ENGOS' COMMENTS ON THE CATEGORIZATION PROCESS AND ENVIRONMENT CANADA'S PROPOSAL ON POLYMERS AND UVCBS

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Executive Summary

Member organizations of the Canadian Environmental Network Toxics Caucus are pleased to provide the following submission on Environment Canada's approach to the categorization of the Domestic Substances List (DSL), and more specifically, its proposed treatment of polymers and Unknown or Variable Composition Complex Reaction Products and Biological Materials (UVCBs). This submission is pursuant to the long-term involvement of environmental non-governmental organizations (ENGOs) in Environment Canada's and Health Canada's efforts around categorization. In November, 2003, the members of the Toxics Caucus prepared a submission on Environment Canada's approach to categorizing organic substances. Additionally, ENGOs have provided comments on Health Canada's work, attended meetings with government and industry, and participated in teleconferences on an ongoing basis.

Recognizing that the categorization of the DSL is a precedent-setting task of significants implications on how substances are assessed, members of the Toxics Caucus support Environment Canada's efforts to complete the work in a thorough, fair, and timely manner. The purpose of this paper is to assist government in enhancing its approach and instilling a rigorous and defensible methodology. It is also anticipated that this paper will highlight opportunities for Environment Canada to advance the level of transparency in its decision-making processes. Our comments are intended to ensure the development of an effective framework for the identification, screening, and management of substances in use, and most importantly, for the elimination of the most hazardous ones.

The paper begins by exploring a number of issues which are shared jointly by Environment Canada and Health Canada, and accordingly should be addressed in a coordinated fashion. The next section focuses on specific issues which arise throughout Environment Canada's process, with an emphasis on the adequacy of data used in categorization decisions and the validity of the scientific approaches being applied. The following section is dedicated to Environment Canada's treatment of polymers and UVCBs, and lists a number of inherent assumptions which have yet to be substantiated. The paper finishes with a brief exploration of the path forward on the categorization efforts post-2006, and the central themes which will require further exploration and discussion as strategies for this phase evolve. The list of our recommendations is included in section 7.0. The environmental community will continue to communicate and respond to Environment Canada and Health Canada regarding proposals for further work on the elimination and reduction of hazardous substances in Canada.

1.0 Introduction

The members of the Toxics Caucus of Canadian Environmental Network (CEN) are aware that the objective of section 73[1] of the *Canadian Environmental Protection Act,*

[1] 73. (1) The Ministers shall, within seven years from the giving of Royal Assent to this Act, categorize the substances that are on the Domestic Substances List by virtue of section 66, for the purpose of identifying the substances on the List that, in their opinion and on the basis of available information,

1999 (CEPA 1999) is to categorize all 23,000 substances on the DSL, and that the deadline for completing this obligation is September 14, 2006. While the task is a daunting one, we would like to congratulate both Environment Canada and Health Canada for the progress they have made to date.

However, it is due to the very precedent-setting nature of the task that we are compelled to comment on, and object to, some of the shortcomings of the categorization effort. The approach to and impact of categorization is of critical importance to Canadians as well as to other countries faced with the challenge of evaluating thousands of marketed substances. We are concerned that the approaches currently taken by Environment Canada and Health Canada lack the strong foundation needed to ensure that all potentially harmful substances are captured in the categorisation process and considered for subsequent screening level risk assessments (SLRA).

The categorisation of the DSL provides Canada with the opportunity to become a world leader in the management and phase out of substances that may pose a risk to the environment or human health. The ultimate goal of categorization is for regulatory action to be taken in respect of those substances.

Recommendation 1: Member organizations of the Toxics Caucus emphasize the importance of establishing a strong categorization framework that effectively identifies *all potentially* hazardous substances. This is a critical requirement before the SLRA phase, where decisive regulatory action should be taken with respect to these substances.

2.0 Purpose of Submission

Member organizations of the CEN's Toxics Caucus are pleased to provide general comments on the categorization process utilised by Environment Canada and Health Canada with specific comments on Environment Canada's documents entitled "*Approach for the Ecological Categorization of Substances on the Domestic Substances List: Unknown or Variable Composition Complex Reaction Products and Biological Materials (UVCBs)*"and "*Approach for the Ecological Categorization of Substances on the Domestic Substances List: Polymers.*"

Additionally, a preliminary list of issues and criteria for the work required after 2006 is presented at the end of the submission. The comments and views presented in this submission expand upon the recommendations outlined in the previous ENGO paper on the proposed categorization approach for organic substances dated November, 2003. A

(a) may present, to individuals in Canada, the greatest potential for exposure; or

(b) are persistent or bioaccumulative in accordance with the regulations, and inherently toxic to human beings or to non-human organisms, as determined by laboratory or other studies.

separate detailed ENGO submission addressing specific issues relating to Health Canada's approach[2] on categorization is under development.

3.0 General Comments on Environment Canada and Health Canada's Approach to the Categorization of the Domestic Substances List

3.1 ENHANCING HEALTH CANADA AND ENVIRONMENT CANADA CO-ORDINATION

Recent communications with senior staff of Health Canada and Environment Canada continue to raise concerns that a lack of coordination may jeopardise the timely and effective completion of the categorization process. For example, it remains unclear how the two Ministries will collaborate in completing the categorization of UVCBs and polymers. The information provided in the June 1, 2005 session in Ottawa left us uncertain of the combined categorization process for these two groups of substances.

Under the assumption that all or nearly all of UVCBs and polymers are persistent (P), Environment Canada has decided to assess these substances for inherent toxicity (iT) to non-human organisms first and then base its path forward on the iT outcomes without assessing bioaccumulation (B) or P. Accordingly, Health Canada is obligated to follow a similar process and begin by assessing the iT to humans of those UVCBs and polymers that do not meet the ecological iT criteria. While we support the determination of iT for all substances, it is unclear how the process for requiring data for P or B is triggered by Health Canada's proposed Integrated Framework for the health-related components of DSL categorization. This is an instance where better communication between the two Ministries could help to resolve any discrepancies, avoid confusion, and keep messages to stakeholders consistent.

Furthermore, in keeping with the requirements of CEPA 1999, it is our view that, where persistence and bioaccumulation data are available for these substances, such data should be made publicly available through the categorization process. CEPA 1999 (section 77) mandates that toxic substances that are both P and B be virtually eliminated. Determining bioaccumulation in addition to persistence is important therefore for flagging substances that should be in the virtual elimination stream.

Recommendation 2: ENGOs support on-going efforts by Environment Canada and Health Canada to coordinate and communicate on their categorization process to ensure that issues relating to categorization approaches are addressed in a timely and effective manner.

Recommendation 3: Health Canada in coordination with Environment Canada should outline the process and criteria by which it identifies polymers and UVCBs that require persistence or bioaccumulation data from Environment Canada.

[2] Refer to Health Canada, "A Proposed Integrated Framework for the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999" (June 2005).

3.2 NEED FOR FOCUS ON SUBSTANCES THAT ARE PERSISTENT AND BIOACCUMULATIVE

For the purposes of categorization, CEPA 1999 only requires Environment Canada and Health Canada to compile a list of substances that meet the criteria for persistence or bioaccumulation and inherent toxicity, or that show the greatest potential for human exposure. It is likely therefore, that a number of potentially hazardous substances will be "categorized out" for failing to meet these criteria, including substances that are considered to be both P and B but not inherently toxic.

Based on the presentation made on June 1st, 2005 (page 5 of "Categorization and Screening of the Domestic Substances List: Path forward towards ecological prioritization of substances for assessment"), we are pleased to see that some consideration has been given to persistent and bioaccumulative substances. Despite these preliminary proposals, we strongly recommend that Environment Canada articulate a path forward for all DSL substances that meet the persistence and bioaccumulation criteria. These substances exhibit the characteristics of Persistent Organic Pollutants (POPs) and should not be simply set aside.

We further recommend that the substances that are identified as POPs, be placed on a separate list for immediate consideration and additional toxicity data gathering, including chronic toxicity (i.e. carcinogenicity, endocrine disruption, developmental toxicity). It is well-documented that Canada continues to be a recipient of POPs from domestic as well as global sources. The existence of a separate and distinct POPs list would provide useful guidance to Canada's domestic and international POPs efforts.

This proposal would assist the POPs Review Committee[3] established under the Stockholm Convention. As Parties prepare to submit nominations of POPs to the Committee, the Committee will be responsible for assessing data and information before making recommendations on which POPs should be added to the Convention for elimination or reduction under Annex A, B or C.

Recommendation 4: Those substances that meet the criteria for persistence and bioaccumulation should be identified and placed on a new and distinct list for further assessment and consideration of POPs traits.

3.3 CONFIDENTIAL DOMESTIC SUBSTANCES LIST (CDSL) AND CONFIDENTICAL BUSINESS INFORMATION (CBI)

The confidential Domestic Substances List (CDSL) has been inaccessible for review by the public throughout the categorization process. This lack of transparency is worrisome given that far-reaching decisions are being made on the basis of concealed Confidential Business Information (CBI). Furthermore, it is unclear to us how the Ministries will identify priorities for the screening level risk assessments of CDSL substances. We ask that Environment Canada and Health Canada explore ways of facilitating public review of the CDSL, or at the very least, public access to summaries of the non-confidential

[3] Stockholm Convention on Persistent Organic Pollutant, United Nations Environment Programme Chemicals, Article 19(6)

components of CDSL entries. Both Canadian and U.S. pesticide legislation offer useful models for providing access to information while protecting competitive advantage.

Recommendation 5: The relevant data on persistence, bioaccumulation, and inherent toxicity data should be made publicly accessible for CDSL substances.

Recommendation 6: Health Canada and Environment Canada should outline their processes for prioritising CDSL substances for SLRAs.

3.4 EFFECTIVENESS OF FEEDERS TO CAPTURE SUBSTANCES OF CONCERN

Environment Canada has identified seven information feeders for the existing substances program:

1. CEPA 1999 S. 73 DSL,
2. CEPA 1999 S. 70 Industry Information
3. Emerging Science
4. International assessment and Data Collection
5. CEPA 1999 S. 81-82 New Substances Notifications
6. CEPA 1999 S. 76 Public Nomination
7. CEPA 1999 S. 75 Provincial or International Decisions

Presentations at both the May 31 and June 1, 2005 meetings emphasized that DSL categorization is not the sole CEPA tool for dealing with toxic substances, and that the other feeders can fill any remaining gaps. ENGOs are unconvinced at this time that these other feeders will be effective in identifying or managing any missed substances, and we seek more information on Environment Canada's plans to utilize these feeders. Given the large amount of resources devoted to categorization, are there enough funds remaining to adequately address substances through the other feeders? What kinds of resources are available and are there plans to secure more? How will the two departments adjust their workplans to integrate and address new information gathered through other feeders?

Stakeholders could better assess the effectiveness of the various feeders if Environment Canada and Health Canada published an annual report summarizing government's use of the feeders and providing concrete information about the utility of these CEPA tools.

Recommendation 7: Environment Canada and Health Canada should prepare an annual report that summarizes the government's use of the seven feeders and provide information about its effectiveness as a CEPA tool for identifying, assessing and managing substances.

3.4.1 CEPA 1999 Section 70

Under section 70[4] of CEPA 1999, industry is obligated to provide information to the Minister where a substance that being manufactured, used, or imported into Canada for commercial use is toxic or capable of becoming toxic.

[4] Section 70. Where a person

Neither CEPA 1999 nor the presentations made on June 1st, 2005 make clear what kind of information is required to be submitted under this section, what the timeframe for submitting relevant information is, and whether this information is intended to be made publicly accessible. Further, it is unknown whether there have been any violations of this requirement (i.e., have there been situations where industry has not provided necessary information on a timely basis?). We are pleased to learn that efforts are underway to update the reporting guidelines for industry under section 70. It is extremely important that Environment Canada establish a clear process for revising the section 70 guidelines. ENGOs recommend that the guidelines include several key requirements to improve public access to information, including broader notification requirements for facilities and the enforcement of CEPA 1999 requirements with applicable fines for non-compliance.

Recommendation 8: Environment Canada should develop guidelines for information submitted under Section 70 of CEPA 1999. The guideline development process should include effective public participation.

3.6 *CEPA 1999* SECTION 71

It is impossible for Environment Canada and Health Canada to fulfill their task of categorizing DSL chemicals for P or B and inherent toxicity (non human and human organisms), and human exposure without reliable data, whether experimental or derived from well-validated models. However, there are many instances when such data is not available, especially for model-difficult substances like polymers and UVCBs. When there is a lack of data on any number of characteristics, including persistence, bioaccumulation, inherent toxicity, production volume, environmental occurrence, and environmental release, section 71[5] should be used to trigger a responsibility on the part of

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(*a*) imports, manufactures, transports, processes or distributes a substance for commercial purposes, or
(*b*) uses a substance in a commercial manufacturing or processing activity,
and obtains information that reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic, the person shall without delay provide the information to the Minister unless the person has actual knowledge that either Minister already has the information.

[5] Section 71. (1) The Minister may, for the purpose of assessing whether a substance is toxic or is capable of becoming toxic, or for the purpose of assessing whether to control, or the manner in which to control, a substance, including a substance specified on the List of Toxic Substances in Schedule 1,
(*a*) publish in the *Canada Gazette* and in any other manner that the Minister considers appropriate a notice requiring any person who is described in the notice and who is or was within the period specified in the notice engaged in any activity involving the substance to notify the Minister that the person is or was during that period engaged in that activity;
(*b*) publish in the *Canada Gazette* and in any other manner that the Minister considers appropriate a notice requiring any person who is described in the notice to provide the Minister with any information and samples referred to in subsection (2) that may be in the person's possession or to which the person may reasonably be expected to have access; and
(*c*) subject to section 72, send a written notice to any person who is described in the notice and who is or was within the period specified in the notice engaged in any activity involving the importation or manufacturing of the substance or any product containing the substance requiring the person to conduct toxicological and other tests that the Minister may specify in the notice and submit the results of the tests to the Minister.
Contents of notice
(2) A notice sent under paragraph (1)(*b*) may require any information and samples, including
(*a*) in respect of a substance, available toxicological information, available monitoring information, samples of the substance and information on the quantities, composition, uses and distribution of the substance and products containing the substance; and
(*b*) in respect of a work, undertaking or activity, plans, specifications, studies and information on procedures.

industry to provide that data within a reasonable timeframe. Although section 71 traditionally has been underused, its appropriate application could be an invaluable means of gathering necessary data and improving our state of knowledge about DSL substances. This, in turn, would lead to better, more defensible assessments on substances.

Recommendation 9: Where there is no data or only low quality data available for a substance, the onus should be placed on industry to supply the required information within a reasonable timeframe. In the meantime, these substances should not be categorized "out" or "set aside" but rather flagged as priorities for further action. This recommendation is consistent with the recommendations proposed under Section 4.1 on Uncertain Substances, below.

4.0 Specific Issues Focused on Environment Canada's Approach to Categorization

4.1 UNCERTAIN SUBSTANCES

The issue of how to deal with uncertain substances is not a new one, and has been addressed in previous submissions as well as in discussions with representatives from both Environment Canada and Health Canada. In our comments on Environment Canada's strategy for categorizing organic and inorganic substances, dated November 7, 2003, we recommended that, "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."[6] At this time, we would like to elaborate upon this recommendation and provide further guidance on how it could be operationalized.

Any discussion on the treatment of uncertain substances should first recognize that the precautionary approach is a CEPA guiding principle. The Preamble of CEPA makes special mention of government's commitment to the precautionary principle. In fact section 2(1) of CEPA 1999 specifies that, in exercising its duties in protecting the environment and human health, the government shall apply the precautionary principle where possible.

This is relevant to many facets of the categorization process. ENGOs recognise that Environment Canada has already attempted to integrate precautionary measures in a number of areas. For instance, evaluators will adopt the most conservative values where a range of data points exist. However, we suggest that the precautionary principle has yet to

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Compliance with notice
(3) Every person to whom a notice referred to in any of paragraphs (1)(*a*) to (*c*) is directed or sent shall comply with the notice within the time specified in the notice.
Extension of time
(4) Despite subsection (3), the Minister may, on request in writing from any person to whom a notice referred to in paragraph (1)(*a*), (*b*) or (*c*) has been sent, extend the time or times within which the person shall comply with the notice.

[6] Canadian Environmental Network Toxics Caucus, "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*" (November 7, 2003) at pg. 5.

be integrated into many other components of Environment Canada's approach. Importantly, the proposed treatment of uncertain and low confidence substances fails to incorporate this principle, contrary to the stated intent of CEPA and current trends within other government departments.

We have identified three primary groups of substances which merit further consideration with respect to this topic: first, those for which some data is available, but the data is considered by Environment Canada to be "low confidence"; second, those for which "data gaps" exist for specific endpoints, such as inherent toxicity; and third, those which lack any readily available data, be it experimental or model-generated or analogue.

4.1.1 Low Confidence Data

With respect to those substances for which some "low confidence" data is available, we must begin by congratulating Government's diligence in assessing the reliability of ecotoxicological and environmental fate studies. It is of critical importance that substances not be "categorized out" or deprived of screening level risk assessments on the basis of studies which are of dubious quality. However, the same studies could and should form the basis for "categorizing in" these substances, or requiring the provision of further data from industry. In other words, if a low confidence study indicates a suspicion of toxicity, this information should be used to trigger further administrative action.

This approach fits squarely within the legislative framework created by sections 71 and 73 of CEPA. It is also consistent with the approach adopted by other government departments, such as the New Substances Program. The Final Report of the Multistakeholder Consultations on the CEPA New Substances Notification Regulations, states that section 84(1)(c) of CEPA[7] should be employed where "a suspicion of toxicity arises and the available information is insufficient to adequately characterize the risk(s)."[8] This interpretation of the precautionary principle would be in accord with our recommended approach.

Having said this, there is some confusion regarding whether Environment Canada has already adopted this approach. According to the most recent "results" chart, it appears that a row has been added entitled "meets categorization criteria – low confidence". However, the April 2005 CD contains a document called "Guidance for evaluation of the reliability of ecotoxicological and environmental fate studies" which indicates that low confidence or unacceptable studies will not be considered for categorization purposes. Further clarification of the schemata would be appreciated.

Recommendation 10: Those substances that have only low confidence data available should be left on the list for further data collection and data generation. These substances should not be categorized "out" or "set aside" but rather flagged as priorities for further action.

[7] The equivalent provision for requiring industry to produce further data with respect to new substances.

[8] Environment Canada and Health Canada, "Consultations on the CEPA New Substances Notification Regulations and New Substances Program: Final Report of the Multistakeholder Consultations" (December 2001) at section 3.1.3.

Recommendation 11: If available science cannot ascertain with certainty whether a substance is harmful to the environment, the precautionary principle must be implemented. For instance, where low confidence data suggests that the categorization criteria have been met, then the substance should be "categorized in" for further consideration.

