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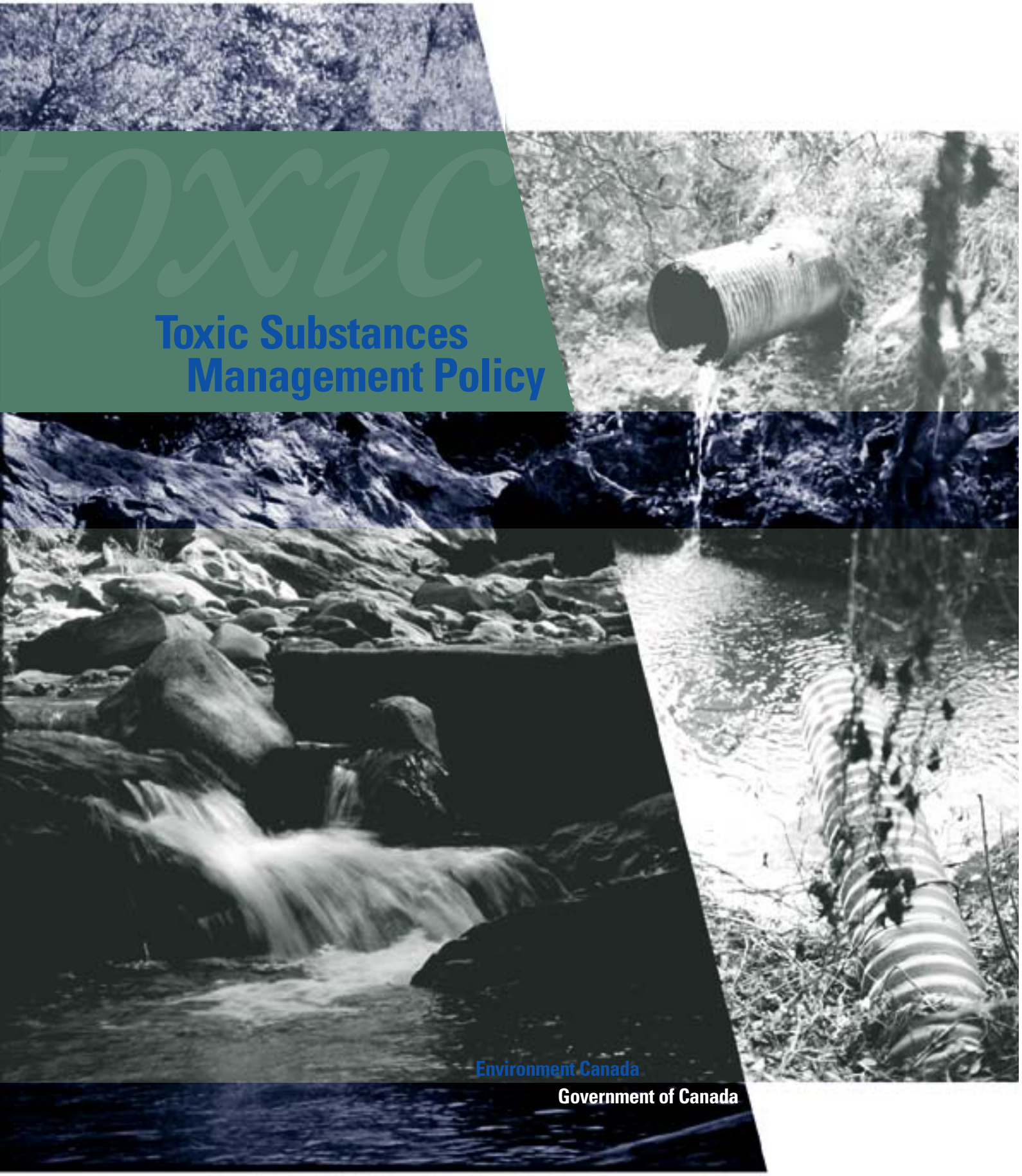

Toxic Substances Management Policy

Environment Canada

Government of Canada

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Toxic Substances Management Policy: Persistence and Bioaccumulation Criteria
Toxic Substances Management Policy: Report on Public Consultations

are available from:
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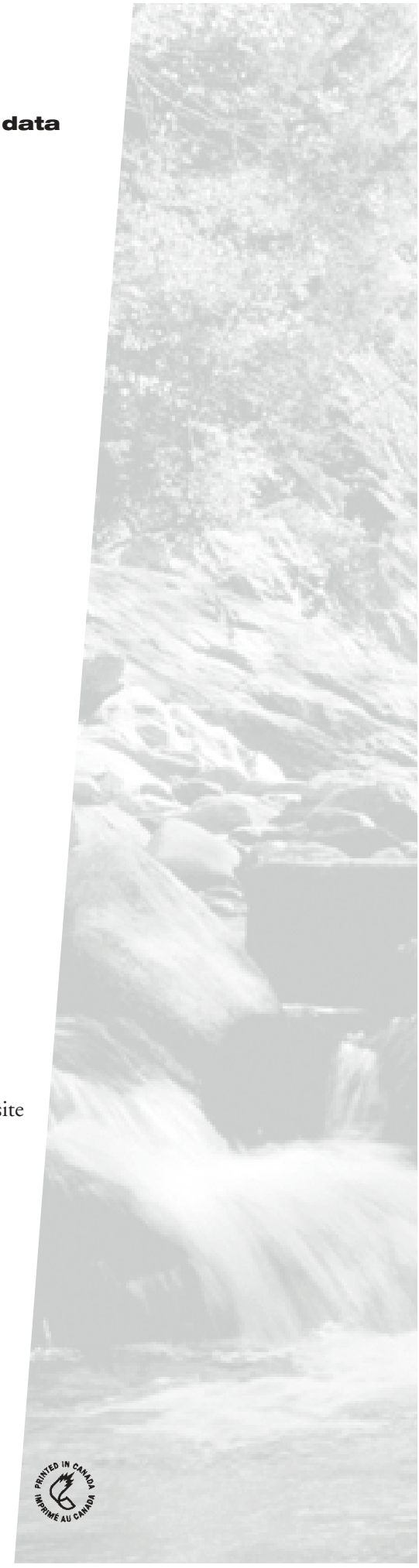
The *Toxic Substances Management Policy* is on Environment Canada's Internet site at **http://www.ec.gc.ca/toxics/en/policy.cfm**



