Non-Governmental Organizations' Preliminary Comments on Path Forward Activities Post September-2006 for Substances Categorized under the *Canadian Environmental Protection Act (*CEPA 1999)

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Submitted to

Environment Canada and Health Canada

Submitted by:

Canadian Environmental Law Association

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Table of Contents

Executive Summary

The following report outlines a number of comments raised and discussed by non-governmental organization (NGO) participants in three meetings organized between July 28 and November 22, 2005 by Environment Canada and Health Canada. The meetings dealt with proposed post-2006 activities by both departments on substances that meet the categorization criteria as outlined in the *Canadian Environmental Protection Act.*

The NGO participants submit these comments to provide guidance to Health Canada and Environment Canada as these departments prepare the public consultation document in the coming weeks. Since 2000, NGOs have identified a number of gaps in the framework proposed by the departments to categorize the 23,000 substances on the Domestic Substances List (DSL). This report should be read in light of previous NGO comments and submissions pertaining to these concerns, and the recommendations submitted in past reports remain relevant. The issues raised in this report specifically pertain to the current categorization framework, as adopted by the two departments.

A number of positions have been outlined by the NGO participants. We expect to provide additional comments and critique when the draft public consultation document is released for public comments. Below are the positions contained in this report.

Position: NGO participants propose that the government should clearly identify and communicate its objectives in using surveys.

Position: Surveys should not be limited to PBiTs alone, but should be broadly applied to low confidence and uncertain substances as well.

Position: Government also should not import an explicit or implicit volume threshold into their use of surveys. Efforts should be made to administer surveys in a comprehensive manner to both high- and low-volume users, including research facilities.

Position: Surveys and SNAcs should be used early in the process, with appropriate and timely deadlines set for industry feedback.

Position: Government should communicate the process it will follow in response to industry's feedback (or lack thereof).

Position: The development and use of surveys should take place in a transparent and inclusive manner, and include participation by NGOs. The results of the surveys and the ensuing decisions by government should be made publicly available through an on-line electronic means, and there should be a open review process through which the adequacy of the data may be validated.

Position: Government is required to undertake screening assessments (SAs) for human health and the environment on all substances found to meet the Section 73 (1)(a) and (b) criteria as of September 14, 2006.

Position: The limitations of the categorization and screening assessment frameworks should be openly communicated, and SAs should specify areas of uncertainty and levels of confidence.

Position: It would assist the transparency of the process if government would clarify what data or information is required in order to complete the SAs.

Position: Government should delineate the transparent thresholds which must be met in the SA to indicate a substance is either "CEPA-toxic", subject to no further action, or subject to the in-depth assessment phase.

Position: Government should respond to information gaps in a precautionary manner, and clearly communicate what steps it will take in response to ambiguous screening assessments. The application of the precautionary principle may include: adopting immediate risk mitigation measures (that include consideration of elimination and phase out of the substance), sending the substance for a full assessment, or issuing a notice requiring additional data under section 71(1)(c).

Position: Government should require an inventory of safe alternatives to be taken at the SA phase, if not sooner. Such an inventory should include not only existing alternatives, but also alternatives in development and those which could be developed within a reasonable timeframe.

Position: There should be an onus on industry either to produce the toxicity information needed to show that a substance will not cause harm, or to adopt safe alternatives.

Position: Post-September 14, 2006, newly submitted industry information should be incorporated into SA decisions, *not categorization decisions.*

Position: It is critically important for government to impose a reasonable timeframe for industry's involvement, and to clearly communicate the implications for industry if deadlines are not met.

Position: EC's and HC's joint timeline should provide for input from the other feeders and periodic re-prioritization on the basis on new information.

Position: Government should provide public progress reports and performance indicators.

Position: There should be further discussion on the scope of, and process for finalizing, the State of the Science reports, in the context of the questions raised above.

Position: In conducting SAs and any subsequent assessments, government should account for the cumulative effects of substances with a common mode of toxicity and for mixtures.

Position: We suggest that a science and toxicology panel be formed to discuss whether the use of the MOE is appropriate in screening assessments as a means of making decisions on toxicity and risk management . Other questions to be discussed should include whether other approaches will be applied in future screening assessments by Health Canada and Environment.

Position: Government should engage stakeholders in further discussions on the consideration and inclusion of endocrine disruptors in the SA process.

Position: Survey information gathered on existing risk management measures should not be used to replace SAs or to conclude on the adequacy of those measures. Rather, the information should be used to inform the screening assessment and risk management phases. For high priority substances (i.e., PBiTs) and those no longer in commerce, it is hoped that the survey information will prompt government to take immediate action (such as adopting pollution prevention measures) to mitigate the risks from these substances.

Introduction and Background to Report

We welcome the opportunity to participate in the recent series of stakeholder meetings between Environment and Health Canada, members of the Industry Coordinating Group (ICG) and NGO participants. At the last three meetings (July 28, September 8 and November 22), discussions proceeded rapidly from categorization issues to path forward issues related to screening assessments (SAs) and risk management. We appreciate the effort put forth by Environment Canada and Health Canada to coordinate these meetings and seek stakeholder input on the topics covered.

Participants have made extensive comments and presentations intended to facilitate progress. Generally, the multi-stakeholder discussions have been very positive and open; however, it is unclear at this time how comments will be considered, responded to, and ultimately integrated into the decision-making process. Additionally, the subject matter under review reflects, and at times overlaps with, significant issues for the upcoming CEPA-review process. Given these realities, we felt it prudent to document some of the concerns and comments which we have voiced in the latest round of discussions. We hope that these comments will be useful as the two departments complete their public consultation document.

The comments submitted below are not intended to diminish or alter the positions and recommendations contained in previous NGO submissions to the departments earlier in the categorization effort. It is our intention to provide formal comments on the consultation document during the public comment period.

Below we have limited our comments to three specific issues: Use of Surveys; Screening Assessments; and Risk Management.

We appreciate the effort put forth by Environment Canada and Health Canada to coordinate these meetings and seek stakeholder input on the topics covered. It is our intention to provide formal comments on the consultation document during the public comment period.

Use of Surveys

Objectives

We appreciate the importance of collecting up-to-date, accurate information on industry's use of certain substances through the application of the survey provisions in section 71(1). When applied in a rigorous manner, surveys have the potential to advance several post-2006 objectives, including timely treatment of "categorized in" substances,

increased understanding of "categorized out" uncertain substances[1], and minimization of resources spent on substances no longer in commerce. It is not only important to keep sight of these end goals when developing the survey process, but useful from a communications perspective for government to clearly articulate its objectives in conducting surveys.

Position: NGO participants propose that the government should clearly identify and communicate its objectives in using surveys.

Scope

The discussions thus far have focussed on developing an acceptable approach for substances which are persistent, bioaccumulative, and inherently toxic (PBiTs). Certainly, PBiTs are an understandable priority for government action. Moreover, this work is expected to contribute significant information to Canada's international activities under the POPs Review Committee, established to identify POPs for addition under the Stockholm Convention on Persistent Organic Pollutants.

However, there is no justification for limiting surveys and Significant New Activity (SNAc) notices to this group of substances. There is a recognition that low confidence (categorized in) and uncertain (categorized out) substances also merit proactive treatment through surveys. While information gaps for some of these substances may ultimately be filled through monitoring or through international initiatives, the use of surveys and/or SNAcs is one of the few ways in which Canada can actively advance scientific understanding and demonstrate a leadership role in bridging the information gaps on existing substances. Our concern is that these potentially toxic substances will otherwise remain active in Canadian commerce and on the "categorized in" list or the uncertain "list" for years or even decades. There is no justifiable reason for limiting the application of these important tools to PBiTs alone at this time.

Accordingly, we would support the broad application of surveys to achieve a wide array of end goals, including but not limited to: gathering information to identify stakeholders, quantities, uses/applications, and target sectors; informing prioritization efforts; and filling information gaps in screening assessments (including the assessments of PiTs and BiTs). Government also should not import an explicit or implicit volume threshold into their use of surveys; efforts should be made to contact even low-volume users, such as research facilities. The importance of this is underscored by a recent study which associated maternal exposures to solvents in laboratories and other workplaces with a number of adