An example of an assessment report which has not been finalized is the draft assessment report on radionuclides on non-human organisms which was released in 2000.

Once the assessment report has been finalized by the government, the government may then decide to add the substance to the List of Toxic Substances. This obliges the government to regulate or propose controls on the substance.

Figure 3: Overview of Categorization and Assessment Process under CEPA[31]



Commentary

Evaluations under REACH are intended to be an efficient and effective process for identifying chemicals of concern out of the 30,000 chemicals that will be registered, and will be done on the basis of risk assessment information provided by the registration packages. The European Chemicals Agency and the Member States will have data and risk assessment information, submitted by industry that will enable them to identify quickly the chemicals that need further investigation. Although the evaluation process will rest on the shoulders of government agencies, it appears to be a simpler, faster process than the screening level risk assessment process because of the one year time limit during which Member States have to complete their evaluations.

Industry in Europe will play a much larger role overall in providing the information that, in Canada, is currently generated or compiled by government agencies. For example, in Europe tests for mutagenicity must be conducted and submitted by industry as part of the registration package for all substances manufactured or imported in quantities of one tonne or more. When studies show positive results, further studies for better understanding the mutagenic properties of the chemical will be required.

Europe will also have the advantage of experts in 25 qualified government agencies of Member States to share the work of evaluations.

[31] Information Session on Priority Setting/Assessing Domestic Substances List by Health Canada, Ottawa, Ontario on November 21, 2002

CEPA's current framework can improve significantly by requiring industry to provide data to facilitate assessments at a much earlier point in the process. While there have been collaborative efforts between government and industry to collect data, industry's participation has been voluntary. Up to this point in the process, there have been no mandatory requirements for industry to provide essential data.

Section 71 of CEPA, that allows government to require data from industry, has been underutilized as a result of the government's relying on industry to voluntarily provide information to assist them in completing assessments or categorization. In REACH, the ability of Member States to request information or testing from industry is explicitly described along with a defined timeframe of one year to complete this task. Section 71 of CEPA does not provide explicit detail on the type of information being requested, nor timelines for completion.

Recommendations:

14. CEPA should impose stricter and shorter timelines, particularly at the evaluation/assessment stage.

15. CEPA should extend the DSL categorization of existing substances to make it as broad in scope as the REACH program, in order to capture the following:

- Substances that are known or suspected carcinogens, mutagens or reproductive toxins;
- Substances that affect endocrine systems;
- Substances that affect developmental functions; and
- Substances that cause serious and irreversible effects to humans or the environment, equivalent to these other hazards.

The required health endpoints (in both qualitative and quantitative data) should be articulated in CEPA.

16. CEPA should make Section 71 a mandatory requirement for the categorization and assessment activities. Furthermore, Section 71 should include a timeframe for completing and submitting the information required by government to complete its assessment of substances.

6.3 Authorisations and Risk Management Measures

6.3.1 Authorisation Requirements and Risk Management Measures

Once the hazardous or toxic properties of a chemical have been confirmed, the next step is to control or even to eliminate it from use. In Europe and in Canada, an array of strategies for elimination or control have been considered. Strategies range from

outright bans on substances considered undesirable, to regulations restricting their use, to voluntary agreements, or various other instruments.

Europe's Approach to Managing Risk by Authorisations under REACH

An important new instrument for control -- the authorised use of chemicals -- has been introduced in REACH. Substances with dangerous properties will be listed in an Annex of the proposed REACH Regulation. The European Union will allow the use of these designated substances only with an authorisation.

An estimated 1500 chemicals will be transferred from the European Union's current Dangerous Substances Directive to the Annex of chemicals under REACH that will require authorisation prior to use. Decisions about which substances will be transferred to the Annex, and about the granting of further authorisations, will be made by the European Commission.

Substances designated as dangerous are those that are known to have any of the following properties:

- carcinogenic in categories 1 and 2;
- mutagenic in categories 1 and 2;
- toxic to reproduction in categories 1 and 2;
- persistent; bioaccumulative;
- very persistent; very bioaccumulative;
- endocrine disruptors; and
- substances identified as having serious and irreversible effects on humans or the environment equivalent to these other effects.[32]

When it has been determined through the evaluation process that chemicals in use have these properties, they will be added to the list of chemicals in a specific Annex of REACH. Chemicals listed in this Annex will only be authorised by the European authorities for use under certain conditions. To obtain an authorisation, companies must show that the risks from using these chemicals can be controlled. If the risks cannot be adequately controlled, an authorisation may be granted if a company can show that their use of a hazardous substance is justified on socio-economic grounds and that these outweigh the risk to human health or the environment. Socio-economic grounds will only be accepted, and authorisations granted, however, if there are no suitable alternative substances or technologies.[33]

Again, the intention of REACH is to shift the burden of responsibility to industry. They are obliged to demonstrate that they can control the risks that arise with their use of a chemical or prove that there are sufficient social and economic reasons for its use that

[32] Commission of the Europe Communities, A Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), October 29, 2003

[33] Cefic, Appendix 1, p. 5

such a use can be justified. Each use of a chemical must be authorised, but a company may ask for a blanket authorisation for many uses.

Authorisations for use of hazardous chemicals will be time-limited, based on the assumption that these chemicals are likely to be regulated at a future date.

Substitution (alternative substances or technologies) has become a critical feature of much European legislation, including the Occupational Carcinogens Directive, the Biocidal Products Directive, and the Restrictions on Hazardous Substances in Electric and Electronic Equipment Directive. Each of these Directives requires the substitution of dangerous substances with less dangerous substances or technologies where suitable alternatives are available.

Although substitution is a stated objective of REACH, and is considered by some to be critical to the current REACH proposal, countries like Sweden have argued that the substitution provisions of REACH are not strong enough. Under REACH, hazardous chemicals may be authorised even if they cannot be used safely, if socio-economic reasons outweigh the risk to human health and the environment and *if there are no suitable alternatives.* Sweden has argued during the discussions leading to the REACH proposal, that authorisations should not be granted at all if safer alternatives exist.

Canada's Approach to Risk Management Measures under CEPA

In Canada, dangerous substances are controlled under CEPA by a range of options available to the government in the legislation. However, there is no consistent direction within CEPA that determines how a substance will be controlled.

Once a substance is found to be “CEPA-toxic”, the Ministers of Environment and Health recommend to Cabinet that it be added to the List of Toxic Substances (Schedule 1 of CEPA). At the same time they may also decide to propose the substance for virtual elimination.[34]

Under Section 64 of the CEPA, a substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions that:

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(b) constitutes or may constitute a danger to the environment on which it depends; or

(c) constitutes or may constitute a danger in Canada to human life or health.

[34] In order for the substance to be slated for virtual elimination, the Ministers must be satisfied that the substance is “persistent and bioaccumulative in accordance with the regulations," that it is present in the environment primarily as a result of human activity, and that it is “not a naturally occurring radionuclide or a naturally occurring inorganic substance”: see subsections 77 (2) (c) and (4) of CEPA

The final decision whether to add the substance to the List of Toxic Substances (TSL) is completely at the discretion of Cabinet. Cabinet must agree with the Ministers' recommendation in order to add the substance to the List of Toxic Substances, and publish it in the Canada Gazette. A 60-day public comment period follows. As of August 2003, 68 "CEPA-toxic" substances, classes of chemicals or emissions from specific industrial sectors have been placed on the List of Toxic Substances.

If the substance is finally added to the List of Toxic Substances, the government must implement controls. Following publication of the risk assessment report and recommendation for listing on the Toxics Substances List, the government has two years to develop and propose a regulation or other control instrument for managing the substance.

Options for controlling a substance include a range of regulatory and non-regulatory tools, including: regulations that could impose bans or restrictions on chemical use, pollution prevention plans, codes of practice, and non-regulatory instruments such as guidelines or memoranda of understanding.

The government releases the proposed management options for consultation before deciding on recommending a specific management tool. After an instrument proposal has been published, the Environment Minister must publish the final instrument within a further 18 month period. However, after the publication of a decision on the final control instrument, there is no standard timeline in CEPA for implementation of the final instrument.

Nor is there a statutory obligation on government to impose restrictions or prohibitions on the use of substances found to be toxic. Moreover, the Government of Canada Regulatory Policy (which nominally applies to all regulation-making deliberations by the federal government)[35], favours non-regulatory instruments. Rather than promoting the public interest in environmental and health protection, this policy discourages and imposes barriers to regulations.

Pollution prevention plans are currently an instrument available to the the government for the control of CEPA-toxic substances. Part 4 of CEPA establishes a system whereby the Minister of the Environment may require any person to "prepare and implement a pollution prevention plan in respect of a substance or group of substances specified on the List of Toxic Substances,"[36] or in limited circumstances involving international air or water pollution.

Although pollution prevention plans could be a useful instrument to eliminate toxic chemicals, there are limitations in its current application. For example, there is very little information available on the pollution prevention activities undertaken by facilities. Whereas assessments of toxic chemicals are published, pollution prevention plans do

[35] The Regulatory Policy is identified in a Treasury Board manual as the "key policy governing regulation in Canada": A Guide to the Regulatory Process for TBS Program Analysts (Treasury Board Secretariat, no date), online at http://www.tbs.sct-gc.ca/ri-qr-processguideprocessus_e.asp (accessed 1 December 2003)
[36] CEPA 1999, s. 56

not have to be made public. Facilities are only required to submit declarations first, that they have prepared a pollution prevention plan, and secondly, that they are implementing it. There is no way for the public to monitor or evaluate the effectiveness of the plans. Only if the substance is one of the chemicals monitored under the National Pollutant Release Inventory is it possible for the public to observe whether the industry is still discharging the chemical to the environment, and in what quantities.

Although the availability of various options allows for the strategic control of chemicals with different hazardous properties, there is no clear and mandatory path for control within the legislation. It is also unclear what factors influence the government's decision on a particular control strategy from one substance to the next.

Commentary

The REACH approach is a major departure from previous attempts to control chemicals that present a risk.

By requiring users to apply for authorisations and to justify the use of a hazardous chemical, authorisations will likely motivate industry to seek alternatives to chemicals of concern. Time limits on authorisations will also be a disincentive to use these chemicals. As a consequence, it is likely that the introduction of authorisations will put pressure on downstream users to look at substitutes, and precipitate the development of less hazardous chemicals and the re-engineering of processes that require their use. However, REACH has not developed support for this direction.

Authorisations represent another example of how REACH will transfer the onus to industry for demonstrating that chemicals of concern can be used safely.

Another important feature of the REACH legislation that is not part of CEPA is the promotion of substitution. The approval or authorised use of a hazardous chemical under REACH will specifically require consideration of substitutes for the chemical. Under CEPA, the emphasis is on control rather than avoidance or substitution of hazardous chemicals.

However, there are opportunities in the CEPA framework for addressing substitution. Pollution prevention plans, for example, could mandate consideration of substitution. This would demand an aggressive overhaul of the pollution prevention planning provision to make it work effectively.

It is also interesting to note that the list of authorised chemicals under REACH will be based more on the inherently hazardous properties of the chemicals than on their actual observed effects on the environment or on human health. For example, human health effects such as carcinogenicity or hormone disruption, as well as properties such as persistence or bioaccumulation that threaten the environment, qualify a chemical for inclusion in the candidates for authorisation. However, even though the list is hazard based, the authorisation process itself is still judged on the basis of risk.

In contrast, the effect of current European legislation and CEPA is to force government agencies to establish the harmful effects of the chemical to the environment and human health before controls may be imposed. CEPA, unlike REACH, does not explicitly consider carcinogenicity, mutagenicity or reproductive toxicity as part of its criteria for identifying chemicals that pose a risk to Canadians.

Although CEPA is supposed to be governed by the principles of precaution and the weight of evidence, the government has not demonstrated that these are implemented in an integrated way throughout the CEPA process.[37]

Recommendations:

17. CEPA should be strengthened to include a process of authorisations or approvals for CEPA-toxic substances. These authorisations should be time-limited.

18. Inherent toxicity under CEPA should be articulated to include substances that will be considered hazardous under REACH, those that are:

- Carcinogenic;
- Mutagenic;
- Toxic to reproduction;
- Persistent; bioaccumulative;
- Very persistent; very bioaccumulative;
- Endocrine disruptors; and
- Substances identified as having serious and irreversible effects on humans or the environment equivalent to these other effects.

19. CEPA should include requirements for substitution of any chemical found to be “toxic”. This provision can be required under the pollution prevention planning requirements for CEPA "toxic" substances.

20. All substances that are found to be CEPA-toxic should be added to the National Pollutant Release Inventory to track the effectiveness of control programs to reduce them.

6.3.2 Severe Restrictions and Phase-Outs

It has already become evident that certain chemicals pose too great a risk to the environment or to human health to be used. There are widespread bans, for example, on PCBs, and more recently, in countries like Sweden and Norway, on certain brominated flame retardants.

[37] Also, like the Regulatory Policy, Privy Council Office’s *Framework for the Application of Precaution in Science-Based Decision-Making About Risk*, interferes unnecessarily with the decision-making authority of the CEPA ministers

Europe's Approach to Restrictions under REACH

These chemicals will continue to be banned or severely restricted when REACH is enacted. Already restricted under the European Limitations Directive, there is a list of substances that are banned now, or used only in very restricted instances. This Directive applies restrictions to 42 substances and groups of substances. It covers approximately 900 chemicals. Of these chemicals, about 850 are considered carcinogenic, mutagenic or toxic to reproduction. Restrictions include, for example, most uses of asbestos, benzene in toys and preparations, nickel in jewellery, and trichloroethane.[38] The Limitations Directive list will be transferred to a REACH Annex called "Restrictions." Persistent organic pollutants will also be restricted under REACH in a separate annex.

Restrictions have been described as the "safety net" of the REACH Regulation because they will allow the European Community to restrict chemicals when they find that they present an unacceptable risk to the whole community. Restriction allows for total or partial bans on substances on their own, in articles or in preparations, based on a risk assessment. It enables risk reduction measures to be put into place relatively quickly.

Chemicals that are candidates for restrictions may be proposed by the European Commission or by a Member State, through the submission of a dossier to the European Chemicals Agency. This information would be made available on the Agency's website for a three month public comment period. Decisions on any restriction would be made after a process that includes a review and opinions submitted by two committees of the European Chemicals Agency: a nine month review by the Committee for Risk Assessment and a 12 month review by the Committee for Socio-Economic Analysis.

Within three months of receiving the opinion of the Committee for Socio-Economic Analysis, the European Commission will make a decision on whether to restrict the chemical. The time frame for this process would be approximately a year and a half.

Canada's Approach to Restrictions under CEPA

Regulations have so far been the most effective method of limiting the use of certain toxic chemicals such as benzene in gasoline or solvent degreasing agents. Even when regulations fall short of complete bans on use, regulations give industry a strong incentive to avoid regulated substances and look for alternatives.

Under CEPA, substances that pose a high risk are also proposed for virtual elimination. To date, however, only one substance has been proposed for virtual elimination.

To propose a chemical for virtual elimination, the Ministers must first decide that the substance meets all the criteria:

[38] Ken Geiser and Joel Tickner, New Directions in European Chemicals Policies: Drivers, Scope and Status Final Report, Lowell Center for Sustainable Production, October 2003

- it must be persistent, bioaccumulative and inherently toxic;
- it must result primarily from human activity; and
- it must not a naturally occurring radionuclide or inorganic substance.[39]

After a 60-day public comment period is announced in the *Canada Gazette* and the Ministers' initial proposal for the implementation of virtual elimination is confirmed or amended, the Minister of the Environment may require anyone dealing with the substance to prepare and submit a virtual elimination plan.

The Minister's order for preparation of a virtual elimination plan will include reference to a "level of quantification" (LOQ). Each substance on the Virtual Elimination List will have a corresponding Level of Quantification, defined as "the lowest concentration [of the substance] that can be accurately measured using sensitive but routine sampling methods."[40]

Virtual elimination plans should ultimately be targeted to achieving this level of quantification. However, negotiations about the level of quantification and provision for the plans to include "relevant information respecting measurable quantities or concentrations of the substance, environmental or health risks and social, economic or technical matters" [41] seem likely to make achievement of both the level of quantification and virtual elimination very difficult. As with pollution prevention plans, there is no provision for making virtual elimination plans public, eliminating the possibility for public pressure to hasten, let alone to ensure, the achievement of virtual elimination.

The problem is that virtual elimination does not mean a ban or even a restricted use of the substance; nor does it guarantee that the chemical will not be released into the environment, on any particular timeline or at all.

At least one other option for taking quick action on a substance that poses an unacceptable risk is available to the government. If a substance is found to be extremely hazardous, the government may issue a legally binding interim order requiring control action.[42] Under Section 94, there are two instances in which this type of action may be exercised. A substance may be determined to be extremely hazardous although it is not included in the List of Toxic Substances. Alternatively, an order may be issued if the substance is listed but the Ministers of Environment and Health believe it is not being adequately regulated. The government has indicated that this would only be used in emergency situations.[43]

Given the limited range of conditions under which orders are likely to be issues, several other obstacles to their issuance seem unnecessary and contrary to the purpose of

[39] CEPA 1999, s. 77 (3)
[40] CEPA 1999, s. 65.1
[41] CEPA 1999, s. 79 (2) (b)
[42] CEPA 1999, s. 94
[43] Correspondence from Minister of the Environment dated August 31, 2004 to the Canadian Environmental Law Association and Environmental Defence

CEPA. For example, the need for the Ministers to resort to Cabinet for approval just two weeks after making the interim order[44] should be eliminated.

Commentary

In the case of extremely hazardous chemicals, Europe has already enacted bans or severe restrictions that will continue under REACH. As further evaluations are done, REACH will restrict additional substances that are found to "pose an unacceptable risk to human health and the environment".

CEPA does not bring the same legislative clout to bear on such chemicals. The Virtual Elimination List should be one method to restrict and phase out substances. However, the need to establish a level of quantification has been a barrier to an effective use of this provision.

Although CEPA has tools available within its regulation-making provisions to severely restrict chemicals, these tools have generally not been used effectively to implement complete or partial bans.

Recommendations:

21. CEPA should be amended to prescribe deadlines for implementation of virtual elimination of toxic substances.

22. CEPA should be amended so that addition of a substance to the List of Toxic Substances is a decision of the CEPA Ministers, not a Cabinet decision.

23. The level of quantification should be removed as a condition of virtual elimination under CEPA.

7. 0 CONCLUSION

Although REACH has not yet come into force, it marks a new direction for chemical policy in Europe and potentially abroad. This paper reviewed the REACH proposal in terms of its major components and compared it to key components in the *Canadian Environmental Protection Act*.

The overall finding of this paper is that REACH does provide new approaches to addressing chemicals that are both needed and practical. As such, REACH provides a valid and relevant proposal for discussion in Canada.

In light of the analysis, the paper makes a number of recommendations to improve and enhance CEPA. If these recommendations are accepted, it would serve to better

[44] CEPA 1999, s. 94 (5)

harmonize European and Canadian chemical policies and thus, serve mutual interests both in terms industrial efficiency and environment protection.

