Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative

Report to the North American Working Group on the

Sound Management of Chemicals

by the

Task Force on Criteria

October 1997

Preface

This report on a "Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative" is one of a number of regional undertakings that stem from the North American Agreement on Environmental Cooperation between the governments of Canada, Mexico and the United States. That Agreement established the Commission for Environmental Cooperation (CEC) to "*facilitate cooperation on the conservation, protection and enhancement of the environment in their territories"*. The Council (of Ministers) of the Commission, the governing body of the CEC, agreed to Resolution #95-5 on the Sound Management of Chemicals on 13 October 1995, at its second regular meeting held in Oaxaca, Mexico. The Resolution established "*a working group comprised of two senior officials selected by each Party whose duties pertain to the regulation or management of toxic substances and who shall work with the Commission for Environmental Cooperation (CEC) to implement the decisions and commitments set out in this Resolution"*. The Resolution specifically calls for the development of North American Regional Action Plans (NARAPs) for selected persistent and toxic substances as a first priority in the Parties' common desire to address national and regional concerns associated with the sound management of chemicals. This report is a response to the decision to develop "*refined criteria for identifying persistent and toxic substances for regional action.*"

The NARAPs developed under the Resolution reflect a shared commitment by the Parties to work cooperatively by building on international environmental agreements and existing policies and laws by: bringing a regional perspective to international initiatives that are in place or being negotiated with respect to persistent toxic substances; promoting cooperation with Latin American and Caribbean nations and with countries that have territories in the high Arctic; and encouraging mutually consistent trade and environment policies in their territories. At the same time, each NARAP is unique and reflects the differentiated responsibilities of each of the countries, consistent with their respective production, use, and disposal practices for the particular substance. The Resolution and the NARAP arising from it also take into account each country's respective natural endowments, climate and geographical conditions, and economic, technological and infrastructural capabilities.

An important dimension as regards development and implementation of the NARAPs is development of close working relationships among the intergovernmental bodies that address persistent and toxic substances in the three countries. As well, the North American Working Group on the Sound Management of Chemicals will work closely during the implementation of the plans with another CEC working group, the North American Working Group on Environmental Enforcement and Compliance Cooperation. In addition, when NARAPs are proposed for substances used as pesticides, cooperative arrangements will be developed and maintained with the Technical Working Group on Pesticides established under the North American Free Trade Agreement.

The NARAPs reflect a long-term commitment to regional action. The sharing and transfer of information and best practices are seen as an important means of enhancing national capacity for the sound management of chemicals. Other important elements and outcomes of these cooperative initiatives include collaboration and cooperation in the measurement, monitoring, modeling, research and assessment of selected persistent and toxic substances in environmental media. Such cooperation will improve the quality, availability and relevance of the "environmental information" needed to make informed and responsible decisions throughout the implementation of the action plans.

NARAPs are also intended to help facilitate the meaningful participation of the public, including non-governmental organizations, business and industry, provincial, state and municipal governments, academia, and technical and policy experts, in accordance with the spirit of cooperation reflected in the North American Agreement on Environmental Cooperation and in Council Resolution #95-5 on the Sound Management of Chemicals. Regular public reporting of the progress that has occurred with respect to each action plan will be important to its eventual success.

Executive Summary

Objectives: A key focus of the Sound Management of Chemicals initiative (Resolution #95-5) has been the development of North American Regional Action Plans (NARAPs) for those substances which the Parties agree warrant collective regional action. These substances pose a significant risk to human health and the North American environment, and impact on all three countries. NARAPs set out how the three parties will cooperate to manage and control the substances. To date, NARAPs have been established for DDT/chlordane, mercury and PCBs.

In order that additional substances can be identified for action in a credible way, and in order that the most important substances are addressed first, the North American Working Group on the Sound Management of Chemicals established a Task Force on Criteria. Its mandate was to develop a transparent process to select substances that should be the subject of NARAPs. The focus of the selection process for the short term was to be on persistent, toxic and bioaccumulative substances.

The process developed by the Task Force follows a number of general principles that are outlined in this report. It has built upon some of the procedures, criteria and findings adopted under other international and national initiatives identified by the Task Force, including scientific parameters such as toxicity, persistence, bioavailability, and bioaccumulation or bioconcentration of the substance in biota. It also emphasizes the importance of expert judgment and a number of socio-economic factors such as the potential to receive mutual benefits by the three Parties as a result of action.

Process: The 3-stage process proposed consists of:

(i) a *Nomination Stage* (Stage I) where a 'Nomination Dossier' containing background information on a substance is prepared (this step ensures consistent information and format for initial evaluation);

(ii) an *Evaluation Stage* (Stage II) consisting of two parts:- (1) a *Screening Evaluation*, whichidentifies whether a substance deserves further attention on the basis of scientific considerations (including, evidence of it entering the environment, being capable of transboundary environmental movement, its persistence, bioavailability and bioaccumulation and for which risk assessment documents exist);and (2) a *Mutual Concern Evaluation*, which determines the degree to which all Parties agree there is a problem and that there would be real benefits from collective action; and

(iii) a *Decision Stage* (Stage III) in which a Draft Decision Document is prepared recommending a course of action to the Working Group. This is an evaluation of a variety of issues (based on the science, the transboundary nature of the problem, and the feasibility of developing and implementing an action plan). It considers issues such as national capacity and international commitments, financing, possible implications on trade and on the economy, costs and benefits of developing various management options and the priority and timing for developing an action plan for the substance in the North American context (e.g., the extent to which there is ‘value-added’ by addressing the substance on a regional basis).

Implications: Fundamental to the process described above is the need for a Substance Selection Task Force (SSTF). While this Task Force will not be preparing risk assessments, it will need to have expertise in risk assessment and risk management, as well as in biological, chemical and physical characterization of persistent toxic substances. Due to the complexity and variability of possible candidate substances, the SSTF may need augmenting in other areas of expertise. The SSTF will report its findings to the North American Working Group.

Transparency / Public participation: A transparent approach and opportunity for public input to the selection process is proposed together with a reporting system to ensure public accountability. The reasons for selection or rejection of candidates will be published by the Commission for Environmental Cooperation.

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List of Acronyms

BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CEC	Commission for Environmental Cooperation
CEPA	Canadian Environmental Protection Act
CMA	Chemical Manufacturers Association
EPA	Environmental Protection Agency (United States)
INE	Instituto Nacional de Ecología (National Institute of Ecology)
K_{OC}	Octanol/carbon partition coefficient
K_{OW}	Octanol/water partition coefficient
LRTAP	Long range transboundary air pollution
MMP	Minerals and Metals Policy (Government of Canada)
NAAEC	North American Agreement on Environmental Cooperation
NAFTA	North American Free Trade Agreement
NARAPs	North American Regional Action Plans
OECD	Organization for Economic Cooperation and Development
POPs	Persistent organic pollutants
PCBs	Polychlorinated biphenyls
PTBs	Term for substances which are "persistent, toxic and tend to bioaccumulate" used by Chemical Manufacturers Association
SMOC	Sound Management of Chemicals Initiative
SSTF	Substance Selection Task Force
TSMP	Toxic Substances Management Policy (Government of Canada)
UNCED	United Nations Conference on Environment and Development
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Program

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1. Introduction

This report is being presented to the North American Working Group on the Sound Management of Chemicals (Working Group). It recommends a process for selecting "persistent, toxic and bioaccumulative" substances for North American Regional Action Plans (NARAPs), as required under the Sound Management of Chemicals initiative established by the Commission for Environmental Cooperation (CEC) Council Resolution #95-5.
This report comprises sections that:

- provide background for the substance selection process that has been developed by the Task Force on Criteria;
- review the approaches of other international and national initiatives regarding the selection of persistent, toxic and bioaccumulative substances that were taken into account in designing this selection process;
- document the principles that underlie the selection process;
- identify the stages and content of the selection process;
- describe the opportunities for public participation; and
- provide recommendations on the implementation of the proposed selection process and identify the need to review this process in the future.

