Comments on Environment Canada's "Guidance for Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List: Determining Persistence, Bioaccumulation Potential and Inherent Toxicity to Non-Human Organisms"

Prepared for the Canadian Environmental Network Toxics Caucus

Dr. Susan Sang World Wildlife Fund Canada

Fe de Leon Canadian Environmental Law Association Publication #453 ISBN # 1-894158-98-9

Dr. Kapil Khatter Canadian Association of Physicians for the Environment

November 7, 2003

Table of Contents

EXECUTIVE SUMMARY	1
INTRODUCTION	3
MAIN ISSUES OF CONCERN	4
1. Precautionary Approach	4
2. UNCERTAINTIES IN DATA COLLECTIONS AND MODELLING	4
3. INCORPORATING HEALTH CANADA'S ACTIVITIES ON CATEGORIZATION	
4. CHEMICALS THAT DO NOT MEET P OR B BUT ARE OTHERWISE OF CONCERN	6
5. Environmental Distribution and 5% Cut-off Value	7
6. Use of Analogues and Weight of Evidence	8
7. WEIGHT OF EVIDENCE	
8. ADEQUACY OF DATA	9
9. TOXICITY ESTIMATE BASED ON QSAR	. 10
10. DEFINITION FOR IT IS INADEQUATE	. 10
11. DETERMINING QUALITATIVE FACTORS IN THE CATEGORIZATION PROCESS	. 11
12. SPECIFIC CONCERNS RELATING TO CATEGORIZATION OF INORGANIC SUBSTANCES	11
IN SUMMARY	12

EXECUTIVE SUMMARY

Member organizations of the Canadian Environmental Network Toxics Caucus are pleased to submit their comments on Environment Canada's, "Guidance for Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List: Determining Persistence, Bioaccumulation Potential and Inherent Toxicity to Non-Human Organisms", released in June 2003. As required under the Canadian Environmental Protection Act 1999 (CEPA), Environment Canada and Health Canada must complete the categorization of 23,000 substances listed under the Domestic Substances List (DSL) by September 14, 2006. The members of the Toxics Caucus support the efforts to date by Environment Canada in proposing a categorization process for this task.

Recognizing the significant task facing Environment Canada and Health Canada over the next few years, this submission aims to provide comments and recommendations on specific components of Environment Canada's proposed guidance framework. Members of the Toxics Caucus emphasize the importance of establishing a framework that effectively identifies *all* hazardous substances; this is a critical requirement before the screening level risk assessment (SLRA) phase.

Given the recent developments in chemicals management policy in other jurisdictions, such as the REACH policy on chemicals management by the European Union, the members of the Toxics Caucus recognize that Environment Canada has a unique opportunity to demonstrate its leadership through the DSL categorization process. As other jurisdictions begin to develop their chemicals policy over the next few years, the issue of sharing data on chemicals may become pivotal for Environment Canada and Health Canada.

The issues covered in this submission include:

- use of the precautionary principle and the weight of evidence approach
- developing a precautionary decision-making process in the face of uncertainty
- articulation of the Health Canada effort in the categorization process
- the need to categorize "in" those substances that meet the iT criterion but not P or B or display other hazardous endpoints
- addressing borderline substances those which are close to but do not meet required criteria for P and/or B and iT
- the use of environmental partitioning values as cut-offs
- determining pivotal values for P, B and iT
- use of analogues to complete data collection; and
- expanding the definition for iT

The member organizations of the Toxics Caucus will continue to comment on all proposals on the DSL process presented by Environment Canada and Health Canada to ensure that all hazardous substances are effectively categorized for the purposes of the

SLRA process. A failure to identify all hazardous substances for SLRAs will place the environment and human health at continued risk.

INTRODUCTION

As members of the Canadian Environmental Network Toxics Caucus, we are pleased to have the opportunity to comment on this important guidance document. Faced with the task of categorizing 23,000 chemicals within a seven-year timeframe, we can appreciate Environment Canada's need to develop a methodology that provides a balance between facilitating maximum efficiency of effort, and maximum protection of the environment and human health. Given that many of the substances listed under the DSL have very limited data, members of the Toxics Caucus support efforts by Environment Canada and Health Canada that raise the current knowledge base on chemicals in Canada. In particular, we are supportive of efforts to reduce the amount of time needed to identify substances of concern for further assessment. We note, however, that less than three years remain to complete the categorization exercise. Recognizing that there are a number of improvements that must be made, we are concerned that completion of a fully effective and protective categorization will not be realized within this timeframe.

We would like acknowledge several positive developments in Environment Canada's proposed approach outlined in the report, "Guidance for Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List: Determining Persistence, Bioaccumulation Potential and Inherent Toxicity to Non-Human Organisms", released for comments in June 2003. First, members of the Toxics Caucus support Environment Canada's proposal to select the most conservative value as the pivotal measure for persistence (P), bioaccumulation (B) and inherent toxicity (iT) in situations where more than one acceptable experimental value or reliable QSAR prediction is available, and that categorization will be considered in the context of the most sensitive species.

Second, we are also pleased that Environment Canada has chosen not to accept data related to critical body burden or critical body residue at this point. We have serious reservations about this approach, and, at the very least, feel that a great deal of further research is required.

The members of the Toxics Caucus are fully aware that the objective of section 73 of the *Canadian Environmental Protection Act* (CEPA) 1999 is to complete the categorization of all 23,000 substances in the DSL, and that the Persistence and Bioaccumulation Regulation (PB Regulation) passed in 1999 provides the criteria for categorization. We are also fully aware that this work must be completed in conjunction with Health Canada. In view of recent policy developments on chemicals management known as REACH (Registration, Evaluation, and Authorization of Chemicals) emerging in the European Union, Canada is faced with a unique opportunity to demonstrate its leadership in the area of chemicals management. The DSL categorization and the data collection exercise required in this process will be of significant interest to the European Union. Therefore, as other jurisdictions develop their chemicals policy, the issue of sharing data on chemicals effectively and efficiently with other jurisdictions will be an emerging issue that will require some consideration by Environment Canada and Health Canada.

These developments underscore the importance of the overall goal of the proposed categorization framework, which is, in our view, to identify *all* DSL substances that meet the criteria for P and/or B and iT. Meeting this goal would ensure that the most hazardous substances would be captured and required to undergo the Screening Level Risk Assessment (SLRA) process. The members of the Toxics Caucus understand that completing SLRAs for the hundreds if not thousands of substances which meet the criteria for P and/or B and iT will require significant resource commitments by the departments of Environment and Health. However, should the categorization process fail to capture all appropriate substances, there would be increased risk to the environment and human health.

The NGO community has identified several areas within the proposed categorization process that must be addressed and modified before the DSL categorization process can be said to adequately protect the environment and human health.

MAIN ISSUES OF CONCERN

1. Precautionary Approach

The precautionary approach is a CEPA guiding principle, and members of the Toxics Caucus are pleased to see components of the proposed categorization framework incorporate the precautionary approach to assess data for P, B and iT. In the absence of reliable or sufficient scientific data and information, the precautionary approach is applied to guide action on a substance.

The precautionary approach and a weight of evidence methodology are evident in Environment Canada's proposal for selection of pivotal values for P, B and iT.

It is also evident in Environment Canada's proposal to categorize "in" those substances whose bioaccumulation factors are determined using Log Kow values that fall in the range between Log Kow 4.1 to 5. We support this inclusion since it demonstrates more stringent measures than those required under the PB Regulations. By considering those substances with a Log Kow between 4.1 and 5, more DSL substances with very little experimental data available on bioaccumulation may be categorized "in" for further SLRA activities. At the same time, however, NGOs are concerned that inclusion of these substances may provide industry the opportunity to challenge these data, as deviating from the PB Regulations.

