Toxic Substances Management Policy - Report on Public Consultations

Government of Canada
Environment Canada

June 1995

Aussi disponible en français sous le titre :
Politique de gestion des substances toxiques - rapport sur les consultations publiques

Copies of the documents:

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

are available from:

Enquiry Centre
Environment Canada
Ottawa, Ontario
K1A 0H3
Telephone: 1-800-668-6767
Fax: 819-953-2225
E-mail: ENVIROINFO@CPGSV1.AM.DOE.CA@1GW

Catalogue No. En 40-499/3-1995E
ISBN 0-662-23525-8

Table of Contents

Toxic Substances Management Policy - Report on Public Consultations

BACKGROUND

Canadians are increasingly concerned about the effects of toxic substances on the environment and human health. Experience shows that some substances, especially those that are bioaccumulative and persistent, can cause unforeseen, long-term problems that are difficult and costly to correct. A precautionary and preventive approach to manage these substances, before they cause problems, is the most effective way to protect the environment and human health.

The *Toxic Substances Management Policy* responds to public concerns by setting out how the federal government will deal with toxic substances, both domestically and internationally. The policy calls for decisive federal action that is consistent and predictable, and that benefits the environment, the Canadian public and industry. Copies of the policy are available from Environment Canada.

This report summarizes public comments on a discussion paper, released in September 1994, titled *Towards a Toxic Substances Management Policy for Canada*, and the government's response. The discussion paper outlined the proposed federal policy and included criteria for selecting substances for virtual elimination from the environment. The scientific rationale for these criteria was outlined in a companion document, *Criteria for the Selection of Substances for Virtual Elimination.*

Both documents were distributed to stakeholders via direct mail, news releases, and Environment Canada's electronic Green Lane and other network servers. Interested parties were invited to comment on the proposed policy and criteria by the end of November 1994. Key stakeholders -- from industry, environmental and human health groups, labour, native groups and universities -- were invited to discuss the policy with government representatives. Provinces were consulted throughout the development of the policy.

Environment Canada received nearly 100 submissions -- from industry, non-governmental organizations, the provinces, territories and municipalities, and other federal government departments. While most supported the proposed policy framework, many had questions or reservations regarding specific aspects of the policy and criteria.

As a result of the consultations, the policy and criteria were revised and subsequently adopted as federal policy. The federal government will be putting

forward the policy as its contribution toward the development with the provinces of a national strategy to manage toxic substances.

THE PROPOSED POLICY: COMMENTS AND RESPONSES

Each of the following topics includes a brief description of what was proposed in the original discussion paper, a summary of the stakeholder comments, and the federal response based on the final policy.

The policy framework: a two-track approach to managing toxic substances and other substances of concern

As proposed in the discussion paper

The discussion paper proposed a new framework to effectively manage substances of concern, based on the two management objectives of virtual elimination from the environment and full life-cycle management (Tracks 1 and Track 2). These objectives would be achieved through a variety of regulatory and non-regulatory measures including pollution prevention, remediation and international action.

Comments

Stakeholders acknowledged the need for a clear, consistent, management approach, but were concerned that the policy could complicate existing federal initiatives by creating a new, separate program. While some stakeholders questioned the need for separate tracks, most supported a separate track or mechanism for addressing anthropogenic, persistent, bioaccumulative, toxic substances.

Some said the policy was not clear on what constitutes toxic substances or substances of concern. Would all substances failing to meet Track 1 criteria be subject to life-cycle management? Should Track 2 substances at least meet the criterion for toxicity?

Response

The policy recognizes that if the risks associated with toxic substances are not managed adequately, we could be faced with problems that are either extremely costly or impossible to correct. This is particularly true of toxic substances that result from human activity and that are persistent and bioaccumulative. Recognizing the need for a preventive and precautionary approach, the policy has two key management objectives, based on the risks associated with the use or release of certain substances into the environment and the extent to which Canadians could be exposed to them through the environment. The policy's objectives are:

- virtual elimination from the environment of toxic substances that result predominately 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 as Track 2 substances).

The federal government will consider substances for assessment if federal, provincial or international programs or members of the Canadian public have provided evidence that they are potentially harmful to the environment or human health. Substances determined to be toxic or of concern will be managed in a manner consistent with the policy. Under the policy, a substance is considered toxic if it either conforms or is equivalent to "toxic" as defined in Section 11 of the *Canadian Environmental Protection Act* (CEPA). "Substances of concern" will be identified through scientific assessments, and could include substances that are subject to specific regulatory provisions (such as new substances controlled under the *New Substances Notification Regulations* of CEPA); substances managed under federal-provincial agreements (such as nitrogen oxides and volatile organic compounds managed as smog precursors); and substances managed as a result of international commitments (such as sulphur oxides that contribute to acid precipitation). While these substances of concern may not have been formally determined to be CEPA-toxic or equivalent, their management will be consistent with Track 2 of the policy.

The policy does not create new federal programs or legislation. Rather, it ensures an efficient and consistent federal approach on toxic substances under existing programs and legislation such as the *Canadian Environmental Protection Act* (CEPA), the *Food and Drugs Act*, the *Hazardous Products Act*, the *Pest Control Products Act*, the *Fertilizers Act*, the *Fisheries Act*, and the *Transportation of Dangerous Goods Act*. The policy will guide the development of strategies for virtual elimination (Track 1) and life-cycle management (Track 2) under appropriate federal programs by providing clear objectives for these actions. It will have a similar impact on non-regulatory programs.

The policy also provides the basis for a clear federal position to support bilateral and international negotiations on toxic substances. It will assist Canada in meeting obligations under agreements such as the *Great Lakes Water Quality Agreement* which commits Canada and the United States to virtually eliminate persistent, bioaccumulative toxic substances from the Great Lakes ecosystem.

Applying risk assessment and risk management approaches

As proposed in the discussion paper

Risk assessment and risk management approaches would be applied to both Track 1 and 2 substances under the policy. Risk assessment would be used to decide how dangerous a substance is by describing its hazard, level of exposure and how organisms respond to it. Risk management would be used to decide what to do about an assessed risk, based on a wide range of legal, economic and sociological factors.

Comments

Stakeholders had differing interpretations of risk, hazard, risk assessment and hazard assessment. Questions centred on how risk assessment and risk management would allow for decisive action leading to virtual elimination. Other questions focused on determining how a risk is deemed acceptable or not.

Some argued that, for the policy to be precautionary, assessments should be based on the intrinsic properties of substances, including inherent toxicity (*i.e.*, hazard), and not on discharges into the environment or current impacts on the ecosystem. Others said risk assessment is the only appropriate basis to determine risk reduction measures.

Response

Under CEPA's definition of toxic, harm to the environment or human health is a function of both inherent toxicity (*i.e.*, hazard) and actual or possible exposure. The identification of toxic substances under the policy will be risk-based, regardless of track. However, the severe nature of the environmental risks associated with persistent, bioaccumulative substances will receive special attention when assessing Track 1 substances (see below).

The risks associated with Track 1 and Track 2 substances are managed differently under the policy. For Track 1 substances, the long-term objective of virtual elimination from the environment is predetermined, regardless of the quantitative risks associated with such substances; risks and socio-economic factors are considered in setting targets and time-lines to achieve virtual elimination. For Track 2 substances, the objective is life cycle management, and risk assessment and risk management approaches are used to identify cost-effective targets and time-lines which will reduce releases and exposure.

Interpreting virtual elimination from the environment

As proposed in the discussion paper

The discussion paper proposed that virtual elimination from the environment would be the objective for Track 1 substances. This would be achieved through management strategies that ensure no measurable releases. The onus would be on those who generate or use Track 1 substances to demonstrate that management strategies will eliminate measurable releases into the environment. Track 1 substances that could not be controlled throughout their life cycles would be neither generated nor used. The international community would be engaged to reduce or eliminate Track 1 substances that originate outside Canada. Since many Track 1 substances already exist in the Canadian environment, remediation would be used to achieve their virtual elimination, where appropriate.

Track 2 substances that pose an unmanageable risk to the environment or human health could also be targeted for virtual elimination.

Comments

Some stakeholders said the discussion paper's definition of virtual elimination, which allowed for "no measurable release," was inconsistent with the principles of pollution prevention, and at odds with the definition adopted by the International Joint Commission. Others questioned the need to target substances for virtual elimination at all, arguing that management based on acceptable exposure limits would be preferable. Stakeholders asked for examples of Track 2 substances that would be considered for virtual elimination.

Stakeholders said "no measurable release" should be changed to "virtual elimination of release," "no release above naturally occurring background levels," or "no measurable impacts". Others argued that reliance on "no measurable release" legitimizes end-of-pipe pollution controls rather than processes that avoid the use or generation of toxic substances, and should be replaced by a strategy of "no generation and no use".

Response

The policy has retained the objective of virtual elimination from the environment of Track 1 substances, as proposed in the discussion paper, as well as the approaches to achieving virtual elimination set out in that paper. Pollution prevention strategies will be used to prevent the measurable release of a Track 1 substance. A Track 1 substance that cannot be managed successfully throughout its life cycle will be targeted for phase-out of generation and uses.

The "no measurable release limit" will be based on its quantitation limit -- the lowest concentration that can be quantified with an acceptable degree of accuracy using sensitive but routine analytical methods. 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 from the environment and to assess the need for additional action.

By retaining a management approach based on no measurable release limits, the policy ensures that the target can be monitored for compliance and that any necessary regulations that are developed can be enforced.

The definition of virtual elimination adopted by the International Joint Commission (IJC) calls for "zero discharge" to prevent further releases from all point and non-point sources to all media, and addresses the elimination of releases **to** the environment. The federal policy also addresses releases from all sources to all media. Rather than setting a target of zero discharge, however, it sets a target that can be monitored and enforced through regulations. The policy objective for Track 1 substances is virtual elimination of substances ***from*** the environment, recognizing the need to address Track 1 substances that originate from foreign sources and, where appropriate, to remove those already in the environment.

Track 2 substances that pose unmanageable risks to the environment or human health may be targeted for virtual elimination from specific products, uses or releases. An example is chlorinated fluorocarbons (CFCs) which contribute to the depletion of stratospheric ozone. While these substances do not meet the criteria for bioaccumulation and therefore do not qualify for Track 1, they have been targeted for virtual elimination from the environment, and are subject to appropriate regulations under CEPA.

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 background levels.

Applying pollution prevention and sustainable development approaches

As proposed in the discussion paper

The discussion paper underscored the need for pollution prevention approaches to manage toxic substances.