2. Background

2.1 North American Agreement on Environmental Cooperation (NAAEC)

The North American Agreement on Environmental Cooperation (NAAEC) was negotiated and ratified in 1993 by the governments of Canada, Mexico and the United States. It is a side agreement to the North American Free Trade Agreement (NAFTA). The Governments were "convinced of the importance of the conservation, protection and enhancement of the environment in their territories and the essential role of cooperation in these areas in achieving sustainable development for the well being of present and future generations". They also agreed to "promote pollution prevention policies and practices" and committed to "consider implementing in its law any recommendation developed by the Council under Article 10(5)(b) of that Agreement." The Council (of Environment Ministers) is the governing body of the Commission for Environmental Cooperation, established under NAAEC. The relevant language in Article 10(5)(b) is that *"The Council shall promote and, as appropriate, develop recommendations regarding: b) appropriate limits for specific pollutants, taking into account differences in ecosystems"*.

2.2 The Sound Management of Chemicals Initiative

The three countries agreed that to address problems resulting from the unsound management of chemicals, they should work cooperatively to establish this initiative while building upon their respective

national, bilateral and international commitments. Restitution of degraded environments places financial stress on local, regional and national economies and rehabilitation often involves remedial measures over a long time frame, if it can be accomplished at all. Based on experience/expertise gained under this agreement, economic and foreign policy opportunities arise (e.g., exporting "state-of-the-art" environmental and other technologies and services). Thus the Council of the Commission for Environmental Cooperation (CEC) approved Resolution #95-5 (Sound Management of Chemicals) on 13 October 1995 at its meeting in Oaxaca, Mexico.

The resolution was developed with the recognition that cooperative actions are needed to protect and improve the environment and to achieve sustainable development. It was recognized that certain substances ("...persistent, bioaccumulative and toxic...")[1]) merited special attention due to the risk (especially long-term) they posed to human health and the integrity of ecosystems. Resolution #95-5 is broad enough to promote initiatives for the sound management of chemicals that go beyond persistent, bioaccumulative and toxic substances. As such, advancement of approaches for acting on substances, classes of substances, mixtures *of substances* and industrial clusters/sectors are also possible under this resolution. These approaches could be complimentary to selecting specific persistent and toxic substances as candidates for NARAPs, and could both expand and accelerate North American efforts to implement the decisions and commitments set out in Resolution #95-5 on the Sound Management of Chemicals.

To facilitate the various activities under the Council Resolution #95-5, a North American Working Group for the Sound Management of Chemicals was established consisting of a chair and two members from each country.

2.3 Formation of the Task Forces

The Working Group established four Task Forces. Each Task Force, with two representatives from each country, was charged with the preparation of a report to the Working Group summarizing proposals for addressing their mandate.

For three of the Task Forces, this involved the preparation of North American Regional Action Plans (NARAPs) for the substances initially identified - DDT and chlordane, mercury and PCBs. NARAPs set out how the three parties will cooperate to manage and control the substances. Different objectives may be appropriate for different NARAPs including: 1) phasing-out uses of substances that pose unreasonable or otherwise unmanageable risks to human health and the environment; 2) managing a substance, or 3) acquiring and/or substantiating information on a substance prior to establishing new initiatives. NARAPs can include new policies and regulatory and non-regulatory measures, and, consistent with Resolution #95-5, can:

- incorporate pollution prevention principles and precautionary approaches;

[1] Council Resolution #95-5, Sound Management of Chemicals, North American Agreement on Environmental Cooperation.

- take into account the different ecological, economic, political and regulatory circumstances of the Parties;
- identify opportunities for improving capacity and capabilities for the sound management of chemicals, through technical cooperation, research, and information sharing; and
- provide meaningful public participation.

The fourth Task Force was charged with proposing and evaluating a process for identifying additional substances to be targeted for future joint action by the three countries. This report describes the work of this fourth Task Force.

2.4 Task Force on Criteria

The Working Group provided direction to the Task Force on Criteria in the following areas:

Focus It was noted by the Working Group (10 May 1996) that Resolution 95-5 implies activities for the sound management of chemicals that go well beyond action plans for specific persistent and toxic substances. The Working Group considered a broader mandate for the Task Force, i.e., a criteria-based approach that was broad enough to encompass classes/mixtures of chemicals, industrial sectors, or substances that are not persistent and bioaccumulative, but decided for the present that the priority was to focus on a process and criteria for selecting persistent and toxic substances.

Deliverables The Working Group asked the Task Force to recommend a process for selecting the substances and the criteria to be used within this process. Recommendations on *specific* substances for subsequent development of action plans was not part of the Task Force's mandate.

The Working Group was in general agreement with the Task Force's proposed approach to criteria selection, i.e., to proceed with a multi-stage approach and to have a balance between quantitative and qualitative criteria. The Working Group requested that the more subjective criteria (e.g., socio-economic and political considerations) should be used to assist in the decision-making process with respect to the development of a NARAP or other action, rather than to remove substances from consideration.

The Task Force on Criteria first met on 8 May 1996, using the text of Resolution #95-5 to ascertain the foci for its report to the Working Group. A proposed report format was reviewed on 9 May 1996 at the public session of the Working Group and was subsequently accepted by the Working Group. Following this, face-to-face meetings and conference calls were held to discuss the various drafts of the report, and brief case-studies were commissioned for 'trial' substances as a means of testing and improving the process for identifying additional candidates for action. A stakeholder consultation was held in Mexico City in October 1996 and views expressed by attendees at the meeting and in subsequent written responses were considered by the Task Force. Based on public comments, the Working Group requested that the Task Force convene an expert group on criteria in June 1997 to ensure currency and adequacy of the proposed criteria. The Task Force did this and subjected the

report to an additional, final round of public review. This document reflects the advice received.

3. Review of Existing International and National Initiatives Relating to the Sound Management of Chemicals.

Council Resolution 95-5 acknowledged that considerable interagency, national and international efforts have been directed towards the selection of substances (for bans, phase-outs, use reduction and other risk management options), and stated the intent that the approach to identifying substances should "*coordinate activities with, avoid duplicating the efforts of, and where possible utilize the expertise of existing work groups and other organizations whose efforts are pertinent...*" (page 4, paragraph f) and "*...build upon existing bilateral and multilateral commitments...*" (page 4, paragraph g).

The Task Force identified several national and international initiatives underway that identify chemicals for integrated management. The process and criteria used to select chemicals vary according to the specific mandates of the international agencies or national needs. However, most address persistence, biomagnification /bioaccumulation/ bioavailability, extent to which anthropogenic sources contribute to environmental presence and the risk posed by the substance. The potential for long range transport of a substance is not always included as a criterion.

Four management approaches that were studied by the Task Force are described briefly below[2]. More complete information on three of these initiatives is provided in Appendix I.

3.1 Organization for Economic Cooperation and Development (OECD)

There are a number of initiatives within OECD that address the selection of substances for management action by member countries. The efforts of an *ad hoc* Working Group on Risk Reduction (replaced by a formal Advisory Group on Risk Management reporting to the Chemicals Group and Management Committee under the Environment Policy Committee) address the selection of substances for concerted risk reduction activities. There is a focus on substances: (i) that pose significant risks; (ii) for which there is agreement that opportunities for OECD-wide measures exist; and (iii) for which there is a commitment to act. OECD conditions for joint action include: an internationally-accepted risk assessment (or OECD-approved national assessment) upon which to base risk reduction measures; evidence that an OECD-wide response is mutually advantageous and contributes to risk reduction; and control measures that can be targeted at problems of a shared transboundary or global nature with a focus on risk of exposure.

[2] The Task Force is aware of the conclusion of the Governing Council of the UNEP (4 February 1997) that "...international action including a global legally binding instrument, is required to reduce the risks to human health and the environment arising from the release of the twelve specified persistent organic pollutants." However there is no UNEP process that indicates how substances will be added to the current list of 12 POPs

"Difficult[3]" or sparingly soluble substances, including metals and some metal compounds, have also attracted attention among OECD member countries in the context of initial assessment of high production volume chemicals as well as classification and labeling of chemicals. In 1995, an OECD workshop on aquatic toxicity testing of these substances raised some important issues including how toxicity data should be expressed and interpreted for substances where low solubility and bioavailability are significant. Subsequently, an OECD Metals Working Group was established to develop a protocol for determining the rate and extent of the transformation of these substances to bioavailable forms so that the toxicity test results can be interpreted in a consistent and meaningful fashion. In addressing its mandate, the Working Group is taking account of findings from a number of technical workshops including those listed in Table A appearing in Appendix 1.