Table 2: Summary of obligations and requirements on managing toxic substances in REACH and CEPA

List of topics/issues covered in the table include:

OVERARCHING THEMES
- *Overarching Requirements*
- *Overarching Themes and Principles*
- *Reverse Onus/Shifting the Burden of Proof*
- *Generational Goal*
- *Minimise animal testing*
- *Control versus elimination at source*
- *Pollution Prevention*
- *Promotion of Safe Techniques and Substitution*
- *Precautionary Principle*

SCOPE
- *Scope of application*
- *Number and types of Substances Covered*
- *Distinction between "new substances" versus "existing substances*
- *Application to substances in articles*
- *Exemptions for Chemicals used in Research and Development*
- *Exemptions*

REGISTRATION/NOTIFICATION
- *Registration of Substances*
- *Definition of Toxicity*
- *Definition of Virtual Elimination*
- *Data Collection*
- *Risk Assessment/Evaluation Process*
- *Industry responsibility*
- *Health endpoints considered for toxicity assessment*
- *Consideration of other health endpoints (children's health, other vulnerable sectors of society*
- *Data Sharing*
- *Timelines for completing assessment*
- *Government Departments' Roles*

EVALUATION/ASSESSMENT
- *Evaluation Requirements/Assessments of substances*
- *Authorisation Requirements*
- *Actions in relation to more hazardous substances*
- *Restrictions*
- *Risk Management*
- *Timelines for acting on toxic substances*

OTHER COMPONENTS
- *Public Access to Information*
- *Public Participation*
- *Appeal Procedures*
- *Enforcement Mechanisms*
- *Funding Programs*
- Relationship with Other Jurisdictions

TABLE 2: Summary obligations and requirements on managing toxic substances in REACH and CEPA

Issue/Topic	Proposed Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulations (Relevant Sections)[45]	*Canadian Environmental Protection Act* 1999 Requirement (Relevant Sections)	"Observations" or "Comparison"
1. OVERARCHING THEMES			
Overarching Requirements		Primarily Sections 64-103, CEPA Part 5 – Controlling Toxic Substances	
Overarching Themes and Principles	The "Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle." **(Article I(3))**	To contribute to sustainable development through pollution prevention (Declaration)	The goal outlined in declaration section of CEPA is open to various legal interpretation in achieving its overall goals, while the proposed REACH regulation provides a clear goal for identifying and managing toxic substances.
Reverse Onus/Shifting the Burden of Proof	One of REACH's goals is to reverse the burden of proof from public authorities to industry for ensuring the safety of chemicals on the market and how they are used. It gives greater responsibility to industry to manage the risks from chemicals, to provide safety information on the substances currently in use, and to pass this information down the chain of production. Under REACH, manufacturers and importers must provide information about their substances in the technical documents submitted for registration, and perform	Environment Canada and Health Canada are responsible for the categorization of all existing chemicals, and the assessment of all existing and new substances that may be toxic. Health Canada and Environment Canada are also responsible for proving that chemicals are toxic and negotiating with industry "risk management tools" for the manufacture, use and release of these substances. The Minister does have the capability of requiring information from industry if there is reason to suspect that a substance may be	Under REACH the mechanism for obtaining information from industry on a chemical's toxicity is explicit. In CEPA, data for substances from industry differs for new and existing substances. The *New Substances Notification Regulations* requires specific data to be submitted by industry on new substances or new activity. The information required is based on the type and quantify of the substance. For existing substances even if the necessary

[45] Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH) October 29, 2003

	chemical assessments to demonstrate that these chemicals are being used safely. Where a substance is deemed to be hazardous under the authorisation process, the burden of proof is on the applicant to demonstrate that the risk is adequately controlled or that the socio-economic benefits outweigh the risks, and that there are no suitable alternatives.	toxic or capable of becoming toxic **(Section 71**)[46]	information on toxic substances from industry exists, the timing for obtaining information is left to the discretion of the Ministers of Health and Environment.
Generational Goal	The generational goal is not explicitly stated in REACH. However, it is implicit in the legislation. The timetable for registering all chemicals under REACH within 11 years of the regulation coming into effect (likely 2006) reflects the generational goal of having a safe environment by the year 2020.[47]	There is no articulation of a generational goal within CEPA. The Commissioner of the Environment and Sustainable Development has predicted that the process of assessing and screening substances identified through categorization "may take a few decades to complete".[48]	CEPA should set a target date similar to the proposed REACH regulation by which all substances in commerce will be assessed and management options be implemented.
Minimise animal testing	An objective of the Regulation is to avoid unnecessary animal testing. "Testing on vertebrate animals for the purposes of this Regulation shall only be undertaken as a last resort" **(Aricle 23(1)).** Evaluation of dossiers requires the sharing of data obtained in tests. Where testing is necessary for registering a chemical and involves animals, it will be kept to a minimum by requiring companies to share data **(Article 25);** "In the case of substances previously registered…, the potential registrant shall ask the previous registrant(s)	There is no articulation of any objective, nor are there any provisions within CEPA to minimise animal testing.	CEPA implementation efforts demonstrate a move to minimize animal testing,. However, CEPA should articulate when animal testing is to be applied.

[46] Health Canada and Environment Canada, according to the Auditor General, are struggling to meet their legislated responsibilities; while they are assessing a few substances, the number of substances of potential concern that need to be assessed is growing. REACH addresses this problem by transferring the responsibility for generating the data on chemicals to the industry

Under CEPA, departments of health and environment are responsible for providing evidence of harm from substances.

[47] The1998 Nordic Prime Ministers' Declaration states: "emissions of chemical substances that threaten human health and the environment must cease within a generation". This generational goal has become an important part of the debate in Europe over phasing out toxic chemicals within an ambitious time frame.

[48] Report of the Commissioner of the Environment and Sustainable Development to the House of Commons, 2002, Section 1.23, p. 10

	for the information involving tests on vertebrate animals he requires in order to register **(Article 25(1)).** Where registrants are not able to reach an agreement, the Agency will make the information available **(Article 25(4)).** Pre-registration procedures (registering within the 18 months before the deadline for registrations) will enable manufacturers and importers to see which substances are being registered so that they can form consortia and share information **(Article 26).**		
Control versus elimination at source	Authorisations and restrictions are methods that may be applied for both elimination at source and strict controls on substances. Authorisations will be used to control dangerous chemicals by limiting their use to applicants granted "authorisations". Restrictions will also impose strict controls and, in some instances, complete bans on the manufacture, use or placing on the market of specific substances.	Chemicals that are determined to be toxic under CEPA may be eliminated at source by a regulation prescribing a ban; alternatively, regulations may stipulate the quantity or concentration of a substance in releases of the substance. If a toxic substance is targetted for virtual elimination, it does not necessarily result in eliminating toxic substances at source. A level of quantification is identified for these substances, and release limits are proposed taking into account technical and socio-economic factors as well as risks. CEPA Schedule 1 (Toxic Substance List) provide a list of substances that need to be managed which may include a call for virtual elimination of certain substance.	CEPA should apply a more rigourous approach for managing toxic substance that results in the elimination of toxic substances at the source. The authorisation and restriction requirements found under the proposed REACH Regulation should be followed in CEPA to ensure that a larger number of substances are addressed and tracked based on their impacts on human health.
Pollution Prevention	REACH does not explicitly refer to pollution prevention although many of its provisions are intended to promote it.	If the Governor in Council decides a substance is toxic and lists it on the Toxic Substances List in Schedule 1 of CEPA, the substance will be managed through "regulations or instruments" to establish preventive or control actions in order to reduce or eliminate the risk to the environment or human health. In	Pollution prevention efforts under CEPA should be enhanced to ensure that safe alternatives and techniques to toxic substances are identified, implemented and promoted.

		developing these, the Ministers "shall give priority to pollution prevention actions" (**Section 90 (1.1)**). Other than pollution prevention plans in Part IV, which may not effectively eliminate a substance from use, such "regulations or instruments" may include a "total, partial or conditional prohibition of the manufacture, use, processing, sale, offering for sale, import or export of the substance or a product containing it" (**Section 93(1)),** environmental quality objectives (**Sections 54 (1)(a) and 208),** environmental quality guidelines (**Sections 54(1)(b), 196 and 208**), release guidelines (**Sections 54(1)(c) and 208**), codes of practice (**Sections 54(1)(d), 196 and 208**), pollution prevention plans (**Section 56**), or environmental emergency plans (**Section 199**).	
Promotion of Safe Techniques and Substitution	"An important objective of REACH is to encourage the substitution of dangerous substances by less dangerous substances or technologies where suitable alternatives are available" (**Preamble 7**). The aim of the authorisation requirement is to “ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled or that these substances are replaced by suitable alternative substances or technologies” (**Article 52**). Authorisations will be granted if a substance ”is adequately controlled” (**Article 57(2)),** or if socio-economic benefits outweigh the risk to human health or the environment and “if there are no suitable alternative substances or technologies” (**Article 57(3))**. When an application is made for an authorisation, the Agency will make information on the	There is no articulation of the promotion of safe techniques or the principle of substitution of dangerous substances with less dangerous substances. However, the Governor in Council, on the recommendation of the Ministers, may make regulations (**Section 93(1)(g))** having the indirect effect of promoting safe techniques or substitution.	Substitution of substances and techniques that do less damage to the environment is an important goal of REACH and should be incorporated into CEPA. The authorisation requirement in the proposed REACH Regulation provides added emphasis on substitutions, since the use of certain substances will be contingent on proving that there are no safer alternatives available.

	potential uses of the substance available on its website "with a deadline by which information on alternative substances or technologies may be submitted by interested third parties" (**Article 61(2)).** It is also the expectation of REACH that exemptions from registration requirements for 5 years for chemicals being used in research will lead to the development of safer chemicals to replace the more dangerous ones currently in use. (**Article 7**)		
Precautionary Principle	The provisions of the Regulation "are underpinned by the precautionary principle" (**Article 1(3)**). It is anticipated that risks to human health and environmental quality will be reduced through better and earlier identification of properties of chemical substances, identification of hazards and better management of risks.	CEPA imposes a general duty on government to administer the Act in a way that applies the precautionary principle (**Section 2 (1) (a)** -- the government is to "exercise its powers in a manner that protects the environment and human health, applies the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (**Preamble**). When screening level risk assessments are done, the Ministries must apply "a weight of evidence approach and the precautionary principle (**Section 76(1)).**	In the proposed REACH Regulation, various components such as the authorisation requirements presents opportunities for implementing precautionary approach.
2. SCOPE			
Scope of application	REACH does not cover substances used in medicinal products for human or veterinary use, as food additives or flavourings in foodstuffs, additives in feeding stuffs, substances in animal nutrition, substances on their own or in preparation that have been registered and are exported and re-imported, on site isolated intermediates or transported isolated intermediates, substances in Annexes II and III. (**Article 4**).	CEPA does not apply to substances "manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic" (**Section 81(6)(a)**). CEPA also does not apply to (a), "transient	Both approaches have many similarities. However, in CEPA, the Domestic Substances List covers substances such as polymers and biotechnology products, substances that are not currently covered under the proposed REACH regulation.