Comments

While support for pollution prevention was widespread, many stakeholders stressed that a definition and discussion of pollution prevention should be given

in the policy, and that the policy should cite the key principles of the Canadian Council of Ministers of the Environment's (CCME) *A National Commitment to Pollution Prevention.* Many said pollution prevention should form the basis of the policy's management strategies, or that management strategies should encourage the development and application of new processes to prevent the release of substances. Some called for the removal of "no measurable release" and life-cycle management strategies for Track 1 substances since these were judged inconsistent with the principles of pollution prevention.

Several stakeholders recommended that the policy should be presented in the context of sustainable development.

Response

The proposed federal approach to pollution prevention is outlined in the discussion paper *Pollution Prevention: Towards a Federal Strategy for Action,* released in March 1995. A detailed discussion of pollution prevention was therefore not included in the policy, since pollution prevention is being discussed as part of a separate, on-going initiative. While the policy does not provide a detailed interpretation of pollution prevention, it does call for pollution prevention strategies for managing Track 1 substances and promotes the use of such strategies in managing Track 2 substances. In general, pollution prevention is the government's preferred strategy for safeguarding the environment -- a principle that should guide decision-making with respect to development activity.

The federal government recognizes that pollution prevention is an important means of achieving sustainable development, and that the public expects action to protect the environment and human health while sustaining jobs and a healthy economy.

Applying the policy to specific types or categories of substances

As proposed in the discussion paper

Annex 1 of the discussion paper outlined various programs dealing with new and existing substances, including individual chemicals, groups of compounds, effluents and wastes.

The discussion paper proposed that new pesticides that meet the four criteria for Track 1 would only be registered under exceptional circumstances. A priority scheme would ensure the re-evaluation of existing pesticides, and appropriate application of the policy. Acceptable alternatives might need to be considered before taking regulatory action.

Screening procedures for new substances under CEPA -- the *New Substances Notification Regulations* -- would be made consistent with the policy. Substances meeting the four Track 1 criteria would be prevented from being released into the environment through management to no measurable release limits or by prohibiting their importation, manufacture or use.

Comments

Stakeholders asked for more details on how the policy would be applied to pesticides and new substances, Some raised concerns about how further restrictions on pesticides would affect farmers. Others said the policy did not go far enough in limiting the use of pesticides. Some stakeholders said the *New Substances Notification Regulations* are inconsistent with the policy. Since persistence and bioaccumulation data are often unavailable for new substances, assessment can only indicate a "suspicion of CEPA-toxic".

Many others asked how specific types of substances would be handled under the policy, including chemicals that mimic hormones (such as estrogenic inducers), biotechnology products and pharmaceuticals.

Response

While the policy applies to new and existing pesticides, it does not create new regulations or procedures for pesticides. Under the *Pest Control Products Act* and *Regulations*, pesticide registrants must provide extensive data to support registration, including data on persistence and bioaccumulation. Under the policy, new pesticides that meet the criteria for Track 1 may only be registered under exceptional or emergency circumstances. The policy will guide decisions when re-evaluating pesticides that are already registered. Based on socio-economic considerations, the timing of phase-outs and restrictions may be predicated on the availability of viable alternatives. There are few, if any, new pesticides being proposed for registration that would meet all four Track 1 criteria and thus, there should be little impact on farmers by applying this policy to agricultural pesticides.

The policy is consistent with approaches to assessing new chemicals and polymers under the *New Substances Notification Regulations.* If there is a "suspicion of CEPA-toxic," additional information may be requested, including data on persistence and bioaccumulation if these are suspected or predicted to be problematic. Based on this additional information, if a substance is found to be "CEPA-toxic", bioaccumulative and persistent, it will be managed under Track 1. If it is found to be "CEPA-toxic" or there is a "suspicion of CEPA-toxic", but the substance is not bioaccumulative and persistent, it will be managed under Track 2.

Estrogenic effects associated with certain chemicals released into the environment are recognized as potentially harmful to the environment and to human health. As such, data on estrogenic effects of a substance may be considered when determining if the substance is toxic under CEPA. Toxic endocrine mimics that satisfy the criteria for Track 1 will therefore be managed under that Track.

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.

The 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 and their by-products or wastes that are of concern because of their release to the environment.

Socio-economic considerations

As proposed in the discussion paper

The objective of virtual elimination for Track 1 substances would be set irrespective of socio-economic factors. These factors would be taken into account in developing strategies and time-lines for managing these substances. For Track 2 substances, socio-economic factors would help to determine long term targets, as well as management strategies and time-lines. The Strategic Options Process (SOP) is one approach that would allow government, in consultation with stakeholders, to take various factors affecting competitiveness into account in developing management strategies. No new action would be undertaken for substances that are adequately managed under existing programs.

Comments

Many stakeholders said management and control strategies for toxic substances should be based on cost-benefit considerations that include such factors as economic impact and job loss. There were conflicting opinions about the policy's effects on Canadian competitiveness. Some stakeholders said it would foster innovation and the development of an environmental service industry. Others said it would drive up prices and reduce competitiveness.

Response

Experience has shown that if Track 1 substances are allowed into the environment, environmental and human health problems result that are either extremely costly or impossible to correct. The long term management objective

is thus pre-determined for Track 1 substances under the policy -- virtual elimination from the environment. Socio-economic factors will be taken into account when determining and implementing risk management measures. For example, they will be considered when determining interim targets, appropriate management strategies and time-lines.