An Advisory Group on the Harmonization of Classification and Labeling has been examining the basis for classification decisions relating to substances that are "hazardous to the environment". Endpoints for criteria such as bioaccumulation and toxicity play an important role in the selection of substances for this classification, and are being debated in this forum.

3.2 United Nations Economic Commission for Europe (UNECE)

Under the Convention for Long-Range Transboundary Air Pollution (LRTAP), the UN ECE is preparing legally-binding protocols to control the long-range atmospheric transport of Persistent Organic Pollutants (POPs) and of 'heavy metals'. For the POPs protocol, a 'draft negotiating text' in the proposed protocol (see Appendix 1:UNECE LRTAP 1997, Article 11 and Annex J) deals with the future addition of new substances to the list of existing 'priority substances' in the protocol. Current discussion/decisions about selection criteria will likely be based on considerations of: (a) the potential for long range atmospheric transport of the substance (proposed criteria include vapor pressure <1000 Pa, and an atmospheric half-life of >2 days), OR adequate scientific/monitoring evidence suggesting transport from distant sources; and (b) the potential for significant environmental and/or human health effects (proposed criteria regarding persistence and bioaccumulation under discussion). For the heavy metals protocol, qualitative criteria were employed to develop the initial list of substances (e.g., the volume of emissions of a given substance that is subject to long-range transboundary transport and is expected to contribute significantly to adverse effects on human health and the environment). The Working Group on Strategies has agreed that the protocol will include clear criteria for the addition of other heavy metals, but the criteria have yet to be developed.

3.3 Canadian Toxic Substances Management Policy (TSMP)

The TSMP sets out a science-based management framework for toxic substances of concern with two

[3] The term "difficult" is used by OECD to denote substances, whether organic, inorganic or undefined, that are difficult to test because protocols are unreliable or do not currently exist. In addition to poor solubility, testing problems can include volatility and variability of conditions and concentrations during testing.

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). In most cases, the substances will have been evaluated by risk assessment processes as to whether they are "toxic" under the *Canadian Environmental Protection Act* (CEPA) or assessed under other federal Acts in an equivalent way. There are also provisions in the Policy for incorporating appropriate elements of assessments carried out by other jurisdictions, e.g. provincial/territorial and international organizations.

Substances assessed as "toxic or equivalent" are identified as Track 1 substances if three additional criteria are met: *persistence* (half-life $\geq$ 2 days in air or evidence of long-range transport; $\geq$6 months in water or soil; $\geq$1 year in sediment); *bioaccumulative* (BAF$\geq$ 5000, BCF$\geq$ 5000 or log K_{ow} $\geq$5); and *predominantly anthropogenic*. Toxic substances that do not satisfy all criteria will be addressed under the management objective for Track 2 substances. The Policy recognizes that naturally occurring substances (such as minerals and metals), elements or radio-nuclides are not candidates for virtual elimination (Track 1). 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. A federal Minerals and Metals Policy (MMP) of the Government of Canada builds on the TSMP and recognizes that naturally occurring inorganic substances, such as minerals and metals, behave differently than synthetic organic chemicals in the environment, and, as a consequence, require different risk management approaches. The MMP provides guidance about the risk management approaches considered suitable by Canada for this class of substances.

3.4 Chemical Manufacturers Association - PTB Policy Implementation Guidance

Released in February 1996, this is a guidance document for the CMA member companies which are committed to a goal of reducing the potential human health and environmental risks that may be associated with substances "...that ***p****ersist* in the environment, are ***t****oxic* to humans and/or wildlife and have a strong tendency to ***b****ioaccumulate* in food chains... ('PTBs')" (italics added). The document includes information on a process for characterizing and managing the human health and environmental risks linked with chemical products, their byproducts and with waste materials which contain these PTBs. It incorporates a 'screening evaluation' process as part of the risk characterization, including numerical values for persistence and bioaccumulation but not for toxicity. The values were based on both current criteria which have been used by other organizations for similar purposes and on available scientific data for substances considered to be PTBs. In the process adopted, the issue of a substance's potential for long range transport is considered subsequent to its identification as a PTB.

4. Proposed Principles for Selecting Substances under NAAEC

Substance selection should be based upon the following principles:

- all three countries should benefit in health or environmental terms from development and implementation of NARAPs;
- transboundary environmental movement is a concern;
- concerns about human health or environmental risk are substantiated by scientific evidence;
- application of a precautionary approach to decisions to manage substances in keeping with Principle 15 of the Rio Declaration on Environment and Development;
- to the extent possible, criteria should be consistent with and complementary to ones already developed as part of each country's national or international commitments;
- action should complement and help implement broader regional or international commitments.

Precautionary Principle. Principle 15 of the Rio Declaration (UNCED) states:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

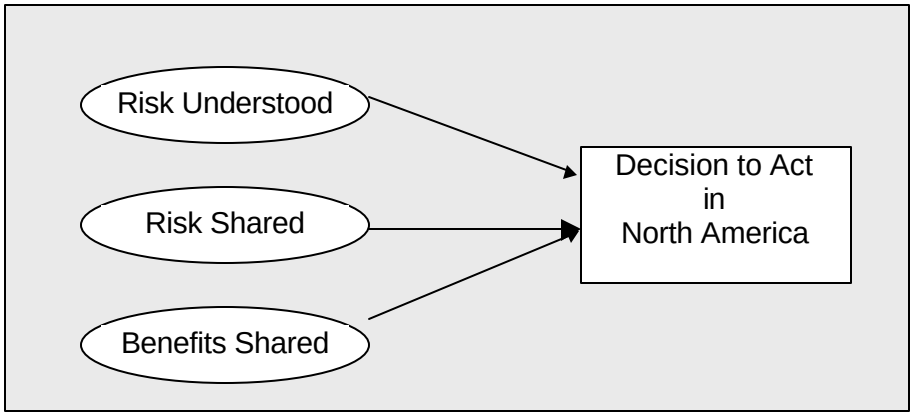
In addition to these principles:

- substance selection should also consider socio-economic factors during the choice of management strategies for action in a manner consistent with health and environmental protection, in support of sustainable development and in keeping with Principle 14 of the Rio Declaration on Environment and Development;
- substance selection should be a transparent process with a reporting system to enable public accountability and with the reasons for selection or rejection made clear;
- substance selection should utilize existing resources of the Parties and make decisions within the North American region in the most effective manner possible;
- substance selection should take account of emerging science and regional needs in the review and development of selection criteria and processes.

Principle 14 of the Rio Declaration (UNCED) states:

"States should effectively cooperate to discourage or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health."

Figure 1: Conceptual Framework for Selecting Substances for Regional Action



The Task Force developed a "conceptual framework" for making decisions on whether to act regionally to manage a toxic substance (Figure 1). There are three elements to be considered in this framework relating to how well the risk is understood, the degree to which the risk is shared in North America and how the benefits are to be accrued and shared by the Parties. The selection process and supporting criteria provide the basis upon which the Parties can judge the elements.

5. Proposed Process for Identifying and Selecting Substances

The process and criteria proposed below have been developed for "persistent, bioaccumulative and toxic substances", as identified in the Task Force's mandate. They draw upon recent international experience in selecting persistent organic pollutants and metals for management. The process and criteria must be applicable for the selection of metals[4] and minerals, and persistent organic pollutants[5], targeting those of greatest concern and with the potential for the greatest benefits from cooperative action. It is understood that expert scientific judgment plays a significant role in acknowledging and addressing the difficulties posed by quantitative criteria for persistence[6] and bioaccumulation, particularly

[4] Wherever the word metals is used in this document within the context of choosing substances for NARAPs, it is intended to include their compounds as well.

[5] Comments were received by the Task Force that, due to the scope of Resolution #95-5, the process should accommodate substances beyond those that are persistent, bioaccumulative and toxic. The Task Force believes that with modifications, the proposed process could be used to identify other toxic substances, classes/clusters of chemicals and industry sectors that may be suitable candidates for regional action. This could enable the Working Group to address more broadly mixtures of substances and waste streams, and, by doing so, more effectively promote sustainable development than by employing the 'one chemical at a time' approach.