4.1.2 Data Gaps

There are also substances which lack data for either a specific endpoint or which lack any data whatsoever. In the case of the former, it is our understanding that full PBiT profiles will be developed in the face of uncertain iT data. We strongly support this treatment and view it as in keeping with the purpose and intent of categorization. Nevertheless, we are concerned that those substances for which all values are uncertain will not ultimately proceed to the screening level risk assessment phase.

At the technical meeting on May 31 with Environment Canada, it became apparent that only high volume uncertain substances would proceed on to receive risk assessments. The rationale for including only the highest volume subset is unacceptable; it is widely recognised that volume alone is not a strong predictor of exposure, and in any case the volume figures being relied upon are based on those quantities reported in 1986. There is absolutely no reason to assume that volumes of use 20 years ago are still comparable to those in existence today. The fact that many of these substances are known to be in High Production Volume (HPV) programs internationally does not lead inevitably to the conclusion that they are the only high volume "uncertain" substances in use in Canada today. Furthermore, if there are currently high production volume chemicals in use in Canada, then Canada should take this opportunity to aggressively request additional toxicity data to aid the categorization process. The current approach of waiting for other countries' HPV programs to address these substances is inadequate.

Environment Canada has argued that the reason for "categorizing out" the remaining medium and low volume uncertain substances is so that resources can be focussed on those substances known to present a hazard, as opposed to those with an unknown hazard potential. While we sympathise with the enormous challenges posed by categorization and the resource constraints under which Government must operate, we would argue that uncertain substances at all volume levels should be found to meet the categorization criteria, and the onus should be placed on industry to provide necessary data. This approach would seem to be more consistent with Environment Canada's treatment of high volume uncertain substances, as well as Health Canada's method of dealing with all substances with unknown exposure or unknown inherent toxicity to humans.

Recommendation 12: All uncertain substances, regardless of volume, should proceed on to the screening level risk assessment phase. Where necessary, industry should be required (S. 71) to provide the data necessary for a thorough assessment.

4.2 INCONSISTENCIES BETWEEN THE APPROACHES FOR CATEGORIZING DIFFERENT GROUPS OF SUBSTANCES

Environment Canada's approach to DSL categorisation process is inconsistently applied to different groups of substances. This may, or may not, be scientifically justified;

however, it also causes confusion and uncertainty in the reliability of the process among stakeholders. This lack of consistency is evidenced by the flowchart on the categorization process often presented by Environment Canada and Health Canada; the flowchart is misleading as it indicates that data for persistence and bioaccumulation are reviewed prior to determining inherent toxicity to the environment or human health. Clearly this is not always the case; for example, Environment Canada's approach to the categorization of polymers and UVCBs determines inherent toxicity before considering P and B. If a substance is not iT to the environment, Environment Canada will only provide P or B information if requested by Health Canada.

4.3 BIOACCUMULATION

In the absence of bioconcentration factor (BCF) and bioaccumulation factor (BAF) data, the K_{ow} is used to measure a substance's ability to bioconcentrate. The K_{ow} is usually expressed as log K_{ow}. An internationally accepted definition for log K_{ow} is the logarithm of the ratio of the chemical's concentration in octanol and water at equilibrium. Log K_{ow} by itself is a poor tool for predicting bioaccumulation potential. A high K_{ow} is not always an indication of a substance's propensity to bioaccumulate. For instance, despite meeting the Toxic Substance Management Policy's[9] (TSMP) log K_{ow} criteria of five, chemicals with high molecular weight are generally not bioavailable since large molecules are not able to penetrate through the cell membrane. In addition, there are substances with log K_{ow} values less than five that are able to extensively bioaccumulate in aquatic organisms.

Examples include some organotin compounds with log K_{ow} values of about 3.3 to 3.6, which have been found to have BCF values of over 5000. Similarly, lindane, an organochlorine pesticide, has a log K_{ow} in the range of 3.2 to 3.7, and yet field measurements suggest a BCF of 10,000 to 50,000 for bream and a BCF of 26,198 in common mussels. In light of these weaknesses in the predictive value of log K_{ow}, it should be used only at the screening stage and be accompanied by BCF and BAF values in the final analysis.

Also, a lower log K_{ow} value should be adopted so that its application includes all substances which may be potentially bioaccumulative. Our concerns with the use of log K_{ow} were raised in the ENGO submission of March 2003.

Additionally, the flow charts for determining bioaccumulation are confusing. The Persistence and Bioaccumulation Regulations (SOR/2000-107) under CEPA 1999 state that a substance is considered to be bioaccumulative if BAF > 5000, BCF > 5000 or log K_{ow} > 5. It is reasonable that Environment Canada considers these criteria in a hierarchical manner by assessing first BAF, then BCF, and finally log K_{ow}. However, Environment Canada's practice of re-examining BAF and BCF predictions through the weight of evidence approach whenever log K_{ow} is >5 seems inconsistent with the Regulations. If BAF and BCF test data is not available, then a substance with log K_{ow}

[9] Toxic Substances Management Policy is a federal policy aimed at virtual elimination and reduction of persistent and bioaccumulative toxic substances. Substances under Tier I are targeted for virtual elimination.

greater than five should be classified as bioaccumulative without imposing further barriers on the basis of modelled data.

Recommendation 13: Substances without bioconcentration or bioaccumulation factor data, that have log K_{ow} >5, meet the bioaccumulation criteria established under the categorization process as well as the Persistence and Bioaccumulation Regulations. These substances should be categorized in to ensure that all bioaccumulative substances are adequately captured for the SLRA.

4.4 REALISTIC PRESENCE IN MEDIUM

The Persistence and Bioaccumulation Regulations require that a substance meet the persistence criteria in any media. The proposed application of the realistic presence approach appears to contradict the requirements of these Regulations.

The rationale for using a 5% realistic presence cut-off is unjustified, and we have yet to be provided with adequate clarification of the science behind this approach. The value of 5% is mentioned as constituting a "significant presence" below which a substance could not be categorized as persistent or bioaccumulative. This seems to lack any basis in the TSMP or the Persistence and Bioaccumulation Regulations. Our view is that if a substance tests or models as P or B according to the Regulations, it should be categorized as such, regardless of partitioning behaviour. In other words, information derived through the application of the realistic presence criteria should not be used to categorize a substance as non-persistent or non-bioaccumulative, where empirical or model data has indicated otherwise.