For Track 2 substances, long-term management goals will be set by considering socio-economic factors as well as the risks associated with the substance. Socio-economic factors will also be considered in establishing targets, strategies and time-lines for achieving the goals. Such factors include: the benefits associated with the use and 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 policy's impact on competitiveness will depend on various factors including actions taken by other countries, the effects on production costs and the rate of technological innovation.

By clearly presenting the federal approach to the management of toxic substances, the policy will enhance the consistency and predictability of government actions, to the benefit of the Canadian public and industry. Introducing the policy and its management framework in international fora will help ensure that other nations undertake similar actions, levelling the international playing field.

Implementing the policy

As proposed in the discussion paper

Risk management strategies would be identified and implemented for substances that are targeted for virtual elimination or life-cycle management. No new action would be taken on substances that are adequately managed under existing programs. Existing legislation or programs would be applied to substances requiring additional management.

Substances that are not covered by an appropriate management strategy would be subject to the Strategic Options Process (SOP). The process, which would include the consideration of socio-economic factors, would be based on the principles of public participation, transparent decision making, cost-effectiveness, flexibility, equity and inter-governmental cooperation. Stakeholders would be invited to take part in each phase of the process and make recommendations to federal, provincial and territorial Ministers.

Measurable release limits would be defined for each substance based on a laboratory's ability to complete the analysis with confidence. The discussion paper did not propose to chase a substance to its last molecule. Progress toward virtual elimination would be monitored.

Comments

Many stakeholders questioned how the government would manage such a far-reaching policy. In light of its own down-sizing, is the government capable of implementing the policy? How would the policy be implemented? Some stakeholders recommended that government should ensure that industry is undertaking appropriate actions, receiving fair treatment, and is held accountable for achieving the policy's objectives. Others recommended that industry and government be held accountable through legally binding mechanisms.

Stakeholders argued that the policy should address what will happen in the event of a toxic substance's accidental release. Will the policy result in controls on the export of toxic substances? Will it include occupational environments?

Response

Plans to achieve the objectives for both Track 1 and Track 2 substances will be consistently implemented through existing federal legislation or programs. The policy provides guidance to these existing programs rather than creating new ones, and resources needed for policy's implementation will be found by reallocating existing resources.

The policy states clearly what the management objectives are, but does not dictate how the objectives will be attained. No new actions will be taken for substances that are adequately managed to meet the objectives of the policy; strategies for substances requiring additional management will be determined through appropriate multi-stakeholder consultations, and could include both regulatory and non-regulatory tools.

As outlined in the policy, federal departments will promote the following general principles and approaches: a precautionary approach to substance management; consistency between departments; public participation, openness and transparency in decision-making; consideration of all available instruments in developing management strategies; consideration of socio-economic factors when choosing management strategies; and timely action in implementing the policy

As it is a federal policy, the federal government is responsible for ensuring that appropriate measures are taken to achieve the policy objectives. The government will use all available administrative provisions and legal mechanisms in achieving policy objectives. The onus will be on industry to demonstrate that a substance can be adequately managed throughout its life cycle, including measures to avoid accidental release. Stakeholders will have the opportunity to comment or participate in the identification of Track 1 and Track 2 substances and in the development of management strategies.

Under the policy, monitoring and test results will be publicly reported through programs such as the National Pollutant Release Inventory and the Environmental Effects Monitoring Program.

Sections 41 to 45 of CEPA already deal with the export of toxic substances. Schedule II of CEPA contains lists of prohibited substances, as well as toxic substances and hazardous wastes requiring export notification. To further ensure adequate controls on export of toxic substances from Canada, Environment Canada will add all Track 1 substances and, when warranted, Track 2 substances to Schedule II of CEPA.

While occupational environments are generally not considered in environmental legislation, strategies leading to virtual elimination of a substance from the environment will generally result in its elimination from the workplace. The policy's objective of no measurable release will promote in-plant, closed-loop technologies. When these are not possible, exposure will be eliminated by prohibiting generation and use.

Opportunity to comment

As proposed in the discussion paper

Industry would be given a fixed period to demonstrate why a proposed Track 1 substance should not be targeted for virtual elimination. The federal government would render a final decision after an open, transparent review of all the evidence.

Comments

Many stakeholders questioned whether the onus should be on industry to demonstrate that a substance poses no risk to the environment or human health. Should the onus for demonstrating risk rest with government?

Some stakeholders criticized the policy for not outlining procedures to implement what they referred to as "reverse onus". Others contended that the current provisions are based on the "right of objection" rather than "reverse onus". According to some, reverse onus should apply to Track 1 substances only; for Track 2 substances, the onus should be on government to demonstrate that a substance is inadequately managed. Others argued that appeals for proposed Track 1 substances should require a public hearing before a board of review, with provisions for intervenor funding.

Response

The federal government will identify Track 1 substances proposed for virtual elimination from the environment. All stakeholders, including industry,

environmental and human health associations and labour, will be given an opportunity to comment on the proposal. This opportunity to comment will involve a fixed period of time during which scientific evidence objecting to or supporting a substance's selection, that is, whether it satisfies the criteria, can be submitted. The federal government will review all the evidence, determine the most appropriate management track for the substance and publish its decision. Specific mechanisms for this opportunity to comment will be developed in consultation with stakeholders.

Manufacturers and importers are already obliged to provide the federal government with information under a variety of programs, including the CEPA *New Substances Notification Regulations* and the *Pest Control Products Regulations*. Government will make greater use of existing capabilities to gather information from industry. This includes Section 16 and 18 of CEPA that may be used to require industry to provide government with information about a substance.

Legislation and regulations

As proposed in the discussion paper

The paper noted that many Track 1 and Track 2 substances are already subject to federal, provincial or territorial legislation, including measures under CEPA, the *Pest Control Products Act*, the *Food and Drugs Act* and various provincial and territorial legislation on the environment and human health. It proposed that the policy would be applied to all federal programs -- regulatory and non-regulatory.

Comments

Stakeholders had conflicting opinions on whether the policy should be incorporated into CEPA. Some argued that doing so would guarantee effectiveness and accountability. Others said existing powers and voluntary programs are sufficient. A number of stakeholders said that if the policy were enshrined in CEPA, it should be coordinated with other environmental legislation such as the *Fisheries Act* and the *Pest Control Products Act*.

Response

The policy applies to all federal departments and activities involving the management of toxic substances. While CEPA is the major federal legislation overseeing the assessment and management of toxic substances, tying the policy specifically to CEPA, to the exclusion of other federal legislation, would limit the scope of applicability of the policy. Further, the policy will guide federal non-regulatory initiatives, in addition to regulatory actions.

Part II of CEPA contains all the necessary provisions for the policy to be implemented on substances under its purview. CEPA is currently under parliamentary review -- one which could result in recommendations for changes to the Act, including modification of the definition of toxic under the Act. If this happens, the policy will need to be reviewed in light of such changes.

Public accountability for the policy will be addressed through the Commissioner for Environment and Sustainable Development in the Office of the Auditor General. Part of the Auditor General's mandate is to determine whether federal departments are efficiently and effectively carrying out government policy.

Harmonizing federal, provincial and international programs

As proposed in the discussion paper

The discussion paper took into account the division of legislative powers between the federal, provincial and territorial governments. It promoted a consistent and proactive approach to all federal environmental initiatives by setting clear objectives and priorities. In discussions with the international community, the federal government would place a priority on substances that had been targeted for virtual elimination from the Canadian environment.

Comments

Most stakeholders called for the harmonization of federal, provincial and international approaches to managing toxic substances. The policy should be consistent with other environmental initiatives to avoid wasteful duplication of resources and regulatory efforts. Effective management of these substances requires the cooperation of all jurisdictions. Since most contaminated sites in Canada are under provincial jurisdiction, how will the policy aid in remediation? Since the provinces are responsible for many aspects of toxic substances management, will the CCME play a leading role in implementing the policy? Is the policy consistent with international approaches? If so, this would help reduce its negative impact on Canadian competitiveness while encouraging greater international efforts to control and manage toxic substances. Stakeholders called on government to ensure that other countries are implementing their own toxic substances management programs before introducing the policy in Canada.

Response

The policy is clearly federal in application. However, it is recognized that consistency and coordination between jurisdictions, both within Canada and internationally, is needed to ensure the most effective management of toxic substances.

Discussions with the provinces took place as the policy was developed. The policy will be taken to the Canadian Council of Ministers of the Environment, where it will serve as the federal government's contribution toward the development of a national strategy on the management of toxic substances.

The need to manage contaminated sites is one of the reasons the federal government seeks to develop a national strategy with the provinces. Where a site or facility under federal jurisdiction is contaminated with a Track 1 substance, analysis will determine whether site clean-up will reduce or increase risks and the attendant costs and benefits. If the substance can be removed without incurring further damage to the environment or human health, the objective of eliminating the substance from the environment will be incorporated into the management strategy for the site. Otherwise, management strategies will seek to minimize the risks posed by the site.

Many of the substances that are expected to fall under Track 1 are already recognized internationally as being of greatest concern, and are being addressed by international bodies such as the Organization for Economic Cooperation and Development and the United Nations Economic Commission for Europe. To prevent entry into Canada from foreign sources, the federal government will engage in bilateral and multilateral discussions to prevent or minimize the release of Track 1 substances into the global environment. The policy will also provide a consistent Canadian position on international programs for the management of Track 2 substances.

THE PROPOSED CRITERIA: COMMENTS AND RESPONSES

Stakeholders commented on the criteria for selecting Track 1 substances that were outlined in the policy and described in greater detail in the companion document *Criteria for the Selection of Substances for Virtual Elimination*. Their comments dealt mainly with the interpretation of CEPA-toxic or equivalent and how the criteria -- including those for persistence, bioaccumulation and predominantly anthropogenic -- would be applied and made consistent with other initiatives.

The four criteria were reexamined and revised as appropriate. The document titled *Toxic Substances Management Policy - Persistence and Bioaccumulation Criteria* provides details about these two sets of criteria, including their numeric values, the process and rationale used in establishing them, and information about how they are applied, and is available from Environment Canada. The reader is referred to that document for a more detailed discussion of persistence and bioaccumulation.

Interpreting CEPA-toxic or equivalent

As proposed in the discussion paper

The interpretation of CEPA-toxic or equivalent was seen as a critical aspect of the policy -- providing the federal government with authority to pursue the objectives for both Track 1 and Track 2 substances.

Comments

Stakeholders were divided on this subject. Some said using CEPA-toxic or equivalent as the criterion for toxicity appropriately incorporates risk assessment into decision-making. Others said it would be more appropriate to rely solely on a substance's inherent toxicity in determining whether it belongs under Track 1 or Track 2.

According to some stakeholders, substances should not be considered for Track 2 management unless they are CEPA-toxic or equivalent.

Response

Inherent toxicity (*i.e.*, hazard) already plays an important role in the assessment and management of substances in many federal programs. However, by itself, inherent toxicity provides a weak scientific basis for pursuing policy objectives such as virtual elimination.

CEPA-toxic, as defined under Section 11 of the act, is a risk-based, scientific determination that allows government to take action under Part II of CEPA to minimize or eliminate identified risks. Making this determination in the context of the policy gives the government authority to pursue the policy's objectives, if necessary, using regulatory approaches.

In assessing the environmental risks posed by CEPA-toxic or equivalent substances under Track 1, the government assumes that long-term exposure will take place, based on a substance's persistence and tendency to bioaccumulate. A full, quantitative exposure assessment, normally required in the case of Track 2 substances, will not always be necessary. Emphasis will be given to environmental effects data -- whether from the laboratory or the field. Data indicating a potential for effects resulting from long-term exposure to low concentrations will be of greatest concern. Government favours this risk assessment approach, and intends to use mechanisms such as the "opportunity to comment" to expedite identification of Track 1 candidates.

Government programs will apply Track 2 management strategies -- both regulatory and voluntary -- to substances that are CEPA-toxic or equivalent.

The same strategies can be applied to other substances of concern, as defined earlier in this document.

Natural and anthropogenic substances

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered predominantly anthropogenic if, based on expert judgment, its presence in the environment is largely due to discharge or release through human activity.

Comments

Stakeholders generally supported the inclusion of "predominantly anthropogenic" as a criterion for Track 1 substances. There were conflicting opinions whether naturally-occurring substances, such as metals, should be subject to Track 1 or Track 2.

Among the questions: Will the policy include anthropogenic sources of natural substances? Do naturally occurring organic compounds fit into the policy? How do we account for geographical or regional differences?

Response

A substance will be considered "primarily anthropogenic" if its concentration in an environmental medium is largely due to human activity, rather than to natural sources or releases. The policy recognizes that a substance may be predominantly anthropogenic in one part of the country and not in another and that natural background levels may be site-specific. Therefore, it will necessary to rely on expert judgement when determining if a substance is "predominantly anthropogenic."

Naturally occurring organic compounds can be candidates for Track 1 if they satisfy this definition of "predominantly anthropogenic". Elements and naturally occurring natural compounds are not candidates for Track 1, because they cannot be prevented from occurring in the environment or being redistributed by natural processes. Organo-metallic compounds that cross cell membranes and bioaccumulate in organisms as complete molecules are eligible.

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.

Persistence – substance half-lives

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered persistent when the half-life criteria were met in any one medium: air ≥ 5 days; water ≥ 182 days; sediment ≥ 730 days; soil ≥ 182 days.

Comments

Stakeholders recognized persistence in various media as an important criterion. They had concerns about using half-life as a measure of persistence, and about using test and field conditions to determine half-lives.

Stakeholder comments illustrated a range of opinions. Some said different half-lives may be required to account for Canada's different climatic zones. Others said half-life criteria ignore the medium into which a substance is released. According to some, the real issue is bioavailability rather than persistence. Others cautioned that it may not be appropriate to determine half-lives by examining chemical and biological degradation in each environmental medium. Stakeholders noted that the policy considered a large number of media.

Response

Half-life is the most common, and often the only available, measure of persistence in laboratory and field studies. The criteria document now allows for the consideration of how half-life data relate to the media of concern in Canada, the test or modelling methods used to determine half-life and other factors such as temperature that influence half-life values.

Since the policy is intended to protect organisms in all environmental media, it was important to adopt persistence criteria for all media, and analysis of data on a number of substances indicated that separate critical values were needed for each medium.

Physical, chemical and biological processes that degrade a substance are considered in determining half-life; dilution or transportation to other locations or media generally are not.

While bioavailability is an important issue, data are available for only a few substances. When such data are available they will be considered.

Persistence -- in air

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered persistent in air when the half-life criterion of ≥ 5 days was met.

Comments

Stakeholders had mixed reactions to the need for a criterion for air. Some said the persistence criterion for air should be deleted since air is primarily a transport medium, rather than a medium for exposure. Others said the air criterion was unnecessary since criteria for persistence in other media and for bioaccumulation are sufficient to identify Track 1 substances.

Opinions differed with respect to the numerical value for the half-life in air. Some said it should be longer than five days. Others said it should be two days rather than five, since that is the criterion that has been proposed as part of the Persistent Organic Pollutant (POP) initiative under the United Nations Economic Commission for Europe (UN-ECE) convention on the Long-Range Transport of Atmospheric Pollutants (LRTAP).

Response

Air is primarily a transport medium for the types of substances addressed in Track 1. Persistence in air is an important factor in the potential long-range transport of a substance from where it is used, generated or released, to areas where it can persist, bioaccumulate and cause harm.

The half-life of ≥ 5 days has been changed to ≥ 2 days. Data show that many substances that have been detected in remote areas have half-lives shorter than 5 days. A half-life value of 2 days is also consistent with the UN-ECE POPs initiative. The criterion was also changed, to allow the use of field evidence of long-range atmospheric transport to remote areas such as the Arctic.

Persistence -- in water

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered persistent in water when the half-life criterion of ≥ 182 days was met. Water would refer to surface water only. Surface water would include lakes and rivers as well as seas and oceans. Because ground water conditions vary significantly from the other environmental media and are site specific, a criterion for persistence in ground water was not proposed.

Comments

Some stakeholders were troubled over the exclusion of ground water as a water medium, and said that a ground water criterion should be established to prevent chemical contamination of this medium.

There was general support for a persistence criterion in water, but opinions varied about the value of the half-life for this medium. According to some stakeholders, the half-life in water should be greater than 360 days. Others argued that the 56 day criterion for persistence in water used by the IJC should be adopted under the policy.

Response

The water criterion was derived from surface water data only. While data on half-lives in ground water and marine water were examined, they were found to be inadequate to allow the derivation of water persistence criteria specific to those environments. Thus, while it is recognized that persistence of a substance in ground water and marine water may be different from that in surface water, only one criterion, based on data for surface water, is identified in the policy. Separate criteria for ground water and marine water may be developed when adequate data become available.

In 1985, the IJC, which administers the Great Lakes Water Quality Agreement, recommended that a substance be considered persistent if it had a half-life in water greater than 56 days. This value was the only criterion used to define persistence. The federal government's policy differs by considering data for all media and setting separate half-life values for each of those media.

The half-life of ≥ 182 days is retained in the policy.

Persistence -- sediments

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered persistent in sediment when the half-life criteria of ≥ 730 days was met.

Comments

Stakeholders supported the persistence criterion for sediments, but raised concerns about the lack of distinction between aerobic and anaerobic sediments and burial in sediments. For example, the policy should consider the depth of the aerobic layer, sedimentation rates and sediment burial. Others said half-life should be set at ≥ 56 days in sediments.

Response

Selecting a half-life value for persistence in sediments is difficult since data are limited and this makes it impossible to distinguish between aerobic and anaerobic sediments. Whatever data are available, including information on sedimentation and burial rates, will be considered in applying this criterion. Since modelling predicts that substances with half-lives of more than one year will build up over time, the critical value for persistence in sediments is reduced from 730 days to 365 days.

Persistence -- soil

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered persistent in soil when the half-life criteria of ≥ 182 days was met.

Comments

Stakeholders supported the need for the persistence criterion for soil, but differed on its critical value.

The proposed criterion came in for criticism on a number of accounts. Most comments on persistence in soil related to pesticides. Some said the half-life is too short and would result in carry over from one year to the next, especially in the case of late season application of pesticides. Some said the half-life should be reduced to ≥ 56 days in soil. Others argued for an increase to 365 days.

Response

Re-examination of the original critical value and modelling predictions showed that the proposed criterion for soil is adequate. Modelling showed that a half-life of less than six months would minimize a substance's potential for build up. In most of Canada, six months is a reasonable time for soil temperature and moisture to favour degradation.

Bioaccumulation criteria

As proposed in the discussion paper

The discussion paper proposed that a substance would be considered bioaccumulative when any of the following criteria were met: BAF ≥ 5,000 or BCF ≥ 5,000 or log K_{ow} ≥ 5.0. Bioaccumulation factors (BAF) would be preferred over bioconcentration factors (BCF); in the absence of BAF or BCF data, the octanol-water partition coefficient (log K_{ow}) could be used.

Comments

Stakeholders were divided as to the most appropriate end point (bioconcentration, bioaccumulation or octanol-water partition coefficient) and its appropriate unit of measure (for example, for BCF -- whole body, wet weight versus lipid-normalized values). There was no consensus on the value for the criterion, with arguments for BAF and BCF values both above and below the 5000 figure. Stakeholders also called for a definition of terms.

Response

Bioaccumulation (BAF), bioconcentration (BCF), bioavailability and biomagnification are now defined and discussed in greater detail in the report on *Persistence and Bioaccumulation Criteria*. Since BAF is usually measured from field data, it is preferred over BCF. In practice, however, BAF values are usually unavailable and difficult to extrapolate. Thus, BCF -- measured on a whole body basis -- is the most commonly used end point.

The report on criteria recommends measurement on a wet weight basis and notes the importance of considering an organism's lipid content. The octanol-water partition coefficient (K_{ow}) is recommended only when other data are unavailable and if the correlations to predict BCF are relevant to the substance of concern.

The values presented in the discussion paper are retained: BAF $\geq$ 5,000 or BCF $\geq$ 5,000 or log $K_{ow} \geq$ 5.0.

Applying the criteria

As proposed in the discussion paper.

The discussion paper did not outline how the criteria would be applied.

Comments

Stakeholders had questions about data sources and how quality controls would be applied. They also asked how criteria will change to reflect scientific advances, and how mixtures and classes of substances will be treated with respect to the persistence and bioaccumulation criteria.

Response

Internationally accepted methods and those generally recognized by the scientific community will be considered in assessing data quality.

The inherent complexity of measuring persistence and bioaccumulation will lead to a range of values for any criterion applied to a substance. A weight-of-evidence approach will be used to interpret data and apply criteria.

The criteria for bioaccumulation and persistence were derived from data analysis, computer modelling and expert judgment. Both the criteria and the critical values may be revised in light of scientific advances in understanding persistence and bioaccumulation processes. As the criteria are key to distinguishing Track 1 and Track 2 substances, proposals to modify them will be subject to stakeholder consultations and Cabinet review.