	REACH does not apply to radioactive substances (**Article 2(1a)**). Pesticides which are used for agriculture and biocides are also excluded from REACH because they are covered under other European legislation (**Article 8**). However, if chemicals manufactured or imported for use as biocides are used for different applications in quantities of over 1 tonne, they would have to be registered under REACH.	reaction intermediates that are not isolated and are not likely to be released into the environment" (b), "impurities, contaminants and partially unreacted materials the formation of which is related to the preparation of a substance" (c), "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" (d), or " a substance that is manufactured, used or imported in a quantity that does not exceed the maximum quantity prescribed as exempt from this section" (e) (**Section 81(6)).**	Under the proposed REACH, a pesticide that is manufactured or imported under REACH for use other than as a biocide and meets the one tonne requirement, must be registered.
Number and types of Substances Covered	An estimated 30,000 chemicals manufactured or imported in quantities of 1 tonne or more in the European Union will be registered; 3,000 new substances (those chemicals that have been introduced since 1981 and assessed under a separate Directive) will be considered as registered when the Regulation comes into effect. The number of existing substances reported in 1981 was 100,106.	There are 23,000 substances listed under the DSL which was first compiled between 1984-86. Substances such as organic and inorganic substances, polymers, unknown variable composition and biological composition are listed under the DSL. Forty four substances have been assessed under the first Priority Substances List; 25 were assessed under the second PSL (PSL assessments must be completed in 5 years). The substances covered through these assessments include substances/classes of substances/emissions of substances from a specific activity or sector. New substances cannot be manufactured until the Minister is notified, relevant information for an assessment has been provided or the period for assessment has finished. More than 700 new substances were assessed in 2001-2002. New substances requiring notification may	The proposed REACH approach would address a larger number of substances in a more consistent manner than currently required in CEPA through the Domestic Substances List and the *New Substances Notification Regulations* process. CEPA covers a wider range of substances than the proposed REACH regulation.

		include polymers or living organisms.	
Distinction between "new substances" versus "existing substances"	REACH eliminates the distinction between "new" and "existing" substances. All substances must be registered when the Regulation comes into effect. All substances can be evaluated and authorised or restricted if they present a potential hazard.	"Existing" substances are placed on the Domestic Substances List for categorization, followed by possible screening or assessment. "New" substances are on the Non-Domestic Substances List (nDSL), and are subject to the *New Substances Notification Regulations* if they are to enter into the Canadian market. Those substances on the nDSL list are substances are listed under U.S. Toxics Substances Control Act (TOSCA). US Environment Agency has undertaken to collect data and evaluate these substances. There is a five-year interval required by the Act to update the nDSL. There are currently 56,000 substances listed on the nDSL. In Canada, new substances require notification and assessment within a time period prior to their use.	CEPA's approach in identifying all the substances in use in Canada is more onerous than the proposed REACH Regulation requirements for registrration.
Application to substances in articles	REACH applies under certain conditions to substances in articles. Producers or importers of articles must register substances contained in articles if they are present in quantities of 1 tonne or more per year, are dangerous, and are released during normal use (**Article 6(1)**). Also, producers and importers must notify the Agency for articles where "the substance is likely to be released during normal and reasonably foreseeable conditions of use" and that may adversely affect human health or the environment (**Article 6(2)**). However, REACH does not require information about the content of dangerous chemicals in articles if they are not released during normal use or do not leak. `	There is no differentiation between substances that are manufactured or imported and substances contained in products. There is no authority within CEPA to regulate the manufacture or point of sale of products which during their use release a toxic substance. If a substance is placed on the Virtual Elimination List, it is difficult to determine a level of quantification to control its use in a product.	REACH applies on a limited basis to substances in products, extending its effectiveness into the area of consumer protection. CEPA does not adequately address substances found in articles and consumer products.

Exemptions for Chemicals used in Research and Development	REACH contains exemptions for research and development with the goal of promoting innovation. For example, substances used in product and process orientated research and development do not need to be registered for a period of 5 years, although the manufacturer or importer must notify the Agency and submit certain information (**Article 7**); these substances are not subject to authorisation requirements either (**Article 53(4)).** Industry will be able to use substances for research and development with fewer restrictions under REACH, since the proposed threshold for registration of substances under REACH is higher at one tonne per year than the currrent European Union threshold of 10 kg/per year limit for new substances.	Exemptions from the application of CEPA are generally unnecessary since both existing and new chemicals are permitted in commerce with few controls. Chemicals currently in use in quantities of less than 100 kilograms per year are not subject to CEPA, while substances not listed on the DSL must meet a threshold of 1000 kilograms before notification is required under CEPA(as outlined in *the New Substances Notification Regulations***, Part 1, Section 8, Schedule IV**). This is part of the notification process required for substances not listed under the non-Domestic Substances List. Data relevant to identifying hazards to human health and the environment is requested and submitted if the data is in the notifier's possession. The notification will be reviewed within a specified time period. If the assessment of these notification applications are not completed within the specified time period, the substance may be used for the specified purpose. **Section 284** allows the Minister to "authorize in writing an analyst to import, possess and use a substance for the purpose of conducting measurements, tests and research with respect to the substance," "subject to any reasonable condition specified by the Minister." (The Minister may designate as analysts any persons or classes of persons who, in the Minister's opinion, are qualified to be so designated: **Section 217**)	Both CEPA and REACH have provisions that allow the use of substances for Research and Development. In both approaches the threshold for notification or reporting substances to be used in research and development should be significantly lower than 1000 kilograms.
Exemptions	Non-isolated intermediate chemicals and polymers are fully exempt; many chemicals in pesticides, pharmaceuticals and cosmetics are covered in other EU legislation	See scope of legislation. Under the *New Substances Notification Regulations*., the information required for new substances or activity may differ	CEPA covers some substances such as biotechnology products and polymers that are exempted under the proposed REACH regulation. Both CEPA and the

		depending on the type and quantity of substances to be assessed. The regulations covers biotechnology products, site-limited intermediate substances, product development substances (research and development) and polymers. Similarly, the Domestic Substances List covers the same type of substances.	proposed REACH regulation do not cover pharmaceuticals and cosmetics which are covered under other Canadian statutes.
3 REGISTRATION/NOTIFICATION PROCESS			
Registration of Substances and Inventories and categorization of substances: *Registration (REACH)* *DSL, N-DSL and NSN (CEPA)*	The registration of chemicals already on the market is an important new element that will be introduced with REACH. Manufacturers or importers of any substance in quantities of one tonne or more per year are required to register it with the European Chemicals Agency (**Article 5**). Substances that are not registered cannot be manufactured or imported into the European Union -- "substances shall not be manufactured in the Community or imported unless they have been registered" (**Article 19(1)).** The technical dossier submitted for registration will include information on: the identity of the substance(s), information on manufacturing and use(s), classification and labelling, guidance on safe use, proposals for testing, and other required information (**Article 9(1a)**)**.** When substances are manufactured or imported in quantities of 10 tonnes or more per year, the technical dossier must also include a chemical safety report based on a chemical safety assessment **(Article 13**). Downstream users will be provided with chemical safety data sheets from the manufacturers and importers if the substances they are using are considered to be dangerous (**Article 29**). Downstream users do not have to	There are no registration requirements under CEPA. Instead, a Domestic Substances List (DSL) is compiled by the Ministers of Health and Environment of all industrial chemicals in commercial use, either "manufactured in or imported into Canada by a person in a quantity of not less than 100 kilograms in any one calendar year" between 1984 and 1986 (**Section 66(1**)). Environment Canada and Health Canada will categorize all substances on the Domestic Substances List by Sept. 14/06 to determine which substances require a screening level risk assessment. Screening level risk assessments will be done on substances that have the greatest potential for exposure to individuals in Canada, or "are persistent or bioaccumulative in accordance with the regulation, and inherently toxic to human beings or to non-human organisms, as determined by laboratory or other studies" (**Section 73(1) and 74**). A "significant new activity" involving the substance may require that the proponent first submit further information (**sections 73(3), 81 (3) and 83**). Where the available information is insufficient, the Ministers "may co-operate	CEPA does not have a formal registration process similar to that proposed under the REACH regulation. The proposed REACH regulation eliminates the distinction between new and existing chemicals and requires all substances to be registered by their users. Failure by industries to register substances means they cannot be used. Aside from the Domestic Substances List, there is no obvious list of the substances found in the Canadian market. Generally, Canadians must rely on government to identify and assess substances of concern. For new substances, the *New Substances Notification Regulations*, will allow the manufacture and import of substances if no decision is made during the assessment period. Furthermore, industry information is protected under confidentiality provisions.

	register substances but they may make it known to their supplier how they are using it so that this use can be taken into account in preparing a chemical safety assessment (**Article 34(2)**). If a downstream use is outside the conditions described in the safety data sheets, downstream users must do their own chemical safety report (Article 34(4)). They must also report this use with the required information to the Agency (**Article 35(1)**); No distinction is made between new and existing (pre-Sept. 81) chemicals for the purposes of registering chemicals. However, "new" chemicals (those that have been assessed since 1981 under Directive 67/548) will be considered automatically registered when the Regulation comes into effect (**Article 22**). Information requirements increase for the registration of substances when there is an increase in the tonnage, and registrations must be updated if industries increase the volumes of substances manufactured or imported (**Article 11**).	with other governments in Canada, governments of foreign states or any interested persons to acquire the information required for the identification" (**Section 73(3)**). The Minister will also maintain a Non-Domestic Substances List (nDSL) for all other substances not listed on the Domestic Substances List (**Section 66(2**)). New chemicals are subject to sections 80-89 ("Substances and Activities New to Canada") and the *New Substances Notification Regulations*. Before introducing a new substance for use, manufacturers or importers must notify the Minister, provide relevant information for a risk assessment, pay a fee and wait until a period for assessing the information has expired (**Sections 80 to 89**). However, the Act does not prohibit the sale or use of a new substance before the assessment is completed (**Section 81(4)**). If the information has been provided to the Minister and the period for assessing new substances has expired, new substances may be used. In addition, manufacturers and importers using substances on the Domestic Substances List must report to the Minister and provide information on "significant new activities", defined in terms of increased quantity or concentration of the substance in a release, or in terms of exposure to the substance (**Section 80(3)**).	
Definition of Toxicity	There is no definition of toxicity in REACH (under **Definitions Article 3**).	A substance "is toxic if it is entering or may enter the environment in a quantity or concentration, or under conditions" that (a)	CEPA's definition for toxicity is a legal definition that is based on three criteria set out in the statute.

	Substances that pose a risk and therefore must be properly controlled or replaced will be included in a list (**Annex XIII**). These are substances defined as carcinogens category 1 or 2, mutagens category 1 or 2, toxic for reproduction category 1 and 2, substances which are persistent, bioaccumulative and toxic, substances which are very persistent and very bioaccumulative, and other substances such as those having endocrine disrupting properties and which are identified as causing serious and irreversible effects to humans or the environment equivalent to the other substances in this list. (**Article 54**).	have or may have an immediate or long-term harmful effect on the environment or its ecological 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".(**Section 64**)	The proposed REACH regulation uses hazardous properties to determine what level of action is required for a particular substance. For substances found to be hazardous under the proposed REACH Regulation, authorisation for use may be required. In CEPA, hazardous properties are reviewed during the risk assessment phase for a substance.
Definition of Virtual Elimination	There is no definition of "virtual elimination" within REACH (under **Definitions Article 3**). Substances that are restricted will be prohibited from being manufactured, used or placed on the market ("unless it complies with the conditions of that restriction") (**Article 64**). Substances that are listed in Annex XIII cannot be used or placed on the market. However, if an authorisation is granted for use, the substance may still be used in a way that ensures "that the level of exposure is reduced to as low as is technically possible" (**Article 57(8)**).	"Virtual elimination" means, with respect to the release of a toxic substance to the environment as a result of human activity, "the ultimate reduction of the quantity or concentration of the substance in the release below the level of quantification specified by the Ministers" in the Virtual Elimination List (**Section 65(1)**), "level of quantification" is defined as "the lowest concentration of a substance that can be accurately measured using sensitive but routine sampling and analytical methods" (**Section 65.1**)	Virtual elimination has proven unworkable within the context of CEPA.
Data Collection	The European Chemicals Agency is responsible for collecting the data required under the Registration process, and ensuring that the registrations comply with the Regulation. Member States are responsible for dossier and substance evaluations. They may request more information from industry when they are doing substance evaluations (**Article 44**).	Health Canada and Environment Canada collect information on substances in commercial use between 1984-1986. Approximately 23 000 substances were identified and placed on the DSL. The two departments are required to categorize all substances on the DSL As part of the efforts to categorize the DSL substances, according to the 2001-2002 CEPA Annual Report, Environment Canada collected data on persistence, bioaccumulation and toxicity information for	Member States and the Agency can require industry to provide the information on substances critical for the Agency and Member States to complete its work on assessment and evaluation of substances. In CEPA, section 71 requires industry to collect and submit information necessary for assessments and evaluations.

		12,000 organic chemicals on the Domestic Substances List. This work is on-going. A pilot project on screening level risk assessments was initiated on 123 organic substances. Health Canada and Environment Canada are also responsible for all risk assessments for new and existing chemicals.	This section has been underutilized by the Government. Government of Canada has generated or collected data to complete its evaluations of substances
Risk Assessment/ Evaluation Process	All registration dossiers for substances manufactured or imported in quantities of 10 tonnes or more per year must include a chemical safety assessment: "A chemical safety assessment shall be performed and a chemical safety report prepared for all substances subject to registration" (**Article 13(1)**). A chemical safety assessment is an assessment that outlines the risk management measures implemented by the registrant himself or proposed for downstream users. It is different from the traditional model of risk **assessment (Article 13**). A chemical safety assessment will include: human health hazard assessment, human health hazards assessment of physicochemical properties, an environmental hazard assessment, an assessment of persistence, bioaccumulation and toxicity, and whether it is very persistent and very bioaccumulative (**Article 13(3)**). Chemical safety assessments do not have to be done for substances manufactured or imported in quantities of less than 10 tonnes per year, for on-site intermediates, or transported isolated intermediates. These assessments are submitted to the European Chemicals Agency as part of the technical dossier for registration.	Categorization of all substances on the Domestic Substances List is the first step in the evaluation process. Then, Environment Canada and Health Canada will decide which substances need further assessment in order to determine whether they are toxic. The criteria for identifying substances for screening level risk assessment are persistence or bioaccumulation and inherent toxicity or potential for greatest exposure (**Section 73**). For those substance that meet these criteria are sent off to screening level risk assessment (**Section 74**). If there is insufficient information to determine their toxicity during the phase, substances may be placed on the List of Priority Substances for a full risk assessment. If there is sufficient evidence to make a determination of toxicity, the substance may be proposed for addition to Schedule 1 (Toxic Substances List) before management options can be considered. New substances are required to submit limited data for an assessment to be undertaken by the government. Different data is required for different substances and the quantity thresholds. Data for acute mammalian toxicity, mutagenicity data, skin irritation and sensitization data, and other information relevant for determining human health hazards may be required under the	REACH proposes a timeframe of 11 years to complete the registration, evaluation/assessments and authorisation of substances. Under this time framework, industry is required to provide information in a timely manner to meet REACH requirements. In CEPA, no timeline is assigned for completing the screening level risk assessments on existing substances. It is uncertain how efficient this process will be without timelines. For new substances, the lack of transparency and public participation for assessing new substances are seen as weaknesses in this process. Furthermore, the government cannot prevent the entry of new substances into the market if a determination of toxicity is not made within the assessment period.

	Evaluations of registrations for chemicals that may pose a risk to human health or the environment will be prioritised by the Agency and done by Member States on the basis of rolling plans.	regulation. The regulation does not currently require information on endocrine disruptors.	
Industry responsibility	Industry must register all substances manufactured or imported into Europe in quantities of one tonne or more per year; they must provide chemical safety reports for substances manufactured or imported in quantities of over 10,000 tonnes per year; failure to register a substance within the phase-in period means that it cannot be used. They are also responsible for managing the risks identified in their chemical safety reports and for supplying downstream users with safety data sheets. Under the authorisation process, they are responsible for demonstrating that the risks of using the authorised chemical are adequately controlled, that the socio-economic benefits outweigh the risks, and that no suitable alternative substances or technologies can be used.	"Prescribed information" [see NSN Regs] must be provided before a person may import or manufacture a substance not on the DSL (**Section 81**). Industry can be required to provide data or do testing where it is suspected that a substance is toxic or capable of becoming toxic (**Section 71(1)).** In addition, industry must provide information to the Minister where they obtain information that reasonably supports the conclusion that the substance is toxic (**Section 70**).	The proposed REACH regulation is much stronger in articulating the role and responsibility of industry. CEPA should be strengthened in this area.
Health endpoints considered for toxicity assessment	Substances that can only be used if authorised will be substances that meet the criteria for classification as: carcinogens (category 1 or 2), mutagens (category 1 or 2), toxic to reproduction (category 1 or 2); persistent, bioaccumulative, and toxic; very persistent and very bioaccumulative; substances having endocrine disrupting properties and which are identified as causing serious and irreversible effects to humans or the environment which are the equivalent to those other substances on this list. (**Article 54**).	A substance is considered toxic when it is entering the environment in a quantity that may constitute a danger in Canada to human life or health (**Section 64 (c)**). Substances are categorized and given priority for further evaluation based on whether they are persistent, or bioaccumulative, and "inherently toxic to human beings" or meet the criteria for potential of greatest exposure (**Section 73(1)**). When the Minister is notified of a decision to	The CEPA approach to categorization of the Domestic Substance List contains several limitations with respects to the consideration of health endpoints. For example, current proposal for determining inherent toxicity for humans is applied to only a subset of substances. Inherent toxicity to humans will be determine only for those substances that meet the criteria for persistence or bioaccumulation but not inherently toxic to non-human organisms.