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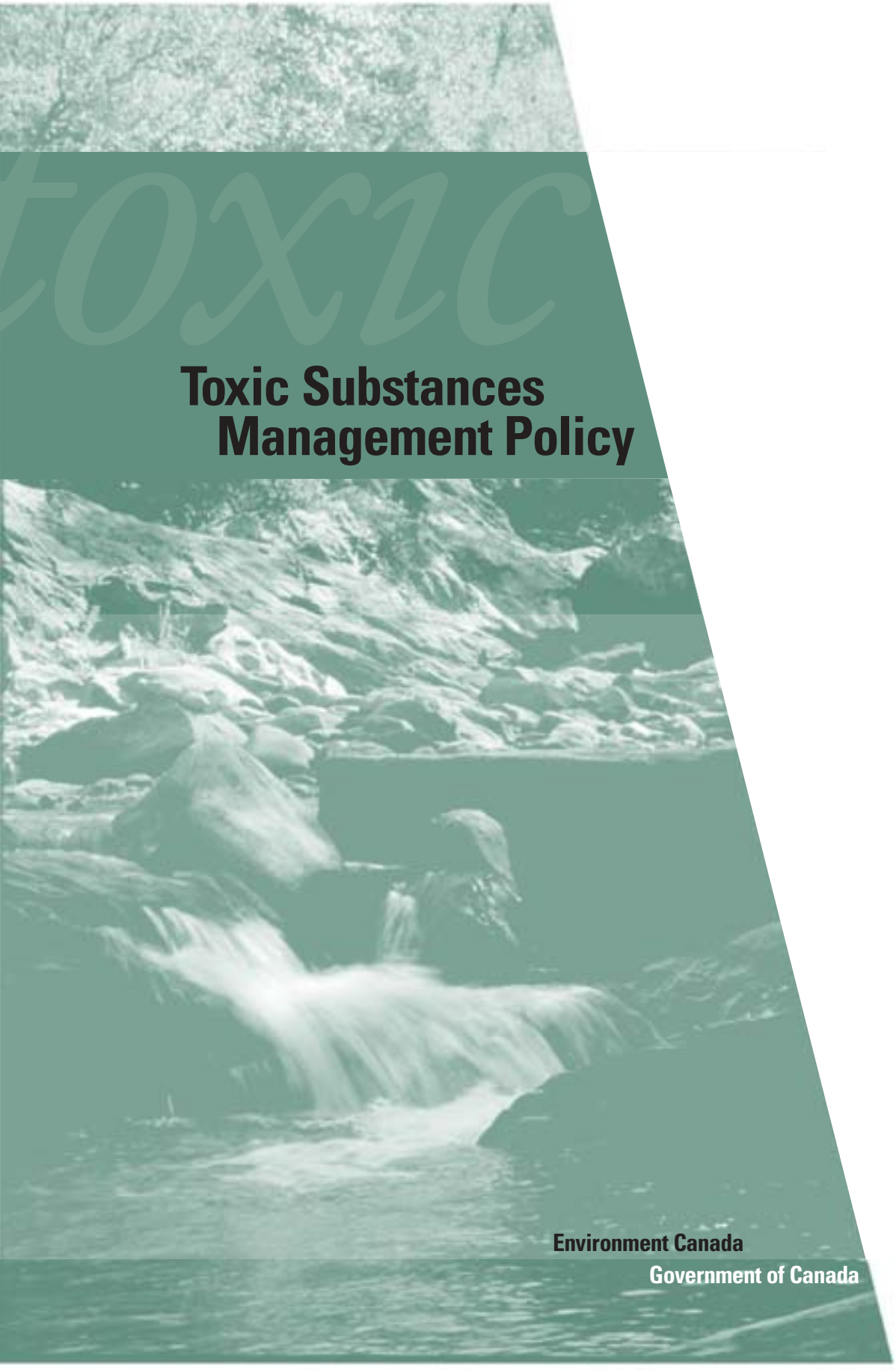

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Executive Summary

The federal *Toxic Substances Management Policy* puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy is the result of consultations with stakeholders, held from September 1994 to April 1995, after the release of the federal government discussion paper *Towards a Toxic Substances Management Policy for Canada* and the companion document *Criteria for the Selection of Substances for Virtual Elimination.*

The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. It also serves as the centrepiece of the federal government's position on the management of toxic substances in discussions with the provinces and territories and negotiations with the world community.

The key management objectives are:

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

Management of both Track 1 and Track 2 substances will address, as appropriate, entry into the environment from both domestic and foreign sources, as well as remediation of areas already contaminated by a substance. Virtual elimination from the environment of Track 1 substances will be based on strategies to prevent the measurable release of the substances into the environment. In cases where no measurable release limits cannot be satisfied, generation or use of a substance will not be acceptable.

While socio-economic factors have no bearing in setting the ultimate objective for Track 1 substances (virtual elimination from the environment), such factors will be taken into account when determining interim targets, appropriate management strategies and time lines for implementation. Socio-economic factors will be considered when determining long-term environmental goals, targets, strategies and time lines for Track 2 substances.

Purpose

Many of the goods and services we rely on either use or produce substances that may be harmful to the environment or to human health. We have learned that if we do not manage the risks associated with these substances adequately, we could be faced with problems that are either extremely costly or impossible to correct. Scientific studies show this is particularly true of substances that result from human activity and that are toxic, persistent — that take a long time to break down — and bioaccumulative — that collect in living organisms.

As science cannot always accurately predict the effects that a substance will have on the environment or on human health, managing toxic substances effectively requires taking a proactive, cost-effective approach to prevent pollution, rather than reacting after it has already occurred.