Recommendation: Therefore, we urge that Environment Canada clarify its intent and articulate its position regarding how these types of substances will be addressed.

2. Uncertainties in Data Collections and Modelling

There are many aspects of the proposed categorization process that deviate from the precautionary approach. We will address these issues in the following pages. In

particular, however, we believe that modifying the way in which uncertainty is managed is of vital importance. The guidance document states that, although there are numerous sources of uncertainty associated with the categorization of DSL substances, Environment Canada considers the overall level of uncertainty acceptable given the state of the science. While acknowledging that Environment Canada is employing the best science and getting the best scientific advice possible, we believe that, owing to the great number and variety of sources of uncertainty and the associated risks, a more precautionary approach is required.

We propose that the following approach be used in cases where there is neither reliable experimental data, nor a well-validated QSAR, nor a close or comparable analogue. When none of these data sources are available, this should trigger a responsibility on the part of industry to provide reliable experimental data within a reasonable period of time to be specified by Environment Canada. For the purposes of categorizing chemicals for P, B and iT, we suggest that, if, by the prescribed date, reliable data has not been received by Environment Canada, a worst-case scenario be assumed¹. Thus, a substance will be assumed to be P or B or iT, depending in which area the uncertainty lies. We understand that this procedure may cause delays, and urge Environment Canada to minimize these delays by beginning work immediately on substances that are suspected to fit this description. We would further add that, although we are well aware of time pressures, these should not be used to reject testing and data collection for substances which do not have reliable data, especially when the lack of data has long been recognized. It is unacceptable to subject Canadian environment and human health to unnecessary risk because pro-active steps were not taken early in the process to require information on these substances.

Recommendation: In the absence of reliable empirical data or model generated information, the onus should be on the industry to provide valid experimental data within a timeframe specified by Environment Canada.

3. Incorporating Health Canada's Activities on Categorization

The current guidance manual does not provide an in-depth discussion of Health Canada's activities in the categorization process despite the requirements by both departments to meet the obligations of S. 73 under CEPA 1999. In our view, the proposed framework is weaker without a critical understanding of how Health Canada's activities in the categorization process relate to Environment Canada's data collection and categorization activities. The most recent document demonstrating how Health Canada's efforts fit into the overall DSL process was released in 2001 as a flow chart.

Since the discussions by the Technical Advisory Group (TAG) on DSL in 2000 and in the months following the work of the TAG, member organizations have expressed the need to integrate Health Canada's activities into the categorization process as proposed by Environment Canada. This integration of activities may highlight gaps in the

¹ It should be added that, as there are less than 3 years until the categorization must be completed,

It should be added that, as there are less than 3 years until the prescribed dates should be provided as soon as possible.

categorization process that have not been fully assessed. In the categorization process there are areas where lack of Health Canada's contribution is evident. For example, developing a process to address those substances that do not meet required criteria for P, B or iT for non-human organisms but do meet iT criteria for humans. According to the 2001 flow chart and Health Canada's presentation on November 2002, it is our understanding that Health Canada will only assess iT in human organisms on those DSL substances that meet P and/or B as identified by Environment Canada. We are concerned that the list of substances that undergo the SLRA process would be reduced significantly if this process were followed. Limiting the number of substances assessed by Health Canada may result in saved resources but fails to add to our knowledge of toxicity and exposure. This may undermined the CEPA requirements that clearly states the involvement of both Departments in the DSL categorization process. Our reading is that CEPA clearly states that the DSL categorization process must identify all DSL substances that may present, to individuals in Canada, the greatest potential for exposure, not just those which fit the PB Regulation and present the greatest potential for exposure. Thus, Health Canada's role must be clarified.

Recommendation: The flow chart released in 2001 outlining the roles of Health Canada and Environment Canada in the categorization process should be reviewed and incorporated into the guidance manual to demonstrate how each department undertakes the categorization process and where in the process each department's data is considered.

Members of the Toxics Caucus have requested meetings with Health Canada officials on this file with very minimal response. Currently, Environment Canada is conducting these consultations in isolation, with very little update being received from Health Canada on its efforts. We feel that this process would improve significantly if Environment Canada facilitated a meeting between the two departments and NGOs.

Recommendation: Environment Canada should facilitate a dialogue that includes participation from Health Canada, Environment Canada and NGOs on the categorization of DSL substances.

4. Chemicals that Do Not Meet P or B but are Otherwise of Concern

We are concerned that the proposed categorization process does not provide a safety net for chemicals that do not exactly meet the criteria for P or B, but do meet the criterion for iT to humans. We appreciate the difficulty of finding an efficient yet sufficiently precautionary method for categorizing organic substances on the DSL within a tight timeline. Nevertheless, we believe that, without addressing this issue, and without including substances that are iT to humans (i.e., substances with known chronic and subchronic characteristics), the process for categorization of DSL substances will not be sufficiently protective of human health. Therefore, it is imperative that Health Canada is fully engaged in the categorisation process along with Environment Canada in order to ensure that both wildlife and human health are protected.

A precautionary approach is required in situations where:

- 1) substances meet the criterion for iT only; and
- 2) substances that exhibit other hazardous endpoints such as endocrine disruptors.

Recommendation: For substances that meet the iT criteria but not P or B criteria, should be categorized "in" for SLRA phase. In addition, where other hazardous endpoints (e.g., endocrine disruptors) exist for a substance, these factors should also be considered for further assessment. See Table 1.

Table 1

Substance	(P)ersistent	(B)ioaccum	(i)nherent	Categorized	Other hazard
Name		mulation	(T)oxicity	(in)/(out)	endpoints
X	YES	YES	YES	IN	
Y	NO	YES	YES	IN	
Z	YES	NO	YES	IN	
A	NO	NO	YES	IN	YES

Data from other hazardous endpoints should be collected and reviewded to provide support for categorizing a substance "in."

5. Environmental Distribution and 5% Cut-off Value

The guidance document proposal to determine persistence using partitioning and a cut off value of 5% to determine "realistic presence" requires additional rationale. As outlined, it is unclear whether substances can be categorized "in" as P if they partition to a given media at a relatively small percentage. The value of 5% is mentioned as constituting a "realistic presence" in a given media, below which a substance cannot be categorized "in."

It is unclear whether the proposed cut off of 5% will effectively capture substances that are found to be carcinogenic or otherwise toxic at very low doses. In addition, an across the board cut off of 5% does not take into account the fact that a high production volume chemical partitioning to a given media at less than 5% could still constitute a significant presence, due to the sheer volume of overall emissions.

Another factor is that exposure pathways can differ greatly in their impact on organisms – a given organism has different vulnerabilities to different exposure pathways to different substances. For example, while only a small portion of the total environmental releases of polycyclic aromatic hydrocarbons (PAHs), remains in the atmosphere, human exposure to PAHs is significant because humans are more sensitive to certain PAHs via inhalation. In general, there is a need for a partitioning formula that accounts for or exempts low dose toxicity (such as some carcinogens), and considers organism-specific pathways that could be characterized as particularly vulnerable for a given substance, e.g., human inhalation of PAHs.

Our view is that, if a substance is identified as B or P, it should be categorized as B or P, regardless of partitioning behaviour. It is simply unacceptable that a substance with properties that suggest long-distance transport could be disqualified from being considered persistent in air because it is predicted that it partitions less than 5% to air. Substances other than PAHs where cut off values should not be applied include metals such as arsenic, cadmium, nickel, and chromium V1, dioxins, dibenzofurans, and PCBs. These substances are of particular interest since they are relatively stable, very toxic, with a tendency to bioaccumulate in human and wildlife species.

Recommendation: Environment Canada should provide a clear rationale on how they arrived at the 5% cut off value for determining "realistic presence" of a substance for all media. This should include a determination of the identity and number of substances that meet the 5% cut off value as well as values lower than 5%.

Recommendation: Substances that may cause toxic effects at very low doses, and substances that are produced at high volumes or have high emission rates should be exempted from the 5% cut off value. In addition, judgements on whether or not to apply the 5% partitioning cut off to a given substance should be sensitive to media-specific and organism-specific vulnerabilities.

6. Use of Analogues and Weight of Evidence

In the absence of experimental data, the use of analogues may be required to obtain critical data for determination of P and/or B. We are concern that the use of analogues may grossly underestimate the toxicity of certain substances and disregard the precautionary approach and weight of evidence approach in the categorization process.

The technical workshop on DSL in October 2002 revealed that the use of analogues would have a significant role in providing data for P, B and iT. For iT, in particular there is concern that the lack of data will force Environment Canada to select analogues that provide incomplete or contradictory data, and that the determination of iT could depend on a process that compares essentially different substances. For example, choosing toluene as an analogue for benzene would be in line with Environment Canada guidance on page 15, as the two molecules are identical except for a single methyl group (on toluene). Yet benzene is substantially more toxic. These types of issues in selecting analogues are not clearly articulated in the proposed guidance. In our view, gaps such as these should be identified immediately and targeted for further research to support the gathering of toxicity data.

Recommendation: There are significant issues associated with the selection of analogues. Environment Canada should identify problematic areas in the use of analogues, and ensure that activities are undertaken to support the gathering of more reliable toxicity data.

Polycyclic aromatic hydrocarbons are an example of a family of substances, one or more of which may be used as an analogue to predict the characteristics of another substance from the PAHs group. There is a concern with such an assumption since there may be significant differences between the toxicity of the two analogues. In situations where existing data is insufficient to reliably estimate toxic potency, a precautionary approach should be used, and the contaminants should be considered for priority testing. We are also concerned with the use of qualitative information in the determination of P, B and iT. Environment Canada's proposal provides a list of what constitutes a "qualitative analysis", outlined on page 15. Structural features, molecular weight, water solubility, consideration of reactivity, stability of a substance and molecular descriptors are all important factors. However, there may be other factors that should be included on this list. Because of the significance of these factors in creating a weight of evidence for a substance, all factors, science-based or otherwise, should be considered and accompanied by a rationale.

7. Weight of Evidence

In addition, a weight of evidence approach must address the level of uncertainty associated with data for P and/or B and iT. The proposal should include a brief discussion on what would be considered as a *minimum weight of evidence* to support the data that currently exist. In our view, any definition of *minimum weight of evidence* should include sufficient reliable data to identify iT, as all DSL substances are required to meet this criterion under CEPA. While articulation of what constitutes a minimum weight of evidence may initiate debate among different stakeholders, such a debate may be useful in determining how a precautionary approach could be applied within the categorization process.

Recommendation: Environment Canada should articulate what criteria would constitute a minimum weight of evidence. This addition may demonstrate how the proposed categorization process could support a precautionary approach.

8. Adequacy of Data

A distinction should be made between substances for which there is an adequate database for reliable scientific assessment and those for which the database is inadequate. The latter group may still be categorized by the two departments, but be identified as a "List B" to indicate a lower level of confidence in the categorization. In addition, those substances whose values lie close to the P, B or iT criteria, and for which the margin of error or the level of uncertainty makes their classification particularly uncertain should be placed on this list. Placement on "List B" should trigger a requirement for additional data generation by industry. One of the lynchpins of the new EU chemical policy is the requirement that industry generate reliable data on which to base a categorization of toxicity and environmental fate. Especially in cases where data is inadequate, Canada would do well to adopt a similar approach. We also recommend that, instead of looking preferentially at acute data, the more conservative of the two toxicity values – acute and chronic – be used to determine the iT categorization, assuming reliable data.

Recommendation: Environment Canada and Health Canada should make a distinction between substances that have adequate data for making a scientific assessment and those substances that have inadequate data. The departments should be required to categorize these substances. Substances with inadequate data or with data that place them close to the P, B or iT criteria should be placed on "List B", and the categorization would be considered to have a lower level of confidence. Placement on "list B" would trigger a requirement for industry to provide additional reliable data – whether experimental or based on well-validated models – within a reasonable timeframe.

9. Toxicity Estimate Based on QSAR

In addition to concerns expressed on the use of analogues to provide data, we are also concerned with the use of the QSAR method to provide measures of toxicity in the absence of reliable empirical data. In our view, these approaches are not sufficient to draw a reliable semi-quantitative estimate of toxicity. We suggest, however, that QSAR models could be used to set prioritization of contaminants for empirical toxicity testing.

Recommendation: In the absence of reliable empirical data or validated QSARs to estimate the toxicity, industry should be required to provide valid experimental data within a reasonable timeframe.

10. Definition for iT is Inadequate

The current definition for iT is unacceptably limited in scope. For example, the proposed definition does not account for chronic effects. It is imperative that the definition of 'inherently toxic' be broadened to include chronic endpoints. It is unacceptable that a DSL substance that does not exhibits 'acceptable' acute effects, (i.e., does not meet the iT) criterion, but may result in chronic effects such as carcinogenicity or toxicity to the reproductive system could be categorized "out" or as requiring no further action. Thus, the definition and the categorization of substances as iT must be appropriately broadened. For example, one definition of "toxic" used in the European Union is:

"the capacity of a substance to cause toxic effects, to organisms or their progeny such as: reduction in survival, growth and reproduction; carcinogenicity, mutagenicity or teratogenicity; adverse effects as a result of endocrine disruption."

The current numerical value proposed for iT (i.e. 1 mg/L for acute and 0.1 for chronic toxicity) is understandable from a practical point of view, but it may be limiting as a policy direction. We are concerned that the proposed iT values may rule out consideration of endpoints such as endocrine disruption and developmental neurotoxicity, for which fully validated testing protocols are either still being developed or are not universally utilized. In cases where these kinds of effects are suspected or have been claimed, the substance should be considered for categorization through the presumption

of worst-case scenarios - an example of a precautionary approach. Also, the current proposal should articulate how new testing protocols that focus on different endpoints (e.g., endocrine disruption and developmental neurotoxicity) should be considered in the framework.

Recommendation: Environment Canada should review the proposed iT value to ensure that it captures all other toxic endpoints. The definition for iT, as per EU definition, should assume that the iT of a substance is a function of acute, chronic and sub-chronic toxicity, including toxic endpoints such as carcinogenicity, neurotoxicity, endocrine disruption, mutagenicity and teratogenicity.

Recommendation: The proposal should articulate how new testing protocols that focus on different endpoints will be incorporated in the framework.

Finally, with respect to Health Canada's efforts in determining iT, the definition of iT should take into consideration the susceptibility of developing children to the impact of chemicals. It is questionable whether current criteria for iT are protective of developing children or whether lower values should be considered. The importance of including this discussion in the proposed guidance framework should be emphasized as it may play a significant role in categorizing substances with little data on P, and/or B and iT for non-human organisms.

Recommendation: In setting iT criteria, Health Canada should pay special attention to the children's vulnerability and consider lower exposure values for protection of children.

11. Determining Qualitative Factors in the Categorization Process

The proposed guidance document does not provide a comprehensive list of qualitative factors that will be considered during the categorization process. In our view, it is critical to provide a list of non-science factors in order to provide transparency on how categorization decisions are made, and how those decisions are grounded in science and policy. This level of transparency and detail will trigger the need for additional research.

Recommendation: Environment Canada along with Health Canada must propose a list of qualitative non-science factors that will be reviewed in its determination of P, B, iT.

12. Specific Concerns Relating to Categorization of Inorganic Substances

One general concern with the inorganic process for categorization as outlined in the guidance document is that it represents our first "exposure" to the proposed methodology for determining P, B and iT for inorganics. Thus, we have had little time to research and discuss potential concerns. We are uncomfortable with this from a process point of view – NGOs and other organizations must be given sufficient time to complete their consideration of the proposed process for inorganics.

A number of issues emerging from the discussion of organic substances may also be applied to the categorization of inorganic substances. These are expressed in point form as follows:

- * Definition of moiety of concern is it adequate to reflect the uniqueness of inorganic substances for the purposes of the DSL process?
- * A precautionary approach dictates that, if the inorganic substance contains an organic moiety that has already been identified as meeting the criteria, it should automatically be sent to SLRA. Does the proposed framework support this?
- * It is unclear how the toxicological significance of an inorganic substance will be assessed. If subjective judgement is used, then EC must describe in detail the process and criteria used for determining the identity of the "moiety of concern."

Recommendation: As members of the Toxics Caucus did not participate in the development of the categorization process for inorganics, and this document represents our first view of the process, we request an extension on the time period for comments, in order to discuss and articulate our viewpoints and concerns on the proposal for inorganic substances.

IN SUMMARY

The framework to categorize the 23,000 substances listed in the DSL is of significant importance to the management of toxic substances in Canada, and will help to map a course for action and chemicals management policy for years to come. CEPA 1999 obligates federal agencies to complete this process by September 14, 2006. The effectiveness of the categorization framework will be of great interest to other jurisdictions involved in efforts to address data gaps in chemicals management.

The proposed framework for categorization of DSL substances by Environment Canada has the potential to demonstrate innovation and leadership in chemicals management, globally, with the following additions and modifications:

- 1) outlining a comprehensive framework for the categorization, including the activities of Health Canada;
- in the absence of acceptable empirical data for determination of P and/or B, and iT articulation of how non science data can be used to complete the categorization process;
- 3) a clear framework for assessing weight of evidence and applying the precautionary approach in situations where sources of uncertainty are numerous and scientific data insufficient;
- 4) categorizing "in" those substances that do not meet criteria for P or B but are found to be iT, or to have other toxic concerns (to non-human or human organisms);

- 5) developing a process that identifies those substances to be known as "List B" with inadequate data for categorization, and a process for requirement of further testing.
- 6) ensuring that the definition of iT recognizes that the iT of a substance is a function of acute, chronic and sub-chronic toxicity, including carcinogenicity, neurotoxicity, endocrine disruption, mutagenicity and teratogenicity.
- 7) implementing a process to determine P of a substance that considers low dose toxicity, high volume emission scenarios, and the differential vulnerabilities of organisms to different substances via different exposure pathways.

In view of these concerns, and in anticipation of Environment Canada releasing a list of substances that meet the proposed criteria for P, and/or B and iT, we would propose that an advisory committee be established to discuss the issues emerging from the proposed guidance manual. Members of the NGO community would like to participate in an open and transparent process to discuss some of the challenges facing Health Canada and Environment Canada. We feel that the existence of the Technical Advisory Group that concluded its work in December 2001 allowed members to obtain scientific data and studies that would not otherwise available to NGOs. Such a forum also allowed for constructive input and discussion by NGOs on significant issues.

Recommendation: A multi-stakeholder advisory committee be established to address issues related to the DSL categorization process.

We hope that the comments, observations and recommendations made by members of the Toxics Caucus in this submission will be considered carefully by both Environment Canada and Health Canada as they finalize the framework for categorization. We are hopeful that this framework provides a foundation for further efforts to take timely and effective action on the most hazardous substances in the Canadian market. The members will be pleased to provide further comments as the process proceeds towards identifying those chemicals moving towards the SLRA phase.