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Chemicals Evaluation Division
Commercial Chemicals Evaluation Branch
Environment Canada

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Administrative Policy and Process for Conducting Environmental Risk Assessments for Priority Substances

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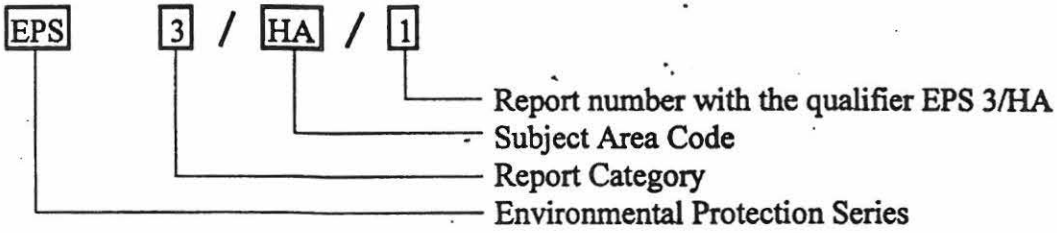

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Readers' Comments

Comments on this publication may be addressed to:

Tanis Lugsdin
Chemicals Evaluation Division
Commercial Chemicals Evaluation Branch
Environment Canada
Hull, Quebec
K1A 0H3

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Abstract

The *Canadian Environmental Protection Act* (CEPA) provides the legal tool for addressing toxic substances in the environment. One of the initiatives under CEPA is the Priority Substances Assessment Program (PSAP). Under this program, federal Ministers are instructed to develop a list of substances that should be given priority for assessment to determine whether they are "toxic" as defined under Section 11 of the Act. Substances that are declared "toxic" move into the risk management phase.

The following document provides guidance to those actively involved or interested in the conduct of environmental risk assessments of substances on the Second Priority Substances List. It sets out the principles and policies adopted by Environment Canada for environmental risk assessments of priority substances. It then outlines the process for conducting assessments, beginning with the definition of responsibilities for those involved in the process and ending with the publication of a Supporting Document, Assessment Report, and *Canada Gazette* Notice.

Résumé

La *Loi canadienne sur la protection de l'environnement (LCPE)* constitue l'instrument juridique à invoquer pour traiter des substances toxiques dans l'environnement. Le Programme d'évaluation des substances d'intérêt prioritaire (PESIP) est l'une des initiatives qui ont été prises aux termes de la LCPE. En vertu de ce programme, on demande aux ministres fédéraux de dresser une liste de substances qu'il y aurait lieu d'évaluer en priorité pour déterminer si elles sont « toxiques » selon la définition donnée à l'article 11 de la loi. Les substances qui sont déclarées « toxiques » passent dans la phase de gestion des risques.

Le document suivant sert de guide à ceux qui participent activement ou qui s'intéressent à la tenue des évaluations, par rapport aux risques pour l'environnement, des substances figurant sur la deuxième liste de substances d'intérêt prioritaire. Il énonce les principes et les politiques adoptés par Environnement Canada pour l'évaluation des risques environnementaux des substances d'intérêt prioritaire. Il précise ensuite les modalités des évaluations, à commencer par l'énoncé des responsabilités de ceux qui participent à l'opération et il termine par un document d'appoint, un rapport d'évaluation et l'avis de la *Gazette du Canada*.

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1 The Priority Substances Assessment Program (PSAP)

The *Canadian Environmental Protection Act (CEPA)* provides the legal tool for addressing toxic substances in the environment. One of the initiatives under CEPA is the Priority Substances Assessment Program (PSAP). Under this program, federal ministers are instructed to develop a list of substances that should be given priority for assessment to determine whether they are "toxic" as defined under Section 11 of the Act. Substances that are declared "toxic" move into the risk management phase.

The overall process of assessing and managing priority substances includes the following steps:

Assessment Phase:

- identify substances that should be given priority for assessment;
- assess the risk these substances pose to the environment and human health;
- publish findings indicating whether the substance was found to be "toxic" under CEPA;

Management Phase:

- develop strategic management options for "toxic" substances;
- implement the options chosen; and
- monitor effectiveness of the implementation of the strategic options.