We also have concerns about the reliability of realistic presence determinations. Partitioning is calculated using estimated rate constants rather than solid empirical data. Environment Canada has argued that the use of the 5% cut-off, as opposed to the 1% cut-off, has a minimal impact on the number of substances assessed as "persistent". However, we are rarely given information about which substances would be categorized in without *any* realistic presence criteria. The Canadian Environmental Modelling Centre's report to Environment Canada on partitioning and persistence predicted that 27% of substances meeting persistence criteria would be excluded using a realistic presence filter. Therefore, realistic presence criteria can have a significant impact on categorization. The fact that the application of these criteria is based on estimated values is of significant concern. In a categorization process already laden with uncertainties, we have yet to see any justification for introducing another uncertainty factor where there is no statutory or regulatory basis for doing so.

Recommendation 14: We reject Environment Canada's application of a realistic presence cut off to confirm P of a DSL substance. Substances which test or model as P or B according to the Regulations should be categorized as such, regardless of partitioning behaviour. These substances should proceed on to Health Canada for human toxicity assessments, and any relevant realistic presence determinations should be considered post-2006 when Environment Canada decides how best to prioritize substances for further action.

4.5 INHERENT TOXICITY ENDPOINT SELECTION

With respect to the nature of the endpoints being considered, we appreciate that Environment Canada is limited in terms of the readily available information it has at its disposal. Additionally, we understand that a more detailed analysis will be carried out during the SLRA phase for those substances which meet the criteria for categorization. However, we are concerned that certain key endpoints are not being systematically considered at the categorization phase.

4.5.1 Limited Consideration of Chronic Toxicity

It has been stated that "Environment Canada prefers to use acute toxicity studies over chronic toxicity studies because more empirical data and QSAR models are available for acute endpoints."[10] The lack of systematic consideration of chronic toxicity endpoints is extremely worrisome, and will result in some substances being "categorized out" on the basis of an incomplete PBiT profile. It is difficult, if not impossible, to accurately predict or extrapolate chronic toxicity on the basis of acute toxicity results; there are many substances, such as dioxin, which have dramatically different short-term and long-term effects. Such problematic substances may have multiple mechanisms of action, or may not exhibit any effects at all during the short duration of acute toxicity studies. For this reason, Environment Canada needs to expand the focus of its iT investigation to include chronic endpoints.

This issue is exacerbated by the fact that Environment Canada's approach to acute toxicity is, in itself, extremely narrow. By focussing primarily on aquatic toxicity, Environment Canada is limiting its review to a single type of ecotoxicology. Not all ecological life forms are aquatic, and not all types of ecotoxicological impacts will be accurately predicted by aquatic data. Furthermore, CEPA 1999 mandates Environment Canada to categorize substances on the basis of their iT to non-human organisms; nowhere in the statute is this language limited to aquatic species, or even to acute toxicity. While we understand that categorization is neither intended to nor capable of mimicking the function of SLRA, it should be capable of prioritizing those substances which are iT to a variety of organisms over both short and longer periods of time.

Recommendation 15: Considering only inherent toxicity to aquatic species is overly limiting and unacceptable for making informed categorization decisions. Other longer term endpoints, including chronic toxicity, should be considered in the categorization decision making process.

4.5.2 Inadequate Consideration of Endocrine Disruptors

The categorization process, as it stands, also fails to consider whether substances function as endocrine disruptors. Including endocrine disruption in inherent toxicity determinations would be consistent with both international efforts to identify endocrine disruptors as well as the New Substances (NS) Program's proposed initiatives. At the international level, a group within the OECD Task Force on Endocrine Disruptor Testing and Assessment has suggested that validated high throughput (or semi-high throughput)

[10] Environment Canada, "Ecological Categorization Criteria and Process for Substances on the Domestic Substances List" (April 2005).

screens will soon be available for identifying endocrine disruptors and for developing databases for use with QSARs. Additionally, models currently in existence are producing promising results.[11] Such information could be considered by Environment Canada in its weight-of-evidence approach. In keeping with the legislative mandate for use of the precautionary principle, Environment Canada should not wait for international acceptance and entrenchment of these methods before considering such information in their categorization decisions.

The Final Report of the Multistakeholder Consultations on the New Substances Notification Regulations included some strong language on the topic of endocrine disruptors. The Multistakeholder Table recognised the critical importance of identifying endocrine disruptors, and suggested that it may be appropriate to require further test data from industry where an endocrine disruptor potential is found to exist. Additionally, it was recommended that:

> The NSN Guidelines Document will be revised, subsequent to these consultations, to include a section dealing with endocrine disruption. In particular, the section will describe Environment Canada and Health Canada's approach to incorporating endocrine disrupting considerations in the course of conducting an assessment and proposed risk management outcomes. *This will include development of a database of substances that have shown evidence of endocrine disrupting effects.* This database, along with other available information, will be used by evaluators to identify whether substances under review are structurally related to substances shown to have endocrine disrupting activity. Depending upon the severity of the effect and the closeness of the analogue fit, this analogue information may form the basis for a suspicion of toxicity. *The guidelines will also indicate that as applicable validated SARs become accessible, they will be used appropriately in the assessment process. Furthermore, where this information leads to a suspicion of toxicity, appropriate control measures will be imposed, or requests for further test data under section 84(1)(c) of CEPA will be made as validated test procedures are determined.* Lastly, the section on endocrine disruption will inform stakeholders of the intent to amend the NS Program (Regulations or Guidelines) to include data requirements for determining endocrine disrupting potential as they become available [footnotes omitted] [emphasis added].

In light of these extensive recommendations, and in the spirit of maintaining consistency with other programs within Environment Canada, ENGOs recommend that government commit to a systematic review of DSL substances for endocrine disrupting potential as substantiated SARs or screens become accessible (either pre- or post-2006). Additionally, it is hoped that ample time and resources will be devoted to the advancement of the above-mentioned endocrine disruptor database, and that, where necessary and appropriate, industry will be required to supply further test data to help inform evaluators and assist in the substantiation of QSARs.

[11] See, for example, the models developed by Ovanes Mekenyan and by the FDA in Arkansas.

Those substances exhibiting estrogenic properties are a good example of how categorization could fail to adequately consider inherent toxicity to non-human organisms. Estrogens are both hormonally active and potentially carcinogenic. There is growing evidence that estrogens can cause harm to humans and non-humans alike. It remains to be seen whether estrogenic substances will be captured, but certainly a robust assessment of toxicity should capture estrogenic substances as inherently toxic.

Recommendation 16: Environment Canada should commit to a systematic review of DSL substances for endocrine disrupting potential as substantiated SARs or screens become accessible (either pre- or post-2006).