The federal government's *Toxic Substances Management Policy* puts forward a preventive and precautionary approach to deal with all substances that enter the environment and could harm the environment or human health. It provides decision makers with direction and sets out a framework to ensure that federal programs are consistent with the objectives of the policy.

The federal government already administers a number of programs to reduce or eliminate the risks associated with toxic substances. This policy underscores the need to apply pollution prevention principles to all those programs and to respond to the growing public demand for government action to protect the environment and human health while sustaining jobs and a healthy economy.

The Policy

This policy provides a framework for making science-based decisions on the effective management of toxic substances that are of concern because they are or may be used and released into the environment or because Canadians may be exposed to them through the environment.

The policy has two key management objectives:

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

Figure 1 shows how toxic substances and other substances of concern are managed under one of two tracks.

The policy guides federal regulatory and non-regulatory programs by defining the ultimate management objective for a substance. It applies to areas within federal jurisdiction, taking into account the division of legislative powers between the federal, provincial and territorial governments.

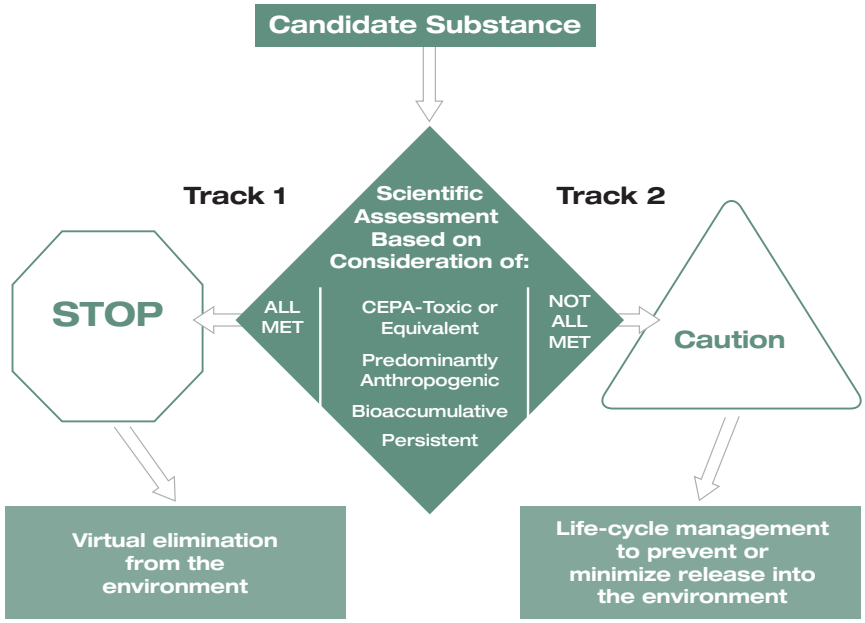
A substance will be considered for systematic assessment if federal, provincial or international programs, or members of the Canadian public, have identified it as potentially harmful to the environment or human health.

A substance is considered toxic if, after rigorous scientific assessment and based on decisions taken under federal programs, it either conforms or is equivalent to "toxic" as defined in the *Canadian Environmental Protection Act* (CEPA).

Other substances that have not been determined to meet the definition of toxic under CEPA or its equivalent may be of concern because of their potential to harm the environment or human health, and may be managed in response to these concerns or to specific obligations. Such substances of concern will be identified through scientific assessments under a variety of existing programs, and could include substances that are subject to specific regulatory provisions (such as new substances controlled under the *New Substances Notifications Regulations* of CEPA); substances managed under federal-provincial agreements (such as nitrogen oxides and volatile organic compounds that are managed as smog precursors); and substances managed as a result of international commitments (such as sulphur oxides that contribute to acid precipitation).

The policy recognizes the need to apply a precautionary approach in identifying substances and implementing cost-effective measures to prevent environmental degradation.

FIGURE 1 **Selection of Management Objectives under the Toxic Substances Management Policy**



Since toxic substances or substances of concern can originate either within Canada or abroad, domestic actions have to be complemented by international measures to protect the Canadian environment. As Canada takes a leadership role in seeking international action, this policy will serve as the centrepiece for the country's position on managing toxic substances in discussions and negotiations with the world community.

Track 1 – Virtual Elimination from the Environment

A substance that meets all four criteria outlined in Table 1, in other words, that is persistent, bioaccumulative, toxic and primarily the result of human activity, will be targeted for virtual elimination from the environment (Track 1 substance). This objective will be achieved by addressing sources of release to the environment or by removing or managing the substance if it is already in the environment.

Pollution prevention strategies will be used to prevent the measurable release of a Track 1 substance from domestic sources. A Track 1 substance that cannot be managed successfully throughout its life cycle will be targeted for phase-out of generation and uses. Through bilateral or multilateral agreements, the federal government will work to eliminate Track 1 substances that originate from sources outside the country.

Remediation may be undertaken when a Track 1 substance is already in the environment. For sites under federal jurisdiction that are contaminated by a Track 1 substance, management plans will consider the elimination of that substance, based on an analysis of risks, costs and benefits. Where the benefits to the ecosystem or to human health of removing the substance outweigh clean-up costs — including the possibility of further environmental degradation — remediation will be considered. Otherwise, management strategies will focus on minimizing exposure and the site's potential risks.

The federal government will identify Track 1 substances proposed for virtual elimination from the environment. Stakeholders will have an opportunity to comment, with a fixed period of time to present scientific evidence objecting to or supporting a substance's selection, that is, whether it satisfies the criteria. The federal government will render a final, public decision after reviewing all the evidence.

The onus will be on those who generate or use a Track 1 substance to demonstrate that the substance will not be released into the environment in measurable concentrations at any point in its life cycle. Measurable release limits will be developed as appropriate for a Track 1 substance to allow verification that no measurable release has been achieved and to allow enforcement of any regulations that may be developed. Limits will be based on the lowest concentration of a substance that can be accurately detected and quantified using sensitive but routine analytical methods. These limits will be established during the development of management strategies as part of consultations with stakeholders.

The objective of virtual elimination of a Track 1 substance from the environment does not mean chasing down that substance to its last molecule. Common sense will apply as progress toward the substance's elimination is monitored. The ultimate objective of eliminating a Track 1 substance from the environment is set irrespective of socio-economic factors. Nevertheless, management plans such as targets and schedules to achieve that long-term objective will be based on analyses of environmental and human health risks as well as social, economic and technical considerations.

The presence of a Track 1 substance in the environment will be monitored to ensure that management plans are achieving the objective of virtual elimination and to assess the need for additional action.

The persistence and bioaccumulation criteria used to identify Track 1 substances can only be applied to chemical substances. Thus, while a chemical substance produced by organisms through biotechnology processes may be considered for Track 1, the organisms themselves will not.

Where a Track 1 substance results from the degradation or transformation of a parent substance in the environment, the parent substance may also be considered for Track 1.

Naturally occurring substances, elements or radionuclides are not candidates for Track 1. However, when warranted, a natural substance that is used or released as a result of human activity may be targeted for reduction to naturally occurring levels under Track 2.

This policy does not apply to pharmaceuticals when used for purposes for which they were approved under the *Food and Drugs Act*. It does apply to those pharmaceuticals, their by-products or wastes that are of concern because of their release to the environment.

Track 2 – Life-Cycle Management

The federal government will identify toxic substances and other substances of concern subject to management under Track 2 through a variety of existing programs. Substances that do not satisfy all four criteria in Table 1 are candidates for full life-cycle management to prevent or minimize their release into the environment.

Management strategies, including pollution prevention, pollution control, remediation, and, in the case of sources outside Canada, international action, will be based on a life cycle approach. Risk assessment and risk management approaches will be used to identify Track 2 substances and management options. Risk assessment estimates the degree and likelihood of adverse effects resulting from exposure to a substance in the environment. Risk management is the process of selecting and implementing management actions on an assessed risk, taking into account a wide range of legal, economic and social factors. These factors will be considered in setting long-term environmental goals for Track 2 substances, as well as for selecting strategies and time lines to achieve these goals.

Pollution control and remediation strategies may be used to achieve the objective set for Track 2 substances. However, pollution prevention is often the most cost effective management strategy and in such cases will be promoted by the federal government as the preferred approach for Track 2 substances.

A Track 2 substance in the environment as a result of human activity relating to specific products, uses or releases may be targeted for virtual elimination from the environment if it poses unacceptable risks to the environment or human health. Elements and naturally occurring substances that are used or released as a result of human activity may be targeted under Track 2 for reduction to naturally occurring levels.

Criteria

Table 1 shows the criteria used to select Track 1 substances.

TABLE 1 Criteria for the Selection of Substances for Track 1

Persistence[1]		Bioaccumulation[3]	Toxicity[4]	Predominantly anthropogenic[5]
Medium	Half-life			
Air	≥ 2 days[2]	BAF ≥ 5,000 or	CEPA-toxic or	Concentration in environment largely resulting from human activity
Water	≥ 182 days	BCF ≥ 5,000 or	CEPA-toxic	
Sediment	≥ 365 days	log K_{ow} ≥ 5.0	Equivalent	
Soil	≥ 182 days			

1 A substance is considered persistent when the criterion is met in any one medium.

2 A substance may be considered as persistent in air if it is shown to be subject to atmospheric transport to remote regions such as the Arctic.

3 Bioaccumulation Factors (BAF) are preferred over Bioconcentration Factors (BCF); in the absence of BAF or BCF data, the octanol-water partition coefficient (log K_{ow}) may be used.

4 A substance is considered toxic if it meets or is equivalent to the definition of "toxic"found in the *Canadian Environmental Protection Act* (CEPA), as determined through a systematic, risk-based assessment. CEPA states: "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) 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."

5 On the basis of expert judgment, the concentration of the substance in any environmental medium is due largely to the quantities of the substance used or released as a result of human activity relative to contributions from natural sources. Elements and naturally occurring inorganic compounds are not candidates for virtual elimination from the environment.

Environmental persistence refers to the length of time a substance resides in environmental media and is usually defined in terms of half-life — the time required for the concentration of a substance to diminish to half its original value. A persistent substance degrades very slowly in the environment and therefore has a long half-life. Physical, chemical and biological processes that degrade a substance are considered in determining its half-life; dilution or transportation to other locations or media generally are not. For a substance to be considered persistent, it must meet a criterion in at least one medium.

Bioaccumulation describes the process by which a substance accumulates in a living organism — either from the surrounding medium or through food containing the substance. A substance's potential to bioaccumulate can be expressed by the bioaccumulation factor (BAF), the bioconcentration factor (BCF) or the octanol-water partition coefficient (K_{ow}). The BAF and the BCF measure the concentration of a substance in a living organism relative to its concentration in the surrounding medium.

The BAF accounts for substance intake from both food and the surrounding medium, while the BCF accounts for intake from the surrounding medium only. The octanol-water partition coefficient (K_{OW}) estimates a substance's tendency to partition from water to organic media, such as lipids present in living organisms. The partition coefficient can be used in place of the BCF or BAF when limited experimental data are available.

Persistence and bioaccumulation depend on many factors, including the intrinsic properties of a substance, conditions in the environment, and the ecosystem under consideration. Thus, a given substance is likely to have a range of persistence and bioaccumulation values. Since substances can occur under a variety of conditions in Canada, expert judgment and the weight of scientific evidence will be used in determining if the criteria have been met.

Persistence and bioaccumulation apply only to individual chemical substances and cannot be applied to groups of substances or complex mixtures or effluents. A substance that satisfies the four criteria for Track 1 and that occurs in a complex mixture or effluent can, however, be a candidate for virtual elimination. In such cases, management strategies will need to take into account that these toxic substances occur within a mixture or effluent.

A document entitled *Toxic Substances Management Policy — Persistence and Bioaccumulation Criteria* provides details about these criteria, including their numeric values, the process and rationale used in establishing them, and information about how they are applied.

For the purposes of this policy, a substance is considered toxic if it meets or is equivalent to the definition of "toxic" found in the *Canadian Environmental Protection Act* (referred to as "CEPA-toxic"). While a variety of non-regulatory instruments may be used to achieve the management objectives under the policy, the federal government has the legislative authority to develop and enforce regulatory actions leading to virtual elimination or life-cycle management for a substance that has been determined to be toxic under this definition.

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

In an assessment of "CEPA-toxic" or "CEPA-toxic equivalent", exposure is an important element in evaluating environmental risk under the policy. Persistence and bioaccumulation can be used as qualitative surrogates for long-term exposure of environmental biota. This approach will expedite the identification of Track 1 substances.

A substance's source of release is a fundamental consideration in selecting risk management strategies. Some substances that are persistent, bioaccumulative and toxic occur naturally and can never be eliminated from the environment. A substance will be considered "predominantly anthropogenic" if its concentration in an environmental medium is largely due to human activity, rather than to natural sources or releases. A substance that is "predominantly anthropogenic" in one part of Canada might not be so in another. Therefore, it will be necessary to rely on expert judgment when determining if a substance is "predominantly anthropogenic." Special consideration will be given to whether the objective of virtual elimination is technically achievable given the substance's origin. Elements and naturally occurring inorganic compounds are not candidates for Track 1.

Implementation and Accountability

Many Track 1 and Track 2 substances are already subject to federal statutory management strategies that are consistent with this policy — the *Canadian Environmental Protection Act*, the *Pest Control Products Act*, and the *Food and Drugs Act* being examples. No new action will be required for a substance that is adequately managed under existing programs. For a substance requiring further management to meet the objectives of the policy, strategies will be identified and implemented under the appropriate federal programs.

Some federal acts, regulations, programs and initiatives may exceed the risk management actions required to meet the objectives of this policy. This policy will not limit such actions. Implementation of this policy with respect to a specific substance will not suspend the application or enforcement of federal legislation.

While socio-economic factors have no bearing on setting the ultimate objective for a Track 1 substance — its virtual elimination from the environment — such factors will be taken into account when determining and implementing risk management measures under this policy. For example, they will help to determine interim targets, appropriate management strategies and time lines.

Socio-economic factors will help to determine long-term environmental goals, targets, strategies and time lines for a Track 2 substance. Such factors include: the benefits associated with the use or generation of a substance; the cost and feasibility of developing and using alternatives or remediation; the impact on employment, Canadian competitiveness, trade and regional development; and fairness and equity.

The federal government will be mindful of international standards and Canada's commitment to facilitate free trade when implementing this policy. By working with the United States and Mexico through the Commission for Environmental Cooperation, Canada has an opportunity to promote the policy's objectives and strategies within a North American context. The policy will also be put forth in other international fora, including the United Nations and the Organisation for Economic Co-operation and Development.

In implementing this policy, federal departments will follow and promote these general principles and approaches:

- adoption of a precautionary approach to substance management, as defined by Principle 15 of the *Rio Declaration on Environment and Development*. "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";
- consistency between departments;
- public participation, openness and transparency in decision making;

- consideration of all available instruments in developing management strategies, including regulatory and non-regulatory approaches;
- consideration of socio-economic factors when choosing management strategies; and
- timely action in implementing all aspects of the policy.

Environment Canada will provide technical and scientific advice to other federal departments, and overall coordination in applying the policy.

Public accountability for the policy's implementation will be ensured through the Commissioner of the Environment and Sustainable Development in the Office of the Auditor General. Part of the Auditor General's mandate is to audit the implementation of federal policies and programs to determine whether federal departments: comply with environmental and related legislation and policies; carry out their responsibilities in regulating and monitoring environmental issues and enforcing environmental laws; integrate environmental concerns into management systems and operational practices; give due regard to efficiency and economy; and have procedures to measure and report on program effectiveness.

Any modification to this policy, including changes to criteria, will be made openly and with consultation. Ministers will be asked to approve proposed changes through Cabinet.

notes

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