[6] Persistence is a measure of a substance's resistance to physical, biological and chemical processes that either degrade the substance, remove it from the media or make it unavailable to organisms. Persistence will increase the duration of exposure of organisms to the substance and may, depending on the frequency and mode of release, increase the exposure concentration. The overall half-life depends on the characteristics of the medium and of degradation/removal processes such as biodegradation, volatilization, sorption, hydrolysis, and chemical complexation. For further discussion of persistence relating to organic substances, see Vallero, D. 1996. Transport,

in relation to naturally occurring substances like metals and minerals. The potential for transformation of some of these substances to complexes or metallic species which are more or less bioavailable, is emerging as an important consideration. Situations where this judgment has a bearing on the selection process are highlighted below.

***Persistence*:** the length of time a substance resides in the environment; commonly measured as half-life ($T_{1/2}$, i.e., the time required for the concentration of a substance to diminish to half of its original value in the environmental medium of interest[6].

Bioavailability: a function of the substance itself (i.e., its properties), and the physical and chemical environment in which it is found; a substance is bioavailable when some of that substance in the surrounding environment can be taken up by an organism; the environment may include water, sediment, suspended particles and food.

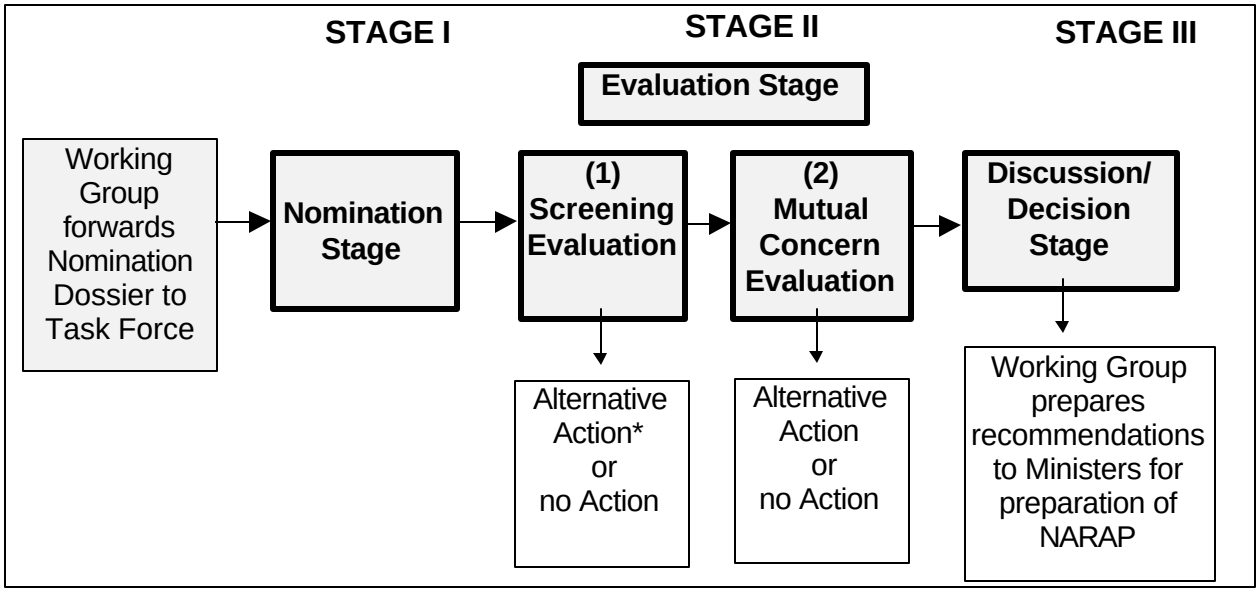
Bioconcentration Factor* (*BCF): a comparison (ratio) of the concentrations observed in biota with respect to concentrations in the water to which it is exposed under steady-state conditions. When the ratio is derived from accumulation through both the medium and the food chain, it is called the *bioaccumulation factor (BAF).*

***Toxicity*:** The nature and extent of the harmful properties of a substance as determined through controlled studies in organisms, isolated tissues, cells or cell components.

A three stage process is proposed for the nomination, evaluation and selection of substances for preparation of NARAPs. Figure 2 and Table 1 illustrate the steps involved. Stage I is the nomination of a substance. Stage II is an 'evaluation stage' consisting of: (1) an initial review of the evidence on entry and movement within the North American environment; and (2) an assessment of the strength of the evidence of harm, transboundary environmental transport, and likelihood of benefits to human health and the environment of North America. Stage III is a subjective examination of socio-economic, health, political, trade and workload equity considerations. The process uses a mixture of qualitative and quantitative considerations and expert judgment.

Transformation and Fate of Endocrine Disruptors: Potential Areas of Exposure Research. In: *Measurement of Toxic and Related Air Pollutants*. VIP-64, US Air and Waste Management Association: 541-552. Persistence can be calculated by source (input) minus rate of degradation for a compound.

Figure 2: Stages in the Selection of Substances for Regional Action



*'Alternative action' although not limited to this, might entail recommendations for acquisition of more information, or taking action in another forum.

Fundamental to this process is the formation by the Working Group of a "Substance Selection Task Force" (SSTF). The SSTF would be responsible for carrying out the three stage review process for substances provided by the Working Group. The SSTF would require 9 to 12 permanent members drawn from the parties with relevant expertise in risk assessment and risk management, and in biological, chemical, and physical characterization of persistent toxic substances. Due to the complexity and variability of possible candidate substances, the SSTF should be augmented from time to time by expertise as designated by the Working Group. This expertise could come from any sector of society where relevant experts are available to provide balanced information.

Table 1: Process for Selection of Nominated Substances for Action

	Nomination Stage I	Evaluation Stage II		Discussion and Decision Stage III
Process	*Nomination* •Party sponsor •Dossier (See Appendix II for guidance on dossier and example)	(1) *Screening Evaluation* • Substance Selection Task Force reviews 4 guidance criteria as a whole. • Screening approach is for persistent, bioaccumulative and toxic substances.	(2) *Mutual Concern Evaluation* • Substance Selection Task Force reviews 3 criteria.	*Draft Decision Document* • Substance Selection Task Force prepares decision document.
Elements (Rationale for regional concern/ benefit) & Guidance values	*Nomination Dossier* • identity / description • sources • presence in environment, biota and humans • levels • transport / environmental fate • toxicity • risk management experience • conclusions / references	(i) 'may enter', 'is entering' or 'has entered' North American ecosystem (emissions, media, biota) AND (ii) available and acceptable risk assessment(s) AND (iii) judgment on measured/predictive data on the following for: (a) POPs- *bioaccumulation* (Preferably field-generated BAF≥ 5000, or BCF≥5000 or Log K_{ow} ≥5) AND *persistence* (Half lives ≥2 days (air), or ≥6 months (water), or ≥1 year (sediments) or ≥6 months (soil)); AND *bioavailable* (expert judgment) (b) Metals and minerals/ naturally occurring substances- *bioaccumulation* (expert judgment) and *bioavailable* (expert judgment); AND (iv) Monitoring evidence of transboundary environment transport for metals or POPs (e.g., appearance in biota) OR indirect evidence of transport potential (e.g., air persistence ≥2 days, and volatility ≤1000 Pa for POPs). Expert scientific judgment is essential in the evaluation of criteria.	*Mutual concern* measured by extent of: (i) hazard/risk (relative) AND (ii) nature and extent of evidence of transboundary environmental transport in North America AND (iii) mutual/demonstrable benefits of action.	Paper to be based on science, emphasizing transboundary nature of problem/feasibility of developing and implementing an action plan. *Considerations:* (i) public health measures available to reduce risk (ii) benefits to public health of the reduced availability or elimination of a substance (e.g. for vector control agents) (iii) sustainability of food production (iv) feasibility and availability of alternatives (v) societal capacity for change (vi) implications/opportunities for the economy and trade (vii) costs and benefits of control measures (viii) national capacity to take action; expertise, technology, financing (ix) jurisdictional and regulatory opportunities for change (x) international commitments and obligations.
Decisions Consequences	• Nomination "stands" and referred to STAGE II evaluation • Commitment to provide existing monitoring data, estimates of exposure, existing risk assessments, • Sponsoring country(ies) review and supply data /info. • Regional reporting.	• Advance to Mutual Concern Evaluation • Commitment to provide sources, fate and environmental/biota levels • Other action required if substance fails screening evaluation.	• Preparation of discussion paper • Substance listed as a candidate • Commitment to supply professional resources to complete data gathering for evaluation and implementation considerations.	• Task Force assesses need and certainty • Working Group consideration • Working Group accepts/rejects Task Force response • Working Group recommends substance for NARAP or other action. Consequence may be broadened knowledge base for recommended substances.

Table 2: Tracking Substance Nominations through the Selection Process

Substance	Nominating/ Sponsoring Country	Date	Response Nomination Stage		Response Evaluation Stage		Discussion and Decision Stage	
			Decision	Reasons	Decision	Reasons	Decision	Reasons
Substance X	Canada	1 Jan. 1997	A	Meets criteria requirements	R	Reasons are as follow: - - -	R	

A = Accepted
R = Rejected
M = More information required

5.1 Stage I: Nomination of a Substance for Possible Tripartite Action

Substances would be nominated by any of the "Parties" (Canada, Mexico and the United States) through the North American Working Group for the Sound Management of Chemicals (Working Group). To promote openness and consistency in the review of all nominated substances, the nominating Party should provide information in a complete and concise "Nomination Dossier" comprising 5–10 pages of text with key references, following the format indicated in Appendix II.

Groups other than the Parties may also wish to suggest substances to be considered by the Working Group. These suggestions would need to be incorporated into a Nomination Dossier submitted by any of the Parties to the Working Group.

Substance: Throughout this report, the term 'substance' should be interpreted in its broadest sense. The Task Force recommends that nominations should be clear about the identity of the substance and the forms it can take in the environment that are important in understanding the risks posed.

The three Parties, through their representatives on the Working Group, would need to accept a substance nomination. Once a Nomination Dossier is accepted by the Working Group, the name of the substance would be identified as a *"Nominated Substance for the North American Agreement on Environmental Cooperation Sound Management of Chemicals Review Process."* It would be included in Table 2 (Tracking Substance Nominations through the Selection Process), together with the name of the nominating Party and date of submission. The Working Group would then refer the nomination to the Substance Selection Task Force (SSTF) for action. At this stage, the SSTF shall assess the Nomination Dossier to determine whether or not it contains adequate basic information for the evaluation process. Additional information would be requested for an incomplete Dossier. Once the Dossier is complete, the SSTF would inform the Working Group that it is proceeding to Stage II of the process.

5.2 Stage II (1) Screening Evaluation Step

The intent of screening is to initiate the evaluation process for substances that have been accepted as Nominated Substances. It investigates whether the substance addresses four basic requirements that justify the initiation of a detailed Stage II (2) assessment. The screening focuses on confirming: that the substance has entered (or could enter) the North American ecosystem; that there is agreement by the Parties that the substance has been sufficiently assessed for its environmental or human health risk; that if present in the environment it is in a form that is judged to be sufficiently persistent, bioavailable and bioaccumulative; and that there are data indicating that the substance is transported (or transportable) environmentally within North America. Although there may be uncertainty related to available data in any of these areas, the decision of the SSTF to proceed to a Stage II (2) evaluation will be influenced by the precautionary principle where the nature of the threat is serious and irreversible.
In addressing the four requirements identified above, the Screening Evaluation considers:

i. availability of valid monitoring or predictive data pertaining to emissions, effluents or levels in environmental media or biota confirming that the substance *may enter, is entering or has entered* the North American ecosystem as a result of human activity; AND

ii. availability of a comprehensive, scientifically-sound risk assessment document that characterizes risks to the environment or human health and that has national or international acceptance; AND

iii. adequate measured or predictive data relating to the persistence, bioavailability and bioaccumulation tendencies of the substance; AND

Application of numerical criteria: The Task Force intends that numerical criteria for persistence, bioconcentration/bioaccumulation and volatility be used to "guide" the evaluation. Expert judgment should play a significant role in determining whether screening elements iii and iv are met and the reasons why (see Table 1).

iv. adequate indirect evidence of transboundary environmental transport such as persistence in biota/media and volatility, or the availability of direct monitoring evidence of transboundary environmental transport.

Screening elements iii and iv include quantitative criteria intended to identify those substances that are persistent and bioaccumulative, and that can undergo transboundary environmental transport. Prior to the deliberations of the Task Force, a number of initiatives referenced in Section 3.0 had already studied and chosen quantitative criteria for purposes similar to the mandate of the Task Force (i.e., identifying substances for management action or for determining the most appropriate management objective).

The quantitative criteria adopted by the Task Force are to be used for guidance in evaluating whether the information available on a toxic substance justifies continuing to the next phase of Stage II. Expert scientific judgment is essential in the evaluation of the screening elements. Where such expert judgment differs from the direct application of the quantitative criteria, then an explanation should be provided. For naturally-occurring substances such as metals and minerals, the Task Force understands that the direct application of the persistence and bioaccumulation criteria proves very difficult. Efforts aimed at clarifying metal classification and the application of criteria-setting for metals are described in Table A of Appendix I. Organo-metals can behave like other persistent organic pollutants in their metallic form and, as certain compounds, metals tend to be infinitely persistent though not necessarily in a form that is bioavailable. In some cases, they naturally bioaccumulate for beneficial purposes in organisms (i.e., essential elements).

If all of the preceding screening elements are met then the SSTF would recommend to the Working Group that the nominated substance proceed to Stage II (2): Mutual Concern Evaluation. This implies a commitment from the Parties to provide available information needed for the next stage, including summaries of data characterizing entry of the substance into the environment (e.g., sources, environmental concentrations).

If not all of the four screening elements are met then the SSTF would recommend to the Working Group that the substance is not a suitable candidate for regional action at this time. A consequence of this recommendation may be that the Parties agree to acquire additional information so that the substance can be reconsidered when there is a more complete database. Alternatively, the parties may consider taking action under other fora or national programs more appropriate for control of the nominated substance.

5.3 Stage II (2) Evaluation of Mutual Concern Step

The intent of the evaluation of 'mutual concern' is to develop a rationale for supporting the selection of a substance as a candidate for regional action. The rationale focuses on the nature and extent or the degree of the problem posed by the nominated substances, and on demonstrating that there is value-added by addressing the substance on a regional basis.

The Stage II Mutual Concern Evaluation involves consideration of the following three elements and the degree to which all the Parties share concern:

i) nature and extent of *risk to human health or the environment* in North America; AND

ii) nature and extent of the evidence of *transboundary environmental transport* in North America; AND

iii) degree to which human health or environmental *benefits in North America can be demonstrated* as a result of collective action.

Defining risk and its assessment:
For the purposes of this document, the term "Risk" as applied to the environment and human health includes the concept of actual or potential biological exposure and injury, as well as the reasonable potential for each of these to occur under various climatic, social and demographic conditions present in North America. The assessment of risk is conducted relatively consistently in North America, relying on qualitative and, where possible, quantitative methods. The assessment is based on good science, and placed within the context of the precautionary principle as defined by UNCED (see page 7). The Task Force recognizes that there is a value in both qualitative and quantitative methods for determining risks.

The SSTF would document the outcome of the screening and evaluation of the nominated substances and describe the weight of evidence of shared concern and mutual benefit to the region of action. It would recommend to the Working Group that either:

- the substance be identified as a *candidate for regional action*. This implies a commitment from the Parties to contribute to the preparation of a Draft Decision Document by the SSTF for consideration by the Working Group; OR

- the substance is not a suitable *candidate for regional action* at this time. A consequence may be that the Parties agree to develop additional information so that the substance can be reconsidered, or that the substance be considered for action in other fora or national programs more appropriate for its control.

5.4 Stage III: Discussion and Decision

A substance which emerges as a *candidate for regional action* during the Evaluation Stage would, at the decision of the Working Group, become the subject of a Draft Decision Document. This stage is intended to explore a range of considerations that influence the priority and timing for developing and implementing a regional action plan. The SSTF may need to avail itself of additional technical expertise to address the range of considerations listed below.

The Draft Decision Document would include the following components: the original "Nomination Dossier" from the Nomination Stage; a review of the results of the Screening and Mutual Concern Evaluation process; an analysis of major implementation considerations; and a summary evaluation (see Table 3) reviewing and concisely presenting the findings of the analysis of the evaluation stage and implementation considerations.

The Stage III Draft Decision Document would also address the following implementation considerations:

i) public health or environmental measures available to reduce risk;
ii) benefits to human health or the environment of the reduced availability or elimination of a substance (e.g., for vector control agents);
iii) sustainability of food production;
iv) feasibility and availability of alternatives;
v) societal capacity for change;
vi) implications for the economy and trade;
vii) costs and benefits of control measures;
viii) national capacity to take action (e.g., expertise, technology, financing);
ix) jurisdictional and regulatory opportunities for change; and
x) international commitments and obligations.

Table 3. Basis of Evaluations for each Nominated Substance by Stage

Nomination Stage		**Evaluation Stage**				**Draft Decision Document Stage**	
		Screening evaluation		*Mutual concern evaluation*		*Implementation considerations*	
Substance	Completeness of dossier		Yes/ No		Relative Weight*		Relative Weight*
		(i) Environment entry		(i) Nature and extent of risk		(i) Human health or environmental measures available to reduce risk; (ii) Benefits to human health (Public, Occupational) or the environment from the reduced availability/ elimination of a substance (e.g., for vector control agents). (iii) Sustainability of food production (iv) Feasibility and availability of alternative substances (v) Societal capacity for change (vi) Implications/opportunities for trade and the economy (vii) Costs and benefits of control measures (viii) National capacity to take action: ·Expertise ·Technology ·Financing (ix) Jurisdictional and regulatory opportunities for change (x) International commitments and obligations	
		(ii) Risk assessment					
		(iii) Bioaccumulation, bioavailability and persistence					
		(iv) Transboundary movement		(ii) Evidence of transboundary environmental transport			
				(iii) Human health and environmental benefits			

* low, medium, high

The Draft Decision Document would assess the significance of the implementation considerations according to: (1) whether they present opportunities or barriers for a regional action plan, and (2) the extent to which any barriers are likely to limit prospects for a regional action plan (e.g., greater costs than benefits or incomplete information on an alternative substance). The Draft Decision Document would include recommendations to the Working Group that either:

- a North American Regional Action Plan (NARAP) be developed for the substance, which implies that the Parties establish a NARAP Task Force for the preparation of an action plan; OR
- the candidate substance not be the subject of a North American Regional Action Plan (NARAP) at this time. The Parties may agree to reconsider this decision when more information, e.g. relating to costs or benefits or alternatives, is available. As indicated in Table 1, 'other action' may also be recommended, for example in relation to rectifying gaps in information.

It is anticipated that the Draft Decision Document could be useful for other purposes in addition to decision making by the Working Group, including: developing national action plans; providing guidance for countries outside the region; and establishing benchmark information on the candidate substance for various purposes.

6. Public Participation

Public participation is an important component of the selection process for candidate substances for regional action and for the development and implementation of North American Regional Action Plans.

This process creates several opportunities for such participation:

- through the CEC Website;
- through open Working Group sessions;
- through the public release of Council documents;
- through formal consultations at certain points in the selection/evaluation process (see below).

The Nomination Dossier should be available for public comment at the time of nomination. Comments received from stakeholders on the adequacy of the Nomination Dossier should be considered by the SSTF in their recommendations to the Working Group.

The conclusions of the SSTF at the end of the evaluation Stage II should also be made available for public comment.

The Draft Decision Document should be released to the public at least six weeks prior to its being considered by the Working Group, and the public should be formally requested (e.g., by Secretariat notice and posting on the CEC Website) to comment on the document and the recommended course of action. Written and oral comments should be considered by the Working Group, along with the analysis appearing

in the document, when determining whether to recommend to the Council of the Commission for Environmental Cooperation that development of a NARAP be initiated.

The decisions on approval or rejection of all nominated substances at different stages of the selection process should be publicly reported. This reporting could take the form of an updated Table 3 which might be communicated in conjunction with regular meetings of the Council of the Commission for Environmental Cooperation and/or through issues of *Eco Region,* the newsletter prepared by the Secretariat of the Commission, and the CEC Website.

7. Recommendations

It is recommended that the Working Group:

1. adopt the proposed three-stage process and the criteria included for the identification of candidate substances for North American Regional Action Plans and evaluate the effectiveness of the process within two years, or after five substance reviews;

2. establish a *Substance Selection Task Force* (SSTF) of 9-12 members from the Parties for each nominated substance and complemented with relevant expertise from other societal sectors, as required, to evaluate nominated substances;[*]

3. provide full and public tracking of the nomination and review process and not less than six weeks for stakeholder review of the Draft Decision Document; and

4. consider revising this process at a later date to address consideration of toxic substances that are not persistent and bioaccumulative, and to better address the selection of classes/clusters or substances associated with particular industry sectors for North American Regional Action Plan development.

[*] Subsequently modified by the Working Group on 10 December 1997 to include two members from each of the Parties and three observers from the academic and industrial communities and environmental nongovernmental organizations. The SSTF representatives would review all nomination dossiers submitted.

Acknowledgments

A large number of individuals assisted the Criteria Task Force in its work and especially during the stakeholder consultation meetings and the Expert Workshop. The Criteria Task Force wishes to thank all of those individuals from governmental departments and agencies, the industrial sector, national and international NGOs as well as members of the general public for their careful consideration of the material in this report. Although it is not possible to include all names, Appendix III lists those to whom particular thanks are expressed.

Appendices

Appendix I: Summaries of Selected National and International Initiatives

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REGION/COUNTRY: Countries of the Organization for Economic Cooperation and Development (OECD)

PROGRAM: **Risk Reduction**

CONTACT NAME: Rob Visser, Paris

Background

- initiated in 1990 under the OECD Council Act on Co-operative Investigation and Risk Reduction of Existing Chemicals in order to promote concerted activities by member countries to reduce the risks of selected chemicals, where appropriate
- began with five pilot substances chosen on the basis of known risks and available documentation
- workshop in Sweden in 1992 addressed criteria for selection and concluded that "at least 2 OECD member countries be in agreement on the need for co-operative risk reduction activities"
- 1994 survey suggested a need to redefine the program's objectives, guiding principles, criteria for selection of candidates for concerted measures, and to broaden scope for cooperative activities.
- ad hoc Working Group met 6-8 November 1995 in Rome to develop proposals for new directions and will meet again in September 1996 to finalize these proposals.

Summary of Objectives

- to promote co-operative efforts to assist national programs to reduce risk of exposure.
- to promote co-operative efforts to reduce risks associated with exposures to specific substances, clusters of substances and/or products or applications.
- to promote concerted OECD efforts to reduce risks posed by substances.
- to influence international chemicals management activities.

Summary of Principles

Rationale for Concerted Risk Reduction Measures

- It is based on a sound assessment of the immediate and longer term risks.
- Clear environmental and/or public health goals should be articulated.
- Options for risk reduction should be considered.

Priorities

- Transparent processes and criteria should be established.

Criteria Included

Candidates should be chosen because:

- they pose significant risks,
- they offer opportunities for OECD-wide measures,
- there is a commitment to act, and
- they meet the following criteria:
  - an agreed risk assessment exists for the substance,
  - an OECD-wide response is mutually advantageous and contributes significantly to risk reduction,
  - *related* action is targeted at problems of a shared, transboundary or global nature and focus on risk of exposure.

Substances Selected

- pilot projects with cadmium, lead, mercury, brominated flame retardants and methylene chloride.

Comments

- intended use is the same as that requested by the Sound Management of Chemicals Initiative under NAFTA/CEC
- qualitative criteria relate more to “thought processes” behind decision making
- subjectivity remains high
- Canada, Mexico and United States are present at discussions of proposals which could facilitate

applicability in NAAEC context

- process is not driven since countries are not accountable for proposals in a specified time-frame

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References

Environment Directorate, 24th Joint Meeting Chemicals Group and Management Committee. December 1995. *Possible Future Work on Risk Reduction*, ENV/MC/CHEM(96)9 [Restricted].

Table A. Synopsis of Recent Meetings on Metal Classification

Workshop/ Meeting	Date, Place	Sponsors	Outcome(s)
OECD Workshop on Aquatic Toxicity Testing of Sparingly Soluble Metals, Inorganic Metal Compounds and Minerals	Ottawa, 5-8 Sept. 1995	Canada, OECD	1) Bioavailability is the key parameter in hazard identification of sparingly soluble metals and inorganic metal compounds. 2) If acute toxicity is not observed, long-term dissolution characteristics and chronic toxicity data may be considered. 3) The OECD should initiate work to develop a dissolution protocol for obtaining the soluble (bioavailable) fraction of a sparingly soluble inorganic metal compound relevant to assessing aquatic toxicity. 4) The OECD should establish a working group to resolve the issue of aquatic toxicity data interpretation for hazard identification.
Technical Workshop, Biodegradation/-Persistence and Bioaccumulation/-Biomagnification of Metals and Metal Compounds	Brussels, 11-13 Dec. 1995	Canada, EU	1) Biodegradation/persistence is unsuitable as a hazard identification criterion for metals and inorganic metal compounds and should not be used. 2) Bioaccumulation factors and bioconcentration factors (BAFs and BCFs) are not valid for hazard identification but may be useful in risk assessment on an individual metal-specific and organism-specific basis. 3) Biomagnification is also unsuitable as a criterion for metals and inorganic metal compounds. 4) Octanol/water partitioning is not an appropriate predictor of the bioaccumulation potential for metals; 5) Measurement techniques to quantify the extent of “degradation” and “transformation” (including dissolution), as well as “removal” characteristics (e.g., precipitation, oxidation/reduction) should be further developed.

Workshop/ Meeting	**Date, Place**	**Sponsors**	**Outcome**
Meeting, *ad hoc* Expert Working Group on Harmonization of Classification Systems for Substances Dangerous to the Aquatic Environment	Washington, 24-26 April 1996	OECD	For metals and inorganic metal compounds, further development (Guidance) is required in the areas of: 1) bioavailability in toxicity testing (transformations); 2) chronic toxicity data when available can be used in classification, since the combination of acute toxicity, persistence and bioaccumulation testing is a surrogate for chronic effects; 3) precipitation/sedimentation data (i.e., removal processes). Also the Washington W/G committed to a scheme "sufficiently transparent to allow for self-classification rather than classification by an expert committee."
Meeting, Metals Working Group	Paris, 18-19 June 1996	OECD	1) A transformation protocol is required for metals and sparingly soluble inorganic metal compounds. 2) Canada will develop a work plan to include areas needing investigation, for review by the MWG and further action, and will coordinate and participate in an international research effort on a dissolution/transformation protocol to determine the fraction of the metal which is bioavailable.
Workshop, Environmental Risk Assessment	Angers, 13-15 Nov. 1996	ICME	1) Risk assessments for metals and inorganic metal compounds should take into account their natural occurrence, pathways, essentiality, speciation, transformations to the bioavailable form, homeostasis, and bio-geochemical cycles. 2) Regulatory agencies involved in risk assessments for metals and inorganic metal compounds need guidance on the needed improvements to risk assessment methodologies and estimates as to when these will be available.

REGION/COUNTRY: Europe, Russia, Canada and the United States

PROGRAM: **UN-ECE LRTAP Draft Protocols on Persistent Organic Pollutants and on Metals under the UN-ECE Convention**

CONTACT NAME: Lars Björkbon (Chair, UN-ECE Working Group on Strategies)
Swedish Environmental Protection Agency.

Background

- At the November 1994 meeting of the Executive Body to the LRTAP Convention of the UN Economic Council for Europe (UN-ECE) it was agreed to instruct Working Groups (Preparatory Working Groups) to prepare draft texts for protocols on persistent organic pollutants and on metals.

- At the November 1995 meeting of the Executive Body, the Working Group on Strategies was given the mandate to begin negotiations on Protocols on POPs and on heavy metals. The draft protocols ("Offenbach drafts") formed the basis of further work to develop comprehensive negotiating texts in preparation for holding substantive negotiations at the August 1996 meeting of the Working Group on Strategies.

- The exact make-up of the list of persistent organic pollutants and metals is still under discussion and drafts of main text and the various articles are still in preparation, with allocated tasks going to different countries.

- The Working Group on Strategies began negotiations of the POPs Protocol in January 1997. Negotiations are expected to be completed by early 1998.

Summary of Objectives

- To take action to control the long-range transboundary transport of substances which pose a significant risk to human health or the environment.

- To apply a sound management of chemicals approach by focusing initially on a short list of persistent organic pollutants and metals for a range of voluntary commitments and legally binding actions.

- To decide on the process for selecting additional substances for control.

- To curb the use of products containing POPs (e.g., elimination of use except for specified applications) and the unintentional release of POP-containing by-products; the implementation of best available technologies and management practices. Also, to reduce transboundary atmospheric emissions of certain heavy metals which adversely impact ecosystems that are long distances from the sources of the metal emissions.

Summary of Principles

- Address problems associated with emissions of chemicals shown to contribute to overall adverse effects resulting from long-range transboundary air pollution

- Adopt a range of actions, both legally binding and voluntary measures/commitments, to control and reduce anthropogenic sources of POPs and certain metals entering the environment and subject to transboundary atmospheric transport.

Criteria Included

The ad hoc Preparatory Working Group on POPs prepared a draft composite negotiating text which is now being used by the Working Group on Substances in its negotiations. In the current draft, Article 11 'Amendments' and Annex J adds details regarding amendments to dealing with the addition of substances.
Evaluation of a substance for inclusion in the protocol is to be based on:

- potential for long-range transboundary transport, based on atmospheric half-life of >2 days and vapor pressure < 1000Pa or evidence (monitoring or equivalent scientific/technical) that suggests transport from distant sources;

- its persistence and bioaccumulation potential for significant environmental and/or human health effects as a result of long-range transboundary transport based on an internationally acceptable risk profile;

- such documentation that includes all available and relevant evidence relating to transport through the atmosphere, exposure, persistence, bioaccumulation and potential effects;

- consideration of socio-economic, technical or other matters related to the recommendations.

Similarly, a composite negotiating text has also been prepared by the ad hoc Preparatory Working Group on Heavy Metals. At present, the definition of "heavy metal" is under negotiation as "heavy

metal" is not a scientific term with a universally recognized definition. Furthermore, the criteria for selecting additional heavy metals for inclusion within the scope of the protocol is a subject of debate.

Substances Selected

Pending a final decision on which POPs to include in the initial Protocol, management options are being considered for up to 18 POPs:

> *POPs protocol*: Aldrin, Chlordane, Dieldrin, Dioxins and Furans, DDT, Endrin, Hexabromodiphenyl, Hexachlorobenzene, Lindane/HCH, Mirex, PAHs, PCBs, Pentachlorophenol, short chain chlorinated paraffins, Toxaphene, Chlordecane and Heptachlor.
> *Metals protocol*: lead, cadmium, mercury.

Comments

- These protocols will be legally-binding instruments.
- Differences (*vis-à-vis* Western Europe and continental America) in the concept of "long-range" atmospheric transport have been addressed.
- A range of voluntary actions as well as obligatory commitments are to be incorporated into the protocols.
- A process for adding other POPs to the protocol in the future is being prepared.

References

UN ECE LRTAP 1997. Executive Body for the Convention on Long-Range Transboundary Air Pollution -Working Group on Strategies. 2: Report of the 21st Session (Geneva, June 1997).
UK Department of the Environment 1995. *'Selection Criteria for Prioritizing Persistent Organic Pollutants'* AEA/CS/RCEC 16419225.

UK Department of the Environment 1995. *Proposed Procedure for Incorporating New Substances into the UNECE Protocol on Long Range Atmospheric Transport of Persistent Organic Pollutants.* AEA/RCEC/16419225/2 (Issue 4).

ICF KAISER INTERNATIONAL 1996. (DRAFT) Review of UN ECE *Selection Criteria for Persistent Organic Pollutants (POPs).*

REGION/COUNTRY: Canada

PROGRAM: **Toxic Substances Management Policy (TSMP)**

CONTACT NAME: John Buccini, Environment Canada, Ottawa

Background

- Following adoption by the Canadian federal Cabinet, the policy was released in June 1995.
- The policy provides a framework for federal programs and initiatives dealing with the management of toxic substances.
- It also forms the basis for federal positions on toxic substances with provincial and territorial governments and with the international community where problems are of a transboundary nature.
- The policy provides 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).

Summary of Objectives

- provide direction for making risk management decisions about toxic substances and substances of concern
- ensure that federal programs and initiatives are consistent in their approach to dealing with toxic substances
- provide a sound basis for dealing with provinces and other countries on toxic substances having a transboundary nature

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Summary of Principles

- adopt a preventative and precautionary approach to identifying and dealing with substances that enter the environment
- actions to implement the policy must be timely
- ensure public participation, openness and transparency in decision-making
- domestic actions have to be complemented by international measures
- decisions must be made on the basis of science
- while the management objective for Track 1 substances is pre-determined (virtual elimination from the environment), socio-economic factors are considered when establishing management targets and time-lines for implementation
- the responsibility is on those who generate or use a Track 1 substance to demonstrate that the release of the substance is virtually eliminated
- the objective of virtual elimination from the environment does not mean chasing down that substance to the last molecule

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Criteria Included

- the policy identifies four criteria to identify substances to be virtually eliminated from the environment under the policy's Track 1:
    - persistent: half-lives $\geq$ 2 days in air, $\geq$ 6 months in water, $\geq$ 1 year in sediment, $\geq$ 6 months in soil, or evidence of long-range atmospheric transport
    - bioaccumulative: BAF $\geq$ 5000 or BCF $\geq$ 5000 or log $K_{ow} \geq 5$
    - predominately anthropogenic: concentration in environment largely resulting from human activity
    - CEPA-toxic or equivalent: "toxic" as defined in the *Canadian Environmental Protection Act* (CEPA), as determined through an assessment under CEPA or through a similar assessment

Toxic substances that do not satisfy all criteria will be addressed under the management objective for Track 2 substances. The Policy recognizes that naturally-occurring substances (such as minerals and metals), elements or radio-nuclides are not candidates for virtual elimination (Track 1).

Substances Selected

- substances likely to be proposed as the first candidates for management under the policy's Track 1 include:

    aldrin, chlordane, chlorinated paraffins (short-chain), DDT (+DDD, DDE), dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, PCBs, polychlorinated dibenzodioxins, polychlorinated dibenzofurans, toxaphene

Comments

- Since many of the Track 1 substances enter the Canadian environment from foreign sources, the federal government is committed to engaging international partners in the management of these substances.

- A federal Minerals and Metals Policy (MMP) builds on the TSMP and recognizes that naturally occurring inorganic substances, such as minerals and metals, behave differently than synthetic organic chemicals in the environment, and, as a consequence, require different risk management approaches. The MMP provides guidance about the risk management approaches considered suitable by Canada for this class of substances.

References

Government of Canada, Environment Canada. June 1995. *Toxic Substances Management Policy*, ISBN 0-662-61860-2.

Government of Canada, Environment Canada. June 1995. *Toxic Substances Management Policy: Persistence and Bioaccumulation Criteria*, ISBN 0-662-23524-X.

Government of Canada, Natural Resources Canada. November 1996. *The Minerals and Metals Policy of the Government of Canada: Partnerships for Sustainable Development*, ISBN 0-662-25154-7.

Appendix II: Guidelines on the preparation of a nomination dossier for proposing a substance for review under the NAAEC Sound Management of Chemicals Initiative

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Purpose

In the interest of full participation by stakeholders in nominating substances for possible measures under Regional Action Plans, it is intended that this dossier will provide the necessary rationale and background information regarding the candidate substance so that the Substance Selection Task Force can properly consider the relative importance of the substance and can make appropriate recommendations to the Working Group.

Contents of Dossier

The Nomination Dossier (maximum 10 pages plus references and appendices) will address the following items:

- Identity/CAS #/Description; Sources; Presence (environment/biota/humans); Transport/Environmental Fate; Toxicity; Risk Management Experience; Conclusions; References. [*A sample text is included below each title*]

Identity, CAS number(s) and Description - A description of the substance, its physical and chemical properties, its CAS number(s) and its main origin or process(es) leading to its formation.

Example: "Chemical X (CAS Number 123456) is a highly persistent oily liquid with a molecular weight of ...., vapor pressure of..... and a K_{oc} of ..... Its Henry's Law constant is .....; Its fugacity within the context of known media exchanges and concentrations is ..... and rate constants for photo-oxidation, hydrolysis are ..... It is a by-product of ..... Chemical X is also sold as a pesticide ...."

Sources - A qualitative summary of past and current sources and releases, when available.

Example: "The major North American sources are ... From 1950 to 1975, the feedstock of incinerators ... Approximately 10,000 metric tones are released from MWIs annually, 98% to the air, and the remainder in solid waste residuals (Ekenfelter, 1995). Another process where Chemical X is produced is in the manufacturing of soap and detergents (500 metric tons annually). Presently, the principal sources... (See Table 1)".

Presence in the Environment - Present levels and trends, the media in which the substance has been found and the fluxes between the different media. Where monitoring data are available from remote locations (e.g., the Arctic), these should be reported.

Example: Levels and Trends: The amount of Chemical X in the atmosphere, soil, surface water, ground water, and sediment has steadily increased since 1945 (See Figure 2) ...

Presence in Biota - Levels and trends, and the extent to which the substance has appeared/ accumulated/bioconcentrated in biota (plants and animals including wildlife, etc.) Known affinity for particular tissues/organs, where,when and under what conditions levels were highest/ lowest. Reporting of monitoring data available from remote locations.

Example: The amount of Chemical X in wildlife has steadily increased since 1945 (See Figure 3) .... fish, ... ducks, ... marine mammals, ... terrestrial animals.

Presence in Human Populations - Information on affinity for human tissues, monitoring data on human populations, what exposure pathways may be important (e.g., in specific sub-populations with certain lifestyles/eating habits/occupations), trends over time and in various regions.

Example: "Chemical X has an affinity for the liver and kidney, ... its high lipophilicity indicates that dermal exposure is also a probable pathway (See Table 8) ..... Levels in human tissues are ..... and have increased over time ....."

Transport and Environmental Fate - Information on how the chemical and physical properties of the substance are linked to its movement between environmental compartments (air/water/soil/biota) and its likely sink. Process(es) which (may) facilitate long-range (regional) transport of the substance. If major breakdown products are toxic and of concern, information on their fate and movement should be included.

Example: "The physical and chemical properties (as shown in Table 11), indicate that Chemical X has a high affinity for sediment and soil, but in an oxidized environment moves readily to the air (Smith et al, 1995).... Laboratory studies have shown Chemical X to be transformed to various ionic forms at pH≤ 4.0 (Hardy, 1994). Field experiments (Davis, 1995., Daemonic, 1996., and Crista, 1996) indicate that 85% of Chemical X is found in a soil complex, therefore, ...

Long-range atmospheric movement is by ..."

Toxicity - Existing evidence of the substance's acute and chronic toxicity and possible target tissues/systems, effect and no-effect levels.

Example: "The acute toxicity of the various forms of Chemical X is shown in Table 12... Chronic toxicity endpoints include liver cancer (Smith....), neural tube disorders (.....). NOAELs have been reported at ..... (Smith.....)."

Risk Management Experience - Examples of individual countries or regional jurisdictions taking action (or planning management options) to control/limit release of, or exposure to the substance.

Example: "Mexico has successfully reduced workplace exposure to Chemical X by...."

Conclusions - Summing up of all the evidence and statement as to why North American regional action is the appropriate option for the substance

Example: "Chemical X toxicity and the likelihood of continuing human and wildlife exposures throughout North America warrants serious consideration for regional actions. Among these,...".

References - Provide full references for literature/reports/articles cited. Actual copies of documents should be appended if these are not in the public domain.

Appendix III: Acknowledgments

The Task Force on Criteria would like to thank those individuals who contributed to the formulation of this document through the submission of written or oral comments. Many of the suggestions, along with those from various stakeholders from the three countries (governmental, non-governmental agencies and the business sector) have been incorporated into the text.

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