Recommendation 17: Adequate time and resources should be devoted to the advancement of an endocrine disruptor database, and, where necessary and appropriate, industry should be required to supply further test data to help inform evaluators and assist in the substantiation of QSARs.

4.5.3 Metabolism

Many would argue that metabolites should not be examined because, in general, metabolic models and processes are complex. There are, however, some metabolic processes which are simple to predict, and these should be included in Environment Canada's evaluation. One such example is hydrolysis. Under Environment Canada's approach, when a substance is determined not to be persistent due to hydrolysis, the daughter products are not addressed. We recommend that all esters, amides, azides and hydrazines be evaluated as their parent and hydrolysis daughters. These substances may be hydrolyzed in the environment and/or in the body. The reason that both parent and daughter substances should be evaluated is that the parent may be bioaccumulative and the daughters generated after accumulation extremely toxic. For instance, hydrolysis of azides and amides often results in primary aromatic amines, which are typically highly toxic.

Recommendation 18: We recommend that all esters, amides, azides and hydrazines should be evaluated as their parent and hydrolysis daughters.

4.6 USE OF QSARS

Environment Canada's document "Guidance for evaluation of the reliability of ecotoxicological and environmental fate studies" explains how the reliability of data is evaluated by assigning confidence ratings to test reports and scientific literature according to a predictable ranking system. There remains, however, some uncertainty regarding whether a parallel system exists for the evaluation of QSARs. If so, it is unclear how government would integrate the two ranking systems in reaching its final determination of high, medium, or low confidence in a substance's overall PBiT profile. We are aware that there are certain rules of thumb which assist evaluators in selecting and interpreting QSARs, but we have not been provided with a detailed analysis of how these rules are applied. The fact that some QSARs being relied upon by Environment Canada have not been substantiated, or have not been substantiated for each endpoint, makes this issue even more pressing. We recognise that, due to the sparse amount of

readily available experimental data, many if not most of Environment Canada's decisions will be made on the basis of modelled or even purely qualitative data.

Additionally, page 22 of the "*Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List*" states that "Environment Canada assumes that the quality of the experimental data used to build a QSAR has been verified by the QSAR builder during development," but there is no substantiation given for why confidence should be placed in this assumption.

Recommendation 19: Environment Canada should clarify how the relative accuracy of QSAR predictions is evaluated and factored into categorization decisions.

4.7 USE OF ANALOGUES

On page 21 of the "*Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List*", Environment Canada states that "substances that are 'model-difficult' and have few or no reliable direct or analogue experimental data will require the application of qualitative analysis with no baseline (i.e., an analogue) from which to extrapolate."[12] Based on the significant assumptions necessarily involved in the application of qualitative information, we question whether this sort of information should be allowed to form the sole basis for categorization decisions.

Recognising that qualitative analysis and basic rules of thumb are used in deciding the suitability of an analogue, it would be helpful to know what criteria and assumptions are used to ensure that such decisions are made in a systemic and consistent manner. Given that analogues are deemed to be an even less desirable source of information than QSARs, we hope that evaluators are very stringent in the application of analogue data.

Recommendation 20: In keeping with the recommendations made below in section 5.1, substances should not be "categorized out" on the sole basis of analogue data, but should be "categorized in" if this data indicates that the categorization criteria have been met.

5.0 Specific comments on Proposed Approach to the Categorization of Polymers and UVCBs

5.1 LOW ECOTOXICOLOGICAL CONCERN POLYMERS AND UVCBS

We have concerns regarding the approach Environment Canada is using to identify low concern polymers and UVCBs. The classification of low concern substances is pivotal to the decision-making process. It takes place early in the course of categorization and is used to determine not only which substances are "categorized in", but also which substances will be reviewed for persistence and bioaccumulation. Thus, it is particularly

[12] Environment Canada, "Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List" (June 2003) at pg. 21.

important that only those truly non-toxic polymers and UVCBs be labelled as low concern.

With respect to low concern polymers, we question the rationale for basing the decision on both Schedule X of the New Substances Notification Regulations and the U.S. EPA Polymer Exemption Manual. While we recognise that DSL categorization does not import the same objectives as NSN assessments, it would seem that Environment Canada should nonetheless strive for consistency in areas where the two processes can be used to inform each other. Under the NSN, a list of low concern monomers has already been identified in Schedule X. This list is based upon the Canadian experience, and purposely does not include U.S.-identified low concern polymers by reference. It is hard to imagine why the Existing Substances branch has chosen to expand the low concern category beyond that which was already thoughtfully selected for the NSN. By doing so, the level of transparency is greatly reduced since the protocols being relied upon are those of a foreign jurisdiction.

Additionally, Environment Canada has indicated that no polymers on a HPV Program will be categorized as low concern. Does this indicate that volume is a consideration in gauging a polymer's toxicity? Further clarification on this point would be of value.

With respect to low concern UVCBs, our concern relates more to the lack of information with which we've been provided. The document "Approach for the Ecological Categorization of UVCBs on the DSL," suggests that the qualitative application of expert judgement and readily available information be used to determine whether UVCBs are of ecotoxicological concern. It would be very useful if Environment Canada could provide some explanation and substantiation of the criteria being relied upon to reach these critical decisions.

Recommendation 21: The identification of low concern polymers should be based upon, and consistent with, the Canadian approach under the NSN Regulations.

Recommendation 22: Environment Canada should provide information and explanation regarding the process by which assessors identify UVCBs of low concern.

5.2 SUPPORTABILITY OF ASSUMPTIONS ON POLYMERS AND UVCBS

While we recognize and appreciate the significant effort made by Environment Canada to undertake the categorization of polymers and UVCBs, there are significant gaps in its proposed approach which threaten the validity of categorization decisions. For instance, there are a number of unsubstantiated assumptions being applied. Some of these may already have been considered and accounted for, in which case the provision of additional data may help to alleviate the concerns expressed by ENGO participants.

The following is a select list of these assumptions, for each of which it would be useful to know its accuracy and how conservative it is:

5.2.1 General

- Many of the experiments and QSARs being relied upon for an indication of persistence do not report half-life. Rather, a number of standardized assumptions are used to extrapolate regulatory half-life criteria from the test data output.
- It is of concern that there are no generic criteria for similarity applied to the identification of groups and sub-groups of polymers and UVCBs. It would seem that the inherent assumptions involved in the grouping exercise would be more supportable if they weren't made on a case-by-case basis.

5.2.2 Specific Assumptions Applied in the Categorization of UVCBs

The following assumptions are made in the categorization of UVCBs:

- UVCBs are grouped according to their chemical compositions and properties. The first assumption made by Environment Canada is that each UVCB has been appropriately allocated to a Tier I, Tier II, etc. grouping.
- Once assigned a group and sub-group, the UVCB will be categorized according to the approach developed for that group. "Should the group be identified as having low ecotoxicological concern, no further categorization work (i.e. no PBiT profile development) will be performed by Environment Canada."[13] This assumes that substances within a group exhibit similar characteristics and pose the same hazards, and should thus be categorized in a similar manner.
- For inorganic UVCBs, Environment Canada's iT is based on a dual consideration of toxicity and solubility. This approach assumes that relatively insoluble substances will not be sufficiently bioavailable to cause a toxic effect. However, for those substances which bioaccumulate and for which there is a large uncertainty in the LC50 values, the water concentration should not be regarded as a central factor in the assessment. Rather, all substances that bioaccumulate and have an LC50 below the criteria should be considered iT.
- For biological UVCBs, when experimental data is not available for the whole UVCB, toxicity will be gauged according to the characteristics exhibited by its organic and inorganic components. How strong a predictor of the whole UVCB's toxicity are the toxicity levels of its component parts?
- For organic, organic metal salt, and biological UVCBs which lack a representative structure or which cannot be modelled, "expert judgement will be used to predict UVCB's bioaccumulation or persistence in the environment compartments." Upon what assumptions are these sorts of decisions based?

5.2.3 Specific Assumptions Applied in the Categorization of Polymers

As with UVCBs, several initial assumptions are made in the process of categorizing polymers:

- In many cases, Environment Canada will evaluate toxicity on the basis of the absence or presence of reactive functional groups. The polymer's reactive functional groups are, in turn, predicted by its qualitative composition (i.e. monomers, reactants, and prepolymers). This approach is based on the assumption that qualitative composition

[13] Environment Canada, "Approach for the Ecological Categorization of Substances on the Domestic Substances List: UVCBs" (April 2005) at pg. 4.

can provide an accurate reflection of reaction potential. However, we have identified instances where some polymers are categorized in and others categorized out on the basis of the same constituent monomer. For example, some (chloromethyl) oxirane polymers are listed as iT (i.e. CAS numbers 68036953, 54910075, 49763102) but others are identified as not iT (i.e. CAS numbers 9003365, 29690822, 37382799), yet the homopolymer (CAS number 24969060) for (chloromethyl) oxirane is still under review.

- When grouping polymers, it is said that larger groups may be justified "when the toxicity of the group is generally low."[14] This seems to imply that the assumptions being made in the grouping exercise are not rigorous enough to chance on a high-risk group of substances.

Recommendation 23: Environment Canada should provide detailed information substantiating the accuracy of the assumptions noted above.

6.0 Specific Comments on Path Forward Towards Ecological Prioritization of Substances for Assessment Post-2006

There are a number of comments and issues of importance regarding activities beyond September 2006. The ENGOs present at the June 1st meeting are pleased to note that some thought and discussion has been initiated on this point. We recognise that the presentation made by Environment Canada at that meeting was preliminary in nature, and accordingly these comments should be regarded as simply setting the groundwork for a more extensive discourse to follow. We anticipate having the opportunity to submit more detailed feedback following future meetings with Environment Canada and Health Canada in which our issues and concerns regarding post-2006 activities can be addressed in depth.

Having said this, we are concerned that both Departments seem to be missing important opportunities to set a national agenda that will ensure the assessment and management of toxic substances in Canada remains a priority for the years to come. ENGOs have consistently advocated for a stronger co-ordination of efforts aimed at ensuring that the worse toxic substances are addressed in an effective and timely manner. Based on our preliminary review of the June 1st presentation, it is our view that the proposed path forward does not go far enough in this direction. The projected timelines for reviewing data and conducting assessment of uncertain and model-difficult substances well into 2025 is disturbing. Based on our experiences with the categorization process to date and with the Priority Substances route, it is clearly evident that the proposed plan adopts a very open-ended approach to managing toxic substances. This approach is unacceptable.

Rather, Environment Canada and Health Canada should address the identification, assessment, and management of substances in an integrated and forward-thinking manner. The categorization requirement in CEPA is unique and should be viewed as the first step towards regulatory action on all hazardous substances. The approach should

[14] Environment Canada, "Categorization Approach for Grouping DSL Polymers to Determine Persistence and Inherent Toxicity to Non-human Organisms" (April 2005) at pg. 2.

reflect a *mandatory* reverse onus obligation whereby government departments require toxicity data from industry in order to demonstrate that substances pose no harm, and priority should be given to the development of safe alternatives and to industries which employ clean technologies. By 2016, we recommend that any substances which still pose an indeterminate risk (i.e. lack toxicity data) should be eliminated from the DSL and subject to the New Substances Notification requirements prior to further use. Furthermore, a subsequent, supplementary categorization and screening of the DSL should be planned post-2006, based upon those endpoints which are absent from, or inadequately incorporated into, Environment Canada's and Health Canada's current approach, including carcinogenicity, chronic toxicity, and endocrine disruption. These steps are critical to ensuring that the path forward leads to the concrete elimination and reduction in use and generation of toxic substances.

To further the discussion of June 1st, we have highlighted the following components which are key to developing a path forward for post-2006:

1) The *legislative* requirements for work beyond 2006 should be articulated.
2) An *integrated approach* that includes both Health Canada's and Environment Canada's proposed activities is required. There is clearly a need to define the responsibilities and objectives for each department and how the two departments will co-ordinate their efforts.
3) Environment Canada and Health Canada should clearly identify how *other aspects* of assessment and management activities will be integrated into the priorities for post-2006 work on categorization and data collection. A coordinated workplan for both departments would demonstrate where additional resources are required.
4) Clear *timelines* are needed.
5) *Stakeholders* and opportunities for stakeholder involvement need to be identified at the outset. As soon as possible, an expert multistakeholder group should be established to oversee the steps leading up to 2006 and beyond; the group should include adequate representation from among the ENGOs.
6) Details are needed on how the various *feeders* are being integrated, and how effective they are expected to be at filling the gaps identified.
7) Mechanisms should be developed to *measure the effectiveness* of the approach adopted.
8) Transparent *public reporting* out on progress is a required element of this effort.

Members of the CEN Toxics Caucus would be interested in further discussions on the development of this post-2006 process.

Recommendation 24: Members of the CEN Toxics Caucus support and encourage active engagement in discussions with Health Canada and Environment Canada as they develop a program on DSL substances beyond 2006.

Recommendation 25: By 2016, any substances which still pose an indeterminate risk should be eliminated from the DSL and subject to the New Substances Notification requirements prior to further use.

Recommendation 26: A subsequent, supplementary categorization and screening of the DSL should be planned post-2006, based upon those endpoints which are absent from, or inadequately incorporated into, Environment Canada's and Health Canada's current approach, including carcinogenicity, chronic toxicity, and endocrine disruption.

Recommendation 27: A multi-stakeholder expert group should be formally established to address the path forward plans for post 2006.

7.0 List of Recommendations

This submission lists 24 recommendations related to various aspects of categorization by Environment Canada and Health Canada on the DSL substances under CEPA.

Recommendation 1: Member organizations of the Toxics Caucus emphasize the importance of establishing a strong categorization framework that effectively identifies *all potentially* hazardous substances. This is a critical requirement before the SLRA phase, where decisive regulatory action can and should be taken with respect to these substances.

Recommendation 2: ENGOs support on-going efforts by Environment Canada and Health Canada to coordinate and communicate on their categorization process to ensure that issues relating to categorization approaches are addressed in a timely and effective manner.

Recommendation 3: Health Canada in coordination with Environment Canada should outline the process and criteria by which it identifies polymers and UVCBs that require persistence or bioaccumulation data from Environment Canada.

Recommendation 4: Those substances that meet the criteria for persistence and bioaccumulation should be identified and placed on a new and distinct list for further assessment and consideration of POPs traits.

Recommendation 5: The relevant data on persistence, bioaccumulation, and inherent toxicity data should be made publicly accessible for CDSL substances.

Recommendation 6: Health Canada and Environment Canada should outline their processes for prioritising CDSL substances for SLRAs.

Recommendation 7: Environment Canada and Health Canada should prepare an annual report that summarizes the government's use of the seven feeders and provide information about its effectiveness as a CEPA tool for identifying, assessing and managing substances.

Recommendation 8: Environment Canada should develop guidelines for information submitted under Section 70 of CEPA 1999. The guideline development process should include effective public participation.

Recommendation 9: Where there is no data or only low quality data available for a substance, the onus should be placed on industry to supply the required information within a reasonable timeframe. In the meantime, these substances should not be categorized "out"

or "set aside" but rather flagged as priorities for further action. This recommendation is consistent with the recommendations proposed under Section 4.1 on Uncertain Substances, below.

Recommendation 10: Those substances that have only low confidence data available should be left on the list for further data collection and data generation. These substances should not be categorized "out" or "set aside" but rather flagged as priorities for further action.

Recommendation 11: If available science cannot ascertain with certainty whether a substance is harmful to the environment, the precautionary principle must be implemented. For instance, where low confidence data suggests that the categorization criteria have been met, then the substance should be "categorized in" for further consideration.

Recommendation 12: All uncertain substances, regardless of volume, should proceed on to the screening level risk assessment phase. Where necessary, industry should be required (S. 71) to provide the data necessary for a thorough assessment.

Recommendation 13: Substances without bioconcentration or bioaccumulation factor data, that have log K_{ow} >5, meet the bioaccumulation criteria established under the categorization process as well as the Persistence and Bioaccumulation Regulations. These substances should be categorized in to ensure that all bioaccumulative substances are adequately captured for the screening level risk assessment.

Recommendation 14: We reject Environment Canada's application of a realistic presence cut off to confirm P of a DSL substance. Substances which test or model as P or B according to the Regulations should be categorized as such, regardless of partitioning behaviour. These substances should proceed on to Health Canada for human toxicity assessments, and any relevant realistic presence determinations should be considered post-2006 when Environment Canada decides how best to prioritize substances for further action.

Recommendation 15: Considering only inherent toxicity to aquatic species is overly limiting and unacceptable for making informed categorization decisions. Other longer term endpoints, including chronic toxicity, should be considered in the categorization decision making process.

Recommendation 16: Environment Canada should commit to a systematic review of DSL substances for endocrine disrupting potential as substantiated SARs or screens become accessible (either pre- or post-2006).

Recommendation 17: Adequate time and resources should be devoted to the advancement of an endocrine disruptor database, and, where necessary and appropriate, industry should be required to supply further test data to help inform evaluators and assist in the substantiation of QSARs.

Recommendation 18: We recommend that all esters, amides, azides and hydrazines should be evaluated as their parent and hydrolysis daughters.

Recommendation 19: Environment Canada should clarify how the relative accuracy of QSAR predictions is evaluated and factored into categorization decisions.

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Recommendation 21: The identification of low concern polymers should be based upon, and consistent with, the Canadian approach under the NSN Regulations.

Recommendation 22: Environment Canada should provide information and explanation regarding the process by which assessors identify UVCBs of low concern.

Recommendation 23: Environment Canada should provide detailed information substantiating the accuracy of the assumptions noted above.

Recommendation 24: Members of the CEN Toxics Caucus support and encourage active engagement in discussions with Health Canada and Environment Canada as they develop a program on DSL substances beyond 2006.

Recommendation 25: By 2016, any substances which still pose an indeterminate risk should be eliminated from the DSL and subject to the New Substances Notification requirements prior to further use.

Recommendation 26: A subsequent, supplementary categorization and screening of the DSL should be planned post-2006, based upon those endpoints which are absent from, or inadequately incorporated into, Environment Canada's and Health Canada's current approach, including carcinogenicity, chronic toxicity, and endocrine disruption.

Recommendation 27: A multi-stakeholder expert group should be formally established to address the path forward plans for post 2006.

8.0 Conclusions

The effort to categorize the 23,000 substances on the DSL is a significant undertaking. The global community will be monitoring Canada's progress as the categorization program unfolds. Hence, the ENGOs have placed great emphasis on the need to build a strong methodology for making categorization decisions. The methodology should be one based on transparency and consistency in approach. The ENGOs' submission outlines a number of areas where improvements to the proposed categorization approach by Environment Canada and Health Canada can be made to ensure that all substances posing a potential hazard to the environment and human health are adequately targeted for SLRAs.

As noted in the introduction of this submission, the categorization process is a critical step towards taking regulatory action on these substances. The discussion on the path forward post-2006 is both timely and needed. Efforts to be undertaken post-2006 will determine how effective the categorization exercise has been and whether the goal of eliminating and reducing some of the worse hazardous substances has been achieved. The ENGOs have outlined a number of critical components required by Environment Canada and Health Canada to ensure that a transparent and progressive process is developed.