		prohibit or restrict a substance in another jurisdiction for environment or health reasons, the Minister must review the decision in order to determine whether the substance is toxic (**Section 75(3)**). Ministers should take into account the weight of evidence approach and the precautionary principle in conducting and interpreting assessments (**Section 76.1**).	CEPA should consider expanding the list of substances for which hazardous properties are reviewed like that in the proposed REACH Regulation.
Consideration of other health endpoints (children's health, other vulnerable sectors of society)	There is no articulation of other health endpoints such as children's health or the health of vulnerable sectors in REACH. However, the new Restrictions process will take over the current list of restrictions under Directive 76/769. Fifteen per cent of the substances or uses of the substances that are restricted under this Directive have been put in place to protect children's health.	Environment Canada and Health Canada, in performing human health risk assessments, take into account available data on affected populations, including children and other vulnerable populations, although this is not explicitly stated in CEPA.	CEPA should provide explicit language that takes into consideration the effects of substances on children's health along with other vulnerable communities.
Data Sharing	The REACH registration process encourages data sharing among manufacturers and importers of chemicals (**Article 10**). When a substance is manufactured by two or more manufacturers or importers, they may form a consortium. One manufacturer may then submit parts of the registration on behalf of the consortium (**Article 10(1)**). This reduces the fees for each of the registrants in the consortium (**Article 10(2)**). If animal tests are involved, then data sharing becomes obligatory. If applicants cannot agree among themselves, the Agency will decide that one company must share its testing data with another company.	Environment Canada and the United States Environmental Protection Agency are collaborating with Canadian and US industry to streamline notification and assessment requirements for new substances through the non-legislative Four Corners Agreement. It involves the exchange of technical data and assessment information. Other similar arrangements have been made with other jurisdictions including Australia.	Data sharing among manufacturers and importers must be distinguished from data sharing among regulators. Further, data sharing is distinct from harmonized regulatory decision-making.
Timelines for completing assessment	The European Chemicals Agency aims to have satisfactory information about all chemicals used in volumes of more than one tonne/year within 11 years.	Categorisation of substances on the Domestic Substances List must be done by September 14/06, seven years after the enactment of the Act on September 14, 1999, in order to identify substances that	The timelines proposed under the REACH regulations are distinct and provide a level of accountability to the public. CEPA does not have an explicit timeline

	All registrations will be completed within that time frame although there is a schedule for phasing them in depending on the production level and whether the substance is of high concern. Within 3 years all substances that are manufactured or imported in quantities of more than 1,000 tonnes per year, or are categories 1 and 2 carcinogens, mutagens or toxic to reproduction (**Article 21(1)** must be registered. Within 6 years all substances that are manufactured or imported in quantities reaching 100 tonnes or more per year will be registered (**Article 21(2)**). And, within 11 years all substances manufactured or imported in quantities of one tonne or more per year must be registered (Article 21(3)). Chemicals that do not need to be phased in are "new" chemicals that were assessed under Directive 67/548/EEC. They will be considered registered and receive a registration number within one year of the Regulation coming into force (Article 22). Chemical safety assessments will be included as part of the technical dossiers submitted for registration for chemicals imported or manufactured in quantities of 10 tonnes or more. When a Member State starts a dossier evaluation, the competent authority of the Member State must prepare a draft decision within 12 months (Article 43).	present the greatest potential for exposure to Canadians or are persistent, bioaccumulative and inherently toxic. The screening level risk assessment (**Section 74**) does not include a mandated timelines.	for completing screening level risk assessments on substances, an obstacle to efficient action on substances.
Government Departments' Roles	The European Chemicals Agency is solely responsible for registration. It manages the process, it ensures consistency of evaluations, provides criteria to guide Member States' selection of substances for evaluation, and takes decisions on requiring	Environment Canada and Health Canada must compile the Domestic Substances List, categorize these substances and identify priorities for further assessment. They jointly assess all new substances. They identify substances for the Priority	Canada should review specific elements of the proposed Agency under the REACH proposal such as its coordination and oversight functions. Some of these elements may be considered in Canada's

	further information for evaluations. It also provides opinions and recommendations in the authorisation and restriction procedures. The competent authorities of Member States do dossier and substance evaluations. As well, Member States are responsible for the enforcement of REACH.	Substances List that require further assessment, and do those assessments, although only the Minister of Environment can request additional information and tests when there is a suspicion that a substance is toxic. They make recommendations for listing substances on the List of Toxic Substances, and possibly for the Virtual Elimination List. For any substance listed on the List of Toxic Substances, Environment Canada must propose a preventive or control regulation or instrument within 2 years of publishing the assessment, and publish a final regulation within 18 months of the publication of the proposed regulation or instrument. Environment Canada must detemine the level of quantification for each substance on the Virtual Elimination List (**Section 65(2)**), taking into account environmental or health risks and relevant social, economic and technical matters before setting enforceable release limits.	approach to toxic substances.
4. EVALUATION / ASSESSMENT			
Evaluation Requirements/ Assessments of Substances *Evaluation (REACH)* *Screening Level Risk Assessments and Risk*	Two types of evaluation of registrations will be done (estimated for about 20 per cent of substances) -- dossier evaluation (**Articles 38-43**) and substance evaluation (**Articles 43a-46**). The "competent authorities" in each Member State will do the dossier evaluations. Dossier evaluations check proposals in registrations that propose testing on vertebrate animals to ensure that no unnecessary testing is done (**Article 39**). Substance evaluations will be done when there is reason to believe that a substance may present a risk to human health or the environment (**Article 43abis(1)**). The Agency will develop criteria for prioritising	After substances on the Domestic Substances List have been categorized, a substance identified as posing the greatest potential for human exposure, or that is persistent or bioaccumulative and inherently toxic to humans or to other other organisms, will require a screening level risk assessment to determine "whether the substance is toxic or capable of becoming toxic" under CEPA (**Section 74**); screening assessments would be required for substances with the greatest potential for exposure, or chemicals that are persistent or bioaccumulative and inherently toxic (**Section 73(1)**). Environment Canada and	Unlike the proposed REACH Regulation, CEPA requires government to provide evidence that substances pose a risk to human health before regulating or taking action. The limited amount of data that can be generated by the government and the capacity of the government departments means the assessment process is slow and resource-intensive. It results in very few substances being evaluated each year. This process allows many chemicals on the market to be used without sufficient information about their

Assessment (CEPA)	chemicals to be evaluated based on risk (**Article 43a**). Member States will take these into account when they are preparing their rolling plans for substance evaluations (**Article 43a)**). When a Member State suspects that a substance, that is not already on the list of substances for which authorisations are required, may present a risk, they can include the substance in a rolling plan and start a substance evaluation (**Article 43abis(1)**). A Member State may require further information from the registrant of the chemical in order to clarify their suspicions (**Article 44**). These evaluations must be finished within 12 months (**Article 44(4)**). Once an evaluation has been done, the Member State may decide whether or not further action should be taken to manage the particular substance. They may recommend authorisation, restrictions or refer the information to the authorities responsible for legislation (**Article 46**).	Health Canada will conduct the screening level risk assessments. Once the assessments have been completed, the Ministers will decide one of three measures: (**Section 77(2)**): 1) no further action be taken for a substance, 2) where there is insufficient information to designate it as toxic or where "priority should be given in assessing whether they are toxic or capable of becoming toxic", the substance may be added to the Priority Substances List for more comprehensive risk assessment (**Section 76**), or 3) a substance may be designated as toxic under CEPA and a recommendation made to the Governor in Council that it be put on the List of Toxic Substances under Schedule 1, possibly for virtual elimination (**Section 77(2)**). The Ministers must also review decisions of other OECD countries, Canadian provinces or territories where substances have been banned or severely **restricted (Section 75(3)**). Ministers can decide that no further action needs to be taken if they have concluded that the substance is not toxic, and even if the substance is toxic, they may decide no further action is needed if the substance can be more effectively managed under other federal or provincial legislation. Substances new to Canada, or substances on the Domestic Substances List that are used for new activities, are assessed by	impacts on health and the environment. Under REACH, industry provides information through the registration process. This information will be used in the evaluations process to identify substances that require further study of their toxicity. The central European Chemicals Agency will prioritize chemicals and co-ordinate their assessments by the Member States. If substances are determined to be chemicals of concern, they would be candidates for authorisation.

		Health Canada and Environment Canada under the *New Substances Notification Regulation*s	
Authorisation Requirements *Actions in relation to more hazardous substances* *Authorisations (REACH) and Toxic Substances List, VE List and possible regulatory action (CEPA***)**	The aim of authorisation "is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled or that these substances are replaced by suitable alternative substances or technologies" (**Article 52**). Substances of very high concern (estimated at about 1500 substances) will be identified and included in Annex XIII (**Article 54**). These substances will include carcinogens category 1 or 2, mutagens category 1 or 2, reproductive toxins category 1 or 2 (CMRs), substances that are persistent, bio-accumulative and toxic (PBTs), substances that are very persistent and/or very bio-accumulative (vPvBs), and substances such as those having endocrine disrupting properties and identified as having serious and irreversible effects on humans or the environment equivalent to the other 3 categories (**Article 54**). "A manufacturer, importer or downstream user shall not place on the market a substance for a use or use it himself if that substance is included in Annex XIII" unless this use has been authorised (**Article 53(1)**). Authorisations will be subject to review and, in certain instances, time-limited (**Article**	If a substance is found to be toxic under CEPA and the Minister of Environment and Health recommend that it be added to the List of Toxic Substances under Schedule 1 (**Section 90(1)),** the Governor in Council may, if satisfied that the substance is toxic based on the assessments, order that the substance be added tot the List. An order for adding the substance must be published in the Canada Gazette for a 60 day public comment period. Any member of the public may file a notice of objection and request a Board of Review be undertaken. If the Governor in Council adds the substance to the List of Toxic Substances, the Minister may sue the provisions of the Act to require that industry "prepare and implement" pollution prevention plans (**Part IV**), or the Minister may develop a proposed regulations or other instrument, to be put into effect by the Governor in Council. When a substance is proposed for the List of Toxic Substances, the Minister has two years from the time of publication of the assessment report within which to develop preventive or control measures. Once the Minister proposes a regulation or other instrument, it is published and there is a further 18 months in which to finalize it.	CEPA has no authorisation[49] provisions as outlined under the proposed REACH Regulations. Under REACH, users must show that they can manage the risks and that there are no suitable substitutes available. CEPA puts less onus on users and producers. "Risk management tools" are limited in number compared to the total number of substances in commerce, and are implemented (if at all) only after many years of assessment.[50]

[49] The time frames in REACH are intended to be much shorter than the time frames allowed for under CEPA. Under REACH a significant amount of information on the most hazardous chemicals and those used in the highest volumes will be available within 3 years through the registration process. Assessments by the Member States must be done within one year of registration.

[50] Under CEPA, the time frame for assessing chemicals [i.e. screening level risk assessment] is not mandated. If a screening level risk assessment is done and the government recommends that a substance be placed on the Priority Substances List for further study, a 5 year time period is allowed for assessment. If a chemical is added to the Schedule 1 - Toxic Substances List up to two years plus 18 months may pass before measures to control its use and release have been finalized

	57(6)).		
Restrictions	REACH also has provisions for restricting chemicals, "a substance on its own, in a preparation or in an article". (**Articles 64-70**). Restriction is considered to be the safety net for eliminating risks from very hazardous chemicals. Restrictions that are currently in place in the European Union under the Limitations **Directive (Directive 76/769/EEC**) will be carried over into REACH, and become Annex XVI. Another Annex, Annex XVII, will restrict substances included in the Protocol on Persistent Organic Pollutants (**Article 64(2)**). The process of restricting other chemicals that pose an unacceptable risk to human health and the environment may be initiated by a proposal from the European Commission or from a Member State by submitting a dossier to the Agency (**Article 66**). Decisions on restrictions of production, marketing and use of a chemical are taken by the Commission after weighing the evidence and opinions of the Agency's expert Committees (**Articles 64-70**).	Where a substance on the List of Toxic Substances and is found to be "CEPA-toxic", predominantly anthropogenic, persistent and bioaccumulative its "virtual elimination" may be proposed (**Section 77(4)**). If the Minister publishes a statement in the Canada Gazette indicating that virtual elimination will be implemented for a substance, the users must submit a plan describing the actions they will take, within time periods set out in the Minister's statement (**Section 79**). In addition, CEPA has provisions for taking immediate action when a chemical poses a significant danger. In this case, where a substance "is not specified on the List of Toxic Substances in Schedule 1 and the Ministers believe that it is toxic or capable of becoming toxic, or is specified on that List and the Ministers believe that it is not adequately regulated, and the Ministers believe that immediate action is required to deal with a significant danger to the environment or to human life or health", the Minister may issue an interim order that has the effect of regulations and that is effective immediately (**Section 94**). For substances considered new in Canada, the notification process will require government to make a determination of toxicity based on information submitted. Under (**Section 84**) the following measures for new substances may be taken:	Restrictions are considered a "safety net" for chemicals under REACH that need to be controlled quickly. It can be used for full or partial bans. This requirement exists in CEPA but in a very limited manner. Under CEPA section 94 , Ministers can take quick action on chemicals. However, this power is only rarely used. Also under CEPA, the potentially most restrictive power, Virtual Elimination, has only been proposed once in five years, and no substances yet appear on the Virtual Elimination List. Those substances targeted for virtual elimination does not necessarily result in a ban of these substances.[51] Under the *New Substances Notification Regulations*, restrictions may be applied to new substances as a result of the assessment completed by government on information provided by notifiers. Any restrictions on a substance must be published in the *Canada Gazette*.

[51] It means the stepwise reduction of the quantity or concentration of a substance in releases of a substance over time, not to the point of zero release but rather, until the substance is no longer detectable by normal analytical equipment.

		(a) permit the manufacture or import of the substance subject to specified conditions; (b) prohibit the manufacture or import of the substance for a period not exceeding two years (this prohibition lapses at the end of this two-year period unless, before the end of this period, a notice of proposed regulation under Section 93 of the CEPA, 1999 is published in the Canada Gazette); or (c) prohibit the manufacture or import of the substance until supplementary information or test results have been submitted to the government and assessed (the assessment period for this supplementary information expires 90 days after receipt of the information, or at the end of the original assessment period, whichever is the later date). Measures under section 84 of the CEPA, 1999 must be taken by the government before the expiration of the assessment period.	
Risk Management	Risks are expected to be managed by manufacturers, importers and users of the chemicals -- "Any manufacturer or importer shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets they supply" (**Article 13(6)).** Downstream users will rely on the safety data sheets for risk management measures prepared by the manufacturer or importer. However if they are using the chemical in a way that is not covered in the safety data sheets or intend	Once a substance is assessed, the Ministers can propose no further action be taken, that the substance be added to the Priority Substances List, or recommend that it be placed on the List of Toxic Substances, possibly for virtual elimination. If a substance is placed on the List of Toxic Substances in Schedule 1, its release must be controlled or prevented through the use of CEPA regulations or instruments. These "regulations or instruments" include regulations such as a "total, partial or conditional prohibition of the manufacture, use, processing, sale, offering for sale,	The proposed REACH regulation outlines a transparent process that takes into account data from all use of a substance including down stream users. This forms the basis of the registration process that is required to initiate the evaluation and authorisation requirements. This is not transparent in CEPA unless a screening level risk assessment or full assessment is undertaken. Under the *New Substances*

	to use different risk management measures, they must notify the Agency in case these unidentified uses are of enough concern to warrant an evaluation.	import or export of the substance or a product containing it" (**Section 93(1**)), environmental quality **objectives (Section 54 (1)(a) and 208**), environmental quality guidelines (**Sections 54(1)(b), 196 and 208**), release guidelines (**Sections 54(1)(c) and 208**), codes of practice **(Sections 54(1)(d), 196 and 208**), pollution prevention plans (**Section 56**), or environmental emergency plans (**Section 199**).	*Notification Regulations*, control measures cannot be challenged. In fact, public participation in assessing new substances does not exist. The public is notified of decisions made under the *New Substances Notificiation Regulations* through the Canada Gazette Notices or through the CEPA Registry.
Timelines for acting on toxic substances	When a Member State begins a substance evaluation, a decision requiring further information must be prepared within 12 months of publication of the rolling plan on the Agency's website (**Article 44(3)**). The evaluation must be done within 12 months after notifying the Agency that an evaluation has started. Within 12 months the evaluation is deemed to be finished (**Article 44(4)**). In the case of restrictions, after dossiers and the suggested restrictions are published on the Agency's website, within 9 months of publication the European Chemicals Agency's Committee for Risk Assessment will form an opinion on the restriction (**Article 67**). Within 12 months of publication, the Agency's Committee for Socio-Economic Analysis will give its opinion (**Article 68**). A Commission decision will be made within 3 months of the completion of these two analyses (**Article 70**).	Chemicals on the Priority Substances List must be assessed within 5 years. For chemicals that are established as toxic under Section 77 (after a screening assessment, by a review of other jurisdictions or an assessment of a substance on the Priority Substances List) and proposed for the List of Toxic Substances, the Minister has two years from the time of the publication of the assessment report to develop proposed preventive or control measures. Once the Minister has decided on a proposed regulation or other instrument and published it(in the Canada Gazette), the Minister then has 18 months within which to finalize it.	Due to the uncertainty in timeframe for completing screening level risk assessment, the overall timeframe proposed within the REACH policy for taking action on toxic substances may be shorter than the CEPA regime. In addition, the proposed REACH regulation may address a greater number of substances for action than CEPA.
5. OTHER IMPORTANT COMPONENTS IN ASSESSING AND MANAGING TOXIC SUBSTANCES			
Public Access	Information on registrations, evaluations,	Public documents relating to the Act are	Both approaches provide

to Information	and restrictions will be available on the website of the European Chemicals Agency. Under REACH, the Agency will give key safety information (excluding confidential information) submitted for registration to the public (**Article 106**). It will be available on-line at Agency's website or on request. Since evaluations may lead to authorisations or restrictions, rolling plans of Member States doing evaluations of chemical substances will be published on the website (**Article 43abis(5)**). Substances that are candidates for inclusion in Annex XIII, for which authorisations would be required, will be publicly available on the Agency's website (**Article 55(3a)**). Where applications have been made for authorisations, the "Agency shall make available…broad information on uses…for which applications have been received, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties" (**Article 61(2)**). Dossiers suggesting restrictions will also be made publicly available on the Agency's website (**Article 66(3)**).	available on the CEPA Registry ("Environmental Registry", **Section 12**). These include information on ongoing public consultations, a National Pollutant Release Inventory (**Sections 48-50**), Priority Substances Assessment Program for the Priority Substances List, requests submitted to government, relevant orders, guidelines, agreements, notices, permits, policies, proposed regulations and decisions of government (**Sections 12-14**).	opportunities for the public to access information.[52] However, additional provisions (for example details of pollution prevention plans) are required in Canada to provide the public with information that will determine whether the efforts by the company adequately protect human health from exposure to toxic substances. In CEPA, the lack of public access and tranparency in the decision making process regarding the assessment for new substances is seen as a weakness within the CEPA approach.
Public Participation	There will be 3 month public comment periods: 1) after publication on the Agency's website of recommendations for the inclusion of substances in Annex XIII, the Annex which lists substances which cannot	The Environmental Registry is the primary vehicle for public participation. Members of the public can request that a substance be added to the Priority	Both processes allow the public to know which substances are being treated as high risk chemicals destined for restrictions. However, REACH will evaluate and restrict a

[52] Increased transparency was one of the objectives of reforming European legislation and creating REACH. Some types of information will remain confidential such as customers' names and exact tonnage, although information on registrations, assessments and restrictions will be made available.

CEPA-related documents produced by Health Canada and Environment Canada are available on the Internet-based CEPA Registry. However, several crucial agreements such as P2 plans between government and industry detailing how chemicals will be controlled are not open to the public. This, combined with inadequate product formulation information, makes it impossible for the public to know whether the risks of toxic chemicals are being adequately controlled.

	be used without authorisation (**Article 55 (3a)), and 2**) after the publication on the Agency's website of dossiers that propose restrictions on substances (**Article 66(3**)).	Substances List, and within 90 days the Minister will inform the person how it will be dealt with and why (**Section 76(3)).** When a substance has been listed on the Priority Substances List for 5 years and no action has been taken, "a person may file a notice of objection with the Minister requesting that a board of review be established" (**Section 78)(1)**). If the Ministers decide not to add a substance that is toxic or capable of becoming toxic to the List of Toxic Substances, this decision undergoes a 60 day public comment period where interested parties may bring forward evidence to support or refute the Ministers' decision (**Section 77(8)**). When a substance is included on the List of Toxic Substances, proposed regulations or instruments to prevent or control its release must be published in the Canada Gazette within two years (**Section 91(1)**). Members of the public can request that a substance be added to the Priority Substances List. Within 90 days the Minister will inform the person how it will be dealt with and why (**Section 76(3)).** When a substance has been listed on the Priority Substances List for 5 years and no action has been taken, "a person may file a notice of objection with the Minister requesting that a board of review be established" (**Section 78)(1)**). When a substance is proposed for virtual elimination, "any person may, within 60 days" file written comments on the	larger number of chemicals more quickly than the CEPA process is designed to handle. The *New Substances Notification Regulations* does not have effective public participation component. The existence of the Four Corners Arrangement facilitates industry's ability for getting toxic substances to market without public review. Transparency in this regard is necessary.

		measures that will be taken and the scientific considerations (**Section 77(5)**). Individuals may "apply to the Minister for an investigation of any offence under this Act" (**Section 17(1)**). CEPA also provides for protection for whistleblowers (**Section 96(4)**).	
Appeal Procedures	A Board of Appeals will becreated under REACH. It will consider any appeals against decisions of the Agency.	A Board of Review under CEPA (**Section 333**) may be established where Ministers make an assessment whether a substance on the Priority Substances List is toxic or capable of becoming toxic and decide not to recommend that it be added to the List of Toxic Substances. Any person may, within 60 days of the decision, file a notice of objection with the Minister and request that a board of review be established (**Section 77(8)**).	
Enforcement Mechanisms	Member States will decide penalties and/or fines and notify the Commission within 18 months after the Regulation comes into effect (**Article 123**).	Enforcement officers have the right to inspect sites, to review reports to ensure compliance with the Act and regulations. They may issue warnings, directions to prevent illegal releases of a regulated substance, write tickets for offences such as the failure to submit reports or write orders to stop an illegal activity, to prevent a violation or require an action to be taken. If a person is convicted of a violation under CEPA, they are liable for fines of up to $1 million per day and imprisonment for up to 3 years or both. They may also have to pay for cleanups and/or forfeit profits. There is also a civil right of action under CEPA that allows a person to request an investigation (**Section 40**); a requirement that government respond to citizen complaints (**Sections 22-38**); and provisions for directors' liability (**Section 280**)	
Funding	The European Chemicals Agency will be	Fees are paid under the New Substances	The fees applied to new

Programs	funded by fees paid by industry under REACH (for registrations and authorisations), by a subsidy from the European Union and by contributions from Member States. (**Article 93(1))**	Fees Regulation to allow for partial cost recovery of assessment and notification processes.	substances in Canada should apply to the use of existing substances as well. The fees recovered from assessing substances should sustain the operations and activities of the departments responsible for assessing and managing toxic substances.[53]
Relationship with Other Jurisdictions	The Agency can exchange data, with confidentiality requirements, with other countries or international organisations that are managing chemicals under legislation similar to REACH (**Article 117**). This is intended to avoid duplication of work internationally and to share experience. Other countries may also participate in the work of the Agency (**Article 103**).	The Minister of Environment must develop procedures for cooperating with other provincial, territorial or aboriginal governments and the OECD to exchange information on substances that are prohibited or restricted in other jurisdictions (**Section 75(2)**), and to review pertinent decisions on these substances **(Section 75(3))**.	

[53] The fees recovered through the New Substances Program is estimated to recover 20% of the total annual cost of operating the program.

APPENDIX I - ISSUES OF CONCERN TO GOVERNMENT FOR CEPA REVIEW

Environment Canada and Health Canada have suggested issues that the Parliamentary committee might consider for the purposes of changing the legislation. Some of the themes under consideration by Environment Canada and Health Canada officials and relevant to substances/chemicals are identified in a "preliminary discussion document" as follows:

- **Risk Assessment, Management of Existing Substances**
  - Removal of obligation to assess substances that are no longer in commerce (with recognition that they would have to be assessed when proposed for entry into commerce);
  - Acknowledgement in the preamble of vulnerability of particular groups to hazards from toxic substances;
  - Streamlining of the regulatory process to allow fewer interventions by Cabinet concerning a single substance;
  - Difficulty of determining the "level of quantification" of a substance contained in a product, where the virtual elimination of the substance is desired;
  - Possibility of eliminating requirement of setting a "level of quantification" for substances whose outright ban is desired;
  - Possibility of regulating manufacturers rather than downstream user facilities;
  - Continuing debate about the relative advantages of voluntary/unenforceable and regulatory instruments;
  - Expansion of the definition of "preventive or control action" to include Canada-wide standards; amendments to allow better use of a combination of tools (e.g. for different types of releases of the same substance).

- **New Substances Notification Program**

Inability for Minister of Environment to prevent unassessed new substances from entering Canadian commerce (The Act currently allows a substance to come on the market after the expiry of a deadline, before a comprehensive assessment of its hazardous properties has been completed. The timeline has the effect of putting an onus on the government to complete the review in a specified timeframe, creating the possibility that some substances may be entering the Canadian market without comprehensive assessment of their toxicity being completed)[54];

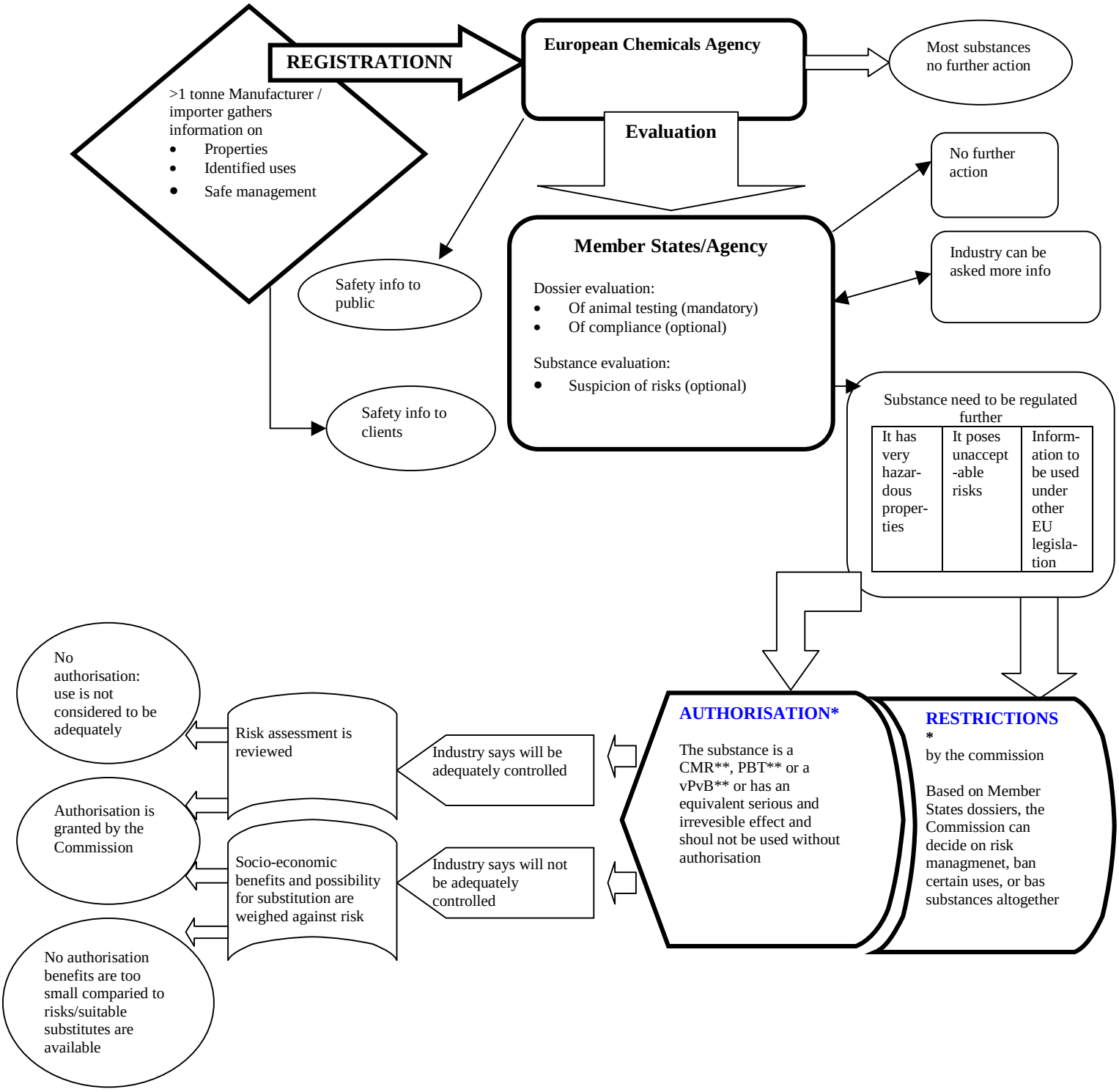
  - Absence of remedial measures (e.g. Ministerial direction that manufacturer give public notice of danger posed by an animate product of biotechnology).

- **Hazardous Wastes**

Changes to allowable terms of waste movement permits.

[54] Environment Canada and Health Canada, Draft Paper, Preparation for the Parliamentary Review of *the Canadian Environmental Protection Act* 1999 (September 23, 2004)

APPENDIX II - Overview of REACH: Registration, Evaluation & Authorisation of Chemicals[55]



[55] Source of diagram reproduced from http://europa.eu.int/comm/enterprise/reach/docs/reach/flowchart-2003_10_29.pdf. **Notes for diagram** * Substances do not have to be registered or evaluated to be placed under authorisation or restriction. They can be identified in other ways.
** Can cause cancer or mutations, or is toxic to reproduction; or is persistent, bio-accumulative and toxic, or very persistent and very bio-accumulative