The criteria for persistence and bioaccumulation can be applied to individual chemical compounds only. They cannot be applied to groups of substances or complex mixtures. As such, individual chemical compounds will be identified for Track 1 using these criteria. However, where those individual compounds occur in mixtures and effluents, their presence in those mixtures and effluents will need to be addressed in pursuing the objective of virtual elimination from the environment.

Consistency with other initiatives

As noted in the companion document to the discussion paper: Criteria for the Selection of Substances for Virtual Elimination

The companion document outlined the process used to derive the criteria, including the consideration and comparison of various criteria used in other programs or jurisdictions.

Comments

Stakeholders had concerns about the differences between the proposed criteria and those used in other programs or by other jurisdictions. They cited the IJC's 56 day criterion for persistence in water compared to the policy's 182 day criterion as an example.

Response

Critical values for persistence and bioaccumulation developed in Canada for other initiatives were examined as a starting point for establishing critical values for the policy. The main sets include those developed by the International Joint Commission (IJC) for its Critical Pollutants List; the Ontario Ministry of Environment and Energy (MOEE) for its Primary List for Bans and Phase-outs; and Environment Canada (EC) for List A of the Accelerated Reduction and Elimination of Toxics (ARET) Program. Also considered were the critical values proposed by Environment Canada (EC) and Health Canada (HC) to screen

substances for nomination to the revised CEPA Priority Substances List (referred to as PSL2).

Under the policy, the criteria are used to identify substances that will be targeted for management actions leading to virtual elimination from the Canadian environment. The sets of critical values identified under the initiatives listed above were developed for purposes different from those of the policy, *e.g.*, screening and identification of substances for voluntary action (ARET); screening and identification of substances for further assessment (PSL2); targeting releases of substances in a specific geographical location - the province of Ontario (MOEE) and the Great Lakes (IJC). As such, critical values should not be expected to be the same in all these initiatives.

IMPLEMENTING THE POLICY: EXAMPLES

Stakeholders expressed an interest in seeing examples of how the policy will be applied to a specific Track 1 and Track 2 substance. Hexachlorobenzene and tetrachloroethylene are cited here to illustrate that process.

Hexachlorobenzene

Hexachlorobenzene was assessed by Environment Canada and Health Canada under the Priority Substances provisions of CEPA, Sections 12 to 14. In 1994, the Ministers of the Environment and of Health concluded that hexachlorobenzene is CEPA-toxic, based on its potential to impair reproduction in species at the top of the food chain and its potential to cause cancer in experimental animals.

Hexachlorobenzene meets the policy's criteria for toxicity, persistence, bioaccumulation and predominantly anthropogenic and is a candidate for virtual elimination from the environment under Track 1.

Environment Canada will initiate a multi-stakeholder consultation, inviting participation from federal and provincial governments, industry, health and environmental groups and other relevant stakeholders. The long-term objective for the substance -- virtual elimination from the environment -- is pre-determined and not subject to socio-economic considerations. Discussions will focus on developing timely and cost-efficient strategies to achieve this objective, taking into account socio-economic and technological factors.

In some circumstances, even the best technology may be unable to achieve the pre-determined no measurable release level. While this is acknowledged, the objective of virtual elimination remains unchanged. Continuous improvements, tied to socio-economic realities, are consistent with the goals of the policy.

Hexachlorobenzene may be released to the Canadian environment as a byproduct from the manufacture or use of chlorinated solvents and pesticides contaminated with the substance, through incineration of wastes and by long-range transport from other countries. Actions under all applicable federal acts and initiatives, including CEPA, the *Pest Control Products Act*, the *Food and Drugs Act*, the *Hazardous Products Act* and the *Fisheries Act* -- will need to be considered to achieve the objective of virtual elimination. Non-regulatory approaches will also be considered.

In discussions on the need for a protocol on persistent organic pollutants (POPs) under the United Nations Economic Commission for Europe Long Range Transport of Air Pollutants initiative, Canada will work to ensure that hexachlorobenzene is included in the list of POP candidates and managed internationally.

The IJC has placed hexachlorobenzene on its list of 11 critical pollutants for virtual elimination. Hexachlorobenzene is also on the Canada-Ontario Agreement's Tier 1 list of substances for virtual elimination. The Ministers of the Environment and of Health are responsible for fulfilling Canada's obligations under the Canada-United States Great Lakes Water Quality Agreement and the Canada-Ontario Agreement.

Tetrachloroethylene

Tetrachloroethylene was assessed by Environment Canada and Health Canada under the Priority Substances provisions of CEPA, Sections 12 to 14. In 1994, the Ministers of the Environment and of Health concluded that tetrachloroethylene is CEPA-toxic, based on exposure levels and its effects on plants and wild animals.

Tetrachloroethylene meets the policy's criteria for toxicity, persistence and predominantly anthropogenic, but not the criterion for bioaccumulation. It is therefore a candidate for life-cycle management under Track 2.

Tetrachloroethylene is imported into Canada and used primarily as a dry-cleaning solvent. Environment Canada has initiated multi-stakeholder consultations under the Strategic Options Process. Representatives from the dry-cleaning industry, federal and provincial governments, industry, health and environmental groups will discuss management goals, targets and time-lines based on an analysis of socio-economic factors. Regulatory and non-regulatory measures will be considered and recommendations made to the Ministers.