The first Priority Substances List (PSL1) was published in 1989 and included 44 substances or groups of substances. Environmental assessments and human health assessments were completed under the Priority Substances Assessment Program by early 1994. The second Priority Substances List (PSL2) was published in the *Canada Gazette* on December 16, 1995 (see Appendix). It contains 25 substances, including individual chemicals, mixtures, and effluents. The PSL2 reflects the recommendations of the Ministers' Expert Advisory Panel; a panel drawn from a broad spectrum of government and nongovernment organizations (Report of the Ministers' Expert Advisory Panel on the second Priority Substances List under the *Canadian Environmental Protection Act*, Environment Canada, 1995). The public may also nominate substances of concern.

The responsibility for assessing priority substances is shared by Environment Canada and Health Canada. Environment Canada is responsible for studying the environmental aspects of priority substances and Health Canada the human health aspects. The purpose of the assessments is to determine if a substance enters or may enter the environment in amounts that pose, or may pose, a risk to the environment, to the environment that supports human life, or to human health, as defined under CEPA, Section 11. A substance, therefore, may be defined as CEPA "toxic" as a function of how it enters into the Canadian environment, its concentration in the Canadian environment, and its toxicity.

When the assessment has been completed, the substance is removed from the Priority Substances List. Substances found to be toxic, however, may be recommended for addition to the List of Toxic Substances in Schedule I of CEPA. These substances then move into the risk management phase of the process where strategic management options are developed. The conclusions of each assessment are

reported in the *Canada Gazette* and documented in a report that is available to the public.

Options in the management phase may take the form of voluntary actions, guidelines, codes of practice, and/or regulations to ban the substance, improve the safety requirements for its use, or limit its use or quantities/ concentrations that may be discharged into the environment. Provincial and territorial governments may be involved in developing and implementing the options. All actions regarding toxic substances should be consistent with the Toxic Substances Management Policy. [1]

The Priority Substances Assessment Program is managed by the *Canadian Environmental Protection Act* Management Committee (CEPA MC). This committee, which includes members from both Environment Canada and Health Canada, is co-chaired by the Director General, Toxics Pollution Prevention Directorate (Environment Canada), and the Director General, Environmental Health Directorate (Health Canada). Membership also includes directors from both departments who are accountable for implementing CEPA on an ongoing basis. In the context of the priority substances assessment process, CEPA MC is specifically responsible for approving the approach and policies used throughout the process and for approving the assessment reports and *Canada Gazette* notices before ministerial approval and publication.

The intent of this document is to provide guidance to those actively involved or interested in the conduct of environmental risk assessments of substances on the second Priority Substances List. (Those interested in the human health assessments, should contact Health Canada's Environmental Health Directorate.) A brief description of the administrative principles/policies and processes currently adopted by the Priority Substances Assessment Program is provided. This document serves as guidance only; specific assessments may use variations on this process depending on the particular circumstances involved. Guidance on the conduct of the scientific aspects of the environmental assessment may be found in companion Environment Canada documents entitled *Environmental Assessments of Priority Substances under the* Canadian Environmental Protection Act*: Guidance Manual (March 1997)* and *Environmental Assessments of Priority Substances under the* Canadian Environmental Protection Act*: Resource Document. (November 1996)*

[1] Toxic Substances Management Policy. Government of Canada, Environment Canada. June 1995.

2 *Principles and Policies Adopted by Environment Canada for Environmental Risk Assessments*

2.1 Objectives

The main objective of the PSAP at Environment Canada is to ensure that scientifically sound environmental risk assessments of the PSL2 substances are carried out in a timely fashion. To achieve this objective, a process has been developed to:

- **enhance the openness and transparency of the assessments**, by inviting scientific and technical experts from industry, government (federal, provincial, and municipal), academia, and environmental groups to participate in the environmental assessment and by informing other interested groups of major decisions during the assessment phase;
- **increase the knowledge base**, by engaging the required expertise when needed during the process, and by conducting research and monitoring when deemed necessary to complete the assessment; and
- **improve efficiency**, by involving risk managers as much as possible throughout the process so that all possible sources of emissions/exposure are located and other information helpful to the risk management process is obtained for substances found to be CEPA "toxic".

2.2 Background

The principles and process to be used have been developed by building on the experience of PSL1 through a series of discussions with interested groups. Meetings were held within the Chemicals Evaluation Division, with other Environment Canada divisions, institutes and regions, with Health Canada, with risk managers in both Environment Canada and Health Canada, with other government departments, and with industry. In addition, provincial and territorial governments and non-government organizations were informed of the process. These potential contributors were asked for their comments on the proposed approach and the role they would like to play in the environmental assessment process. Aspects that emerged as important themes from these discussions included:

- the interest of many groups in remaining informed and/or participating in some way in the process;
- the value of engaging relevant scientific and technical expertise, wherever it is to be found, in the environmental assessment, to ensure a high-quality product;
- the need to provide assessments that are useful for making risk management decisions; and
- the need to generate data to complete some of the environmental assessments of PSL2 substances and the use of CEPA Sections 16 and 18 where necessary to obtain needed information.

From a program perspective, there are a number of advantages to involving people outside the PSAP in the environmental assessment process. This involvement will respond to the desire for openness, should improve the quality of the assessments by engaging additional expertise, and should gain greater acceptance of the results by interested parties who have participated in the process.

2.3 *Contact Group, or Environmental Resource Group*

The assessors will call upon a Contact Group of representatives of other federal government departments who will act as central contacts for their departments, identify relevant data to which they might have access, and identify experts who might assist in the environmental risk assessment.

For each substance a group of scientific and technical experts from various sectors (government, industry, academia, non-government organizations) will be appointed to an Environmental Resource Group (ERG) to contribute actively to the assessment. These experts are invited by Environment Canada and are selected for their personal knowledge, not because they represent an interested party. It is anticipated that membership of an ERG will be worked out gradually throughout the problem formulation stage (Section 3.2). Members may also be added later if necessary. The size and composition of each ERG will vary depending on the substance being considered and the requirements for the assessment. A likely size is between four and eight members. The principal criteria for appointment to the group should be a person's scientific or technical expertise that will improve the quality or completeness of the assessment and a willingness to participate cooperatively in the process and meet the deadlines required. One of the members of the ERG must be a risk manager.

2.4 *Liaison Group*

Interested non-participants will identify themselves upon invitation to do so at the end of the PSL2 Panel process, or through some other means during the assessment process. These people, hereafter referred to as the Liaison Group, will be kept informed by periodic updates on the status of assessments which will be published in newsletters and on the Internet. In particular, the problem formulation stage of the assessments will be made available. Draft assessment documents will also be available to the public before the process is completed. This will provide a specific opportunity for the public to furnish additional supporting or contradictory information to the assessment before it is finalized. Liaison Groups could be program-wide as well as substance-specific.

2.5 *Obtaining/Generating Additional Data*

A conclusion regarding CEPA "toxic" status is expected to be reached for all substances. However, there may be a need to generate additional data through research and/or testing to complete the environmental assessments for some substances. A central review of research needs across the Program will serve to establish program-wide research priorities and maintain consistency of approach to data-generation by those designated to lead the assessments.

The cooperation of interested parties will be sought in providing data needed to complete the environmental assessments, consonant with the principles of user/producer responsibility and "polluter pays". In some cases it may be appropriate to use the authority provided in CEPA Sections 16 and 18 for obtaining supplementary data, including the identification of users and producers, so that all sources of entry can be characterized. Sections 16 and 18 should be used with caution and should be vetted through the Use Patterns Section, Chemicals Control Division.

It is anticipated that Environment Canada laboratories and research institutes will have an interest in completing necessary research/ testing, and also that members of the ERG (Section 2.3) will provide existing information

on a substance or may be prepared to conduct or support, in whole or in part, research/tests to produce new information required to complete the environmental assessment.

2.6 *Working with Risk Managers*

The experience gained through the PSL1 assessment process and the subsequent development of strategic options for "toxic" substances indicates that there is mutual benefit to be obtained by assessors working with risk managers, beginning early in the process. By working collaboratively, each may benefit from the expertise of the other. For example, it is important that all the major sources of a substance's entry into the Canadian environment be located and quantified, as this information is used in developing the exposure sections of the environmental assessment, and also used in the potential subsequent development of management options if the substance enters the risk management phase.

2.7 *Scope of the Environmental Assessments*

The Report of the Ministers' Expert Advisory Panel indicated for each substance whether it should be investigated from a human health perspective, an environmental perspective, or both. These recommendations were based on information revealed through an initial investigation of each substance and the Panel's expert knowledge. Since the information available to the Panel was limited, Environment Canada will investigate, for each PSL2 substance, the possibility of environmental risk by completing the problem formulation step of the environmental assessment — the stage where the scope of the assessment is determined. If this investigation reveals that there is likely no risk posed to the Canadian environment even under hyperconservative scenarios, the detailed environmental assessment will not be undertaken.

2.8 *Financial Issues*

It is expected that, in general, those outside the PSAP interested in the assessment and its outcome will be prepared to provide the necessary resources to ensure that the environmental assessment of a specific substance is as complete and as accurate as possible. Within the environmental assessment process, participants outside the PSAP, e.g., members of ERGs, those who provide information, or those who have requested to review documents, will generally be expected to provide the necessary resources to support that participation. Exceptions will occur where the PSAP's need dictates a contractual arrangement or where important participants demonstrate that they cannot provide these resources. The PSAP resources will be reserved as much as possible for research of a general nature which has applicability to several substances or for fundamental research related to the assessment of a substance.

3 *Environmental Risk Assessments — A Process for Each Substance on the Second Priority Substances List*

The process to be followed for assessing the PSL substances should remain as simple as possible, but should contain sufficient checks and balances to ensure a consistent overall approach by assessors. The process outlined in the following text describes the steps to be followed in the environmental assessment process and the general practices that have been adopted by Environment Canada as a guide to the assessment of each PSL substance. While not illustrated, it should be recognized that this scheme may include a number of loops as progress indicates a need to revisit an earlier step.

The process consists of four major stages: 1) initial steps; 2) problem formulation; 3) detailed assessment; and 4) products, approvals, and publishing.

3.1 Initial Steps

The Program Manager designates a staff member (the "**Lead**") to lead the environmental risk assessment on behalf of the PSAP of Environment Canada. Health Canada appoints its own substance lead to conduct the health assessment and the two activities are conducted with contact and collaboration between the two leads at appropriate junctures in the process.

3.1.1 Roles and Responsibilities of Environment Canada Leads. The Lead is responsible for the delivery of a scientifically sound assessment within a specified time and resource limit but does not necessarily have to perform all the duties him/herself. The following points provide an outline of the associated scientific and administrative responsibilities.

Detailed Assessment:

- collecting and analyzing information;
- providing advice on data needs for which Sections 16 and 18 (CEPA) are required;
- drafting problem formulation;
- presenting problem formulation for peer review and at a possible workshop;
- revising problem formulation following review;
- having essential data generated, if necessary;
- conducting the assessment; and
- drafting environmental sections and conclusions of assessment reports and *Canada Gazette* notices.

Management of the Process:

- developing and following a work plan for the environmental risk assessment;
- identifying to the Program Manager what expertise is required to complete the assessment, and engaging interested parties and resource people with appropriate expertise to participate in the assessment as members of an ERG (Section 2.3) and Liaison Group (Section 2.4);
- maintaining ongoing contact with Health Canada officials with respect to the assessment;
- leading and communicating with the ERG, providing direction and keeping participants involved, conducting meetings, communicating as necessary;

- identifying issues/problems for discussion or resolution with other Leads and the Program Manager and to ensure consistent approaches;
- collaborating with other Leads on aspects of the assessment common to more than one substance (e.g., workshop on sediment issues related to several substances);
- communicating decisions to other Leads and to the Program Management Team;
- coordinating internal and external peer reviews of draft supporting documents and assessment reports;
- submitting the supporting document, assessment report and Gazette Notice to the Program Manager; and
- communicating routinely to the Program Manager the status of the assessment.

3.1.2 Selection of Leads. Most Environment Canada Leads are from the Chemicals Evaluation Division (CED), Commercial Chemicals Evaluation Branch. This Division is responsible for delivery of the PSAP in Environment Canada. Leads are chosen based on their expertise, experience, interest, and availability. For substances of interest to a particular region of Environment Canada, that region is invited, or may volunteer, to participate as Lead.

When Leads are from outside CED, an experienced assessor from within CED is designated as a contact point. This assessor maintains ongoing communication with the external Lead, and acts as adviser on policy or scientific issues, or as a source of contact to obtain additional information.

3.2 Problem Formulation

Problem formulation is the first critical stage of the environmental assessment. It determines the scope of the assessment, i.e., what issues will be addressed in detail and which ones will not be pursued. It is refined as a clearer picture of the issues emerge. The initial problem formulation should reveal what kind of information is available or still required concerning the substance production or its use, fate, concentrations, and toxicological information. Risk managers may give added insight into the issues; questions related to possible risk management should be addressed in the environmental assessment, if feasible. Data that are missing but considered essential for completion of the assessment should be identified in detail (Section 3.3.2). At the end of the initial peer-reviewed problem formulation, the Lead should develop a strategy for conducting the assessment.

The problem formulation should be critically reviewed by a member of the management team within CED when it has been drafted and data gaps identified and described. This is to ensure that the general approach to the assessment is consistent, the data necessary to complete the assessment are defined, and to help with possible problem areas. The problem formulation should then be reviewed by members of the ERG, and provided to the Health Canada Lead. Those who may be able to help fill in data gaps or generate data should be approached. A summary of the problem formulation will be made available to the public on the Internet and provided to the Contact Group and the Liaison Group for input.

3.3 Detailed Assessment

3.3.1 Work Plan. Upon acceptance of the problem formulation, Leads should develop a work plan for the entry, exposure, and effects characterization for the detailed assessment and assign responsibility for various aspects of the work to ERG members as appropriate. The plan, which should be updated as necessary as the assessment proceeds, will form the basis

for measuring progress on the assessment. It should describe, with reference to specific identifiable milestones, the steps that must be followed to complete the assessment all the way through to publication of reports, and the order in which those steps are to be followed. It should also provide a timetable and an outline of the necessary resources, including a proposed budget for the assessment. The work plan should be reviewed by a member of the management team and approved by the Program Manager. When finalized, the schedule will be shared with Health Canada, and a co-ordinated schedule will be presented to the CEPA Management Committee for approval.

3.3.2 Managing Data Needs. The Program Manager is responsible for setting overall research priorities. Leads will be responsible for issuing priorities and developing a strategy to gather the necessary data for their substance(s). Where possible, toxicity studies should be conducted using standard test methods developed by Environment Canada, the United States Environmental Protection Agency, the Organization for Economic Co-operation and Development, etc. If existing test methods are not available, it may be necessary to develop methods, which may entail additional time and expense.

Upon completion of each study, the Lead and relevant ERG members should review the study report critically and, where warranted, obtain additional expert opinion on the acceptability of the report.

3.4 Products, Approvals, and Publishing

3.4.1 Supporting Document. The Supporting Document contains all the information (entry, exposure and effects) critically reviewed in developing the assessment. It includes a description of how the risk characterization has been completed. The Supporting Document may consist of one or several different documents. Each main section of the document will conclude with a summary section upon which the shorter Assessment Report will be based. The summary section should identify the most significant information and develop the case for a conclusion as to whether a substance is CEPA "toxic". The Supporting Document will not include a section where a CEPA Section 11 "toxic" determination is made. The Supporting Document must be as complete as is necessary to develop the evidence required for use in the Assessment Report.

The Supporting Document must be peer reviewed. The entire document can be reviewed as a unit, or each section can be peer reviewed when it is written, in cases where each section will require different expertise. The Supporting Document should be reviewed by all members of the ERG. When revised it should be reviewed by a member of the management team within the PSAP, and then by other experts in the subject area of interest. Any significant changes made should be discussed with the management team member and reviewed again by him/her if necessary.

3.4.2 Assessment Report (AR) and *Canada Gazette* Notices. When the Supporting Document has been reviewed and is complete, the assessment report should be prepared. The environmental sections of the Assessment Report should draw together and summarize the most important information from the Supporting Document, developing the case for and citing the principal reasons for any conclusions reached under the various sections. The Assessment Report will contain a section that assesses whether the substance is toxic under CEPA, Sections 11(a) and (b). The sections of the Assessment Report prepared by Environment Canada staff should be reviewed by ERG members, then by a member of the

management team of CED, followed by a review by external experts. The final Assessment Report should then be submitted to the Program Manager for review and approval. Note that the review process is flexible and can be altered case-by-case, to meet the needs of the particular assessment. For example, the Assessment Report and Supporting Document can be reviewed at the same time.

The Assessment Report will be a joint Environment Canada/Health Canada document in similar fashion to the PSL1 reports. When the environmental portion has been approved, the report should be provided to Health Canada so that preparation of the joint Assessment Report and *Canada Gazette* Notice can begin.

The Gazette Notice should be a short summary of the Assessment Report including the CEPA, Section 11, determination.

3.4.3 Approvals. The final joint Assessment Report and Gazette Notice should be submitted to the Program Managers of Environment Canada and Health Canada for approval. When complete, Environment Canada and Health Canada will submit it for approval to the CEPA Management Committee.

When the draft of the Assessment Report has been approved by CEPA MC, the proposed conclusion will be published in the *Canada Gazette,* to maintain the openness of the process. There will be a 60-day comment period when the public will have the opportunity to provide scientific and technical information to support or refute the proposed conclusions. Leads or their delegates should prepare notices for the Contact Group and the Interest Group, as well as notices to be published on Environment Canada's Green Lane on the Internet. After the public scrutiny stage, the Assessment Report and Gazette Notice should be revised and finalized, and approved by the Program Managers. If significant changes have been made, they should be sent to CEPA MC for approval; otherwise they should proceed through the Ministerial approval process.

3.4.4 Publishing. When all approvals have been received, the Assessment Report and *Canada Gazette* Notice will be published. A fact sheet of findings and recommendations of the environmental risk assessment should be prepared for posting on Environment Canada's Green Lane on the Internet.

Where appropriate, scientific aspects of an assessment or common interesting aspects of assessments for several substances should be published in peer-reviewed journals.

Appendix Substances on the Second Priority Substances List (PSL2)

Acetaldehyde
Acrolein
Acrylonitrile
Aluminum chloride, aluminum nitrate, aluminum sulphate
Ammonia in the aquatic environment
1,3-Butadiene
Butylbenzylphthalate (BBP)
Carbon disulfide
Chloramines
Chloroform
N,N-dimethylformamide (DMF)
Ethylene glycol
Ethylene oxide
Formaldehyde
Hexachlorobutadiene (HCBD)
2-Methoxy ethanol, 2-ethoxy ethanol, 2-butoxy ethanol
N-Nitrosodimethylamine (NDMA)
Nonylphenol and its ethoxylates (NPE)
Phenol
Releases from primary and secondary copper smelters and copper refineries
Releases from primary and secondary zinc smelters and zinc refineries
Releases of radionuclides from nuclear facilities (effects on non-human species)
Respirable particulate matter less than or equal to 10 microns
Road salts
Textile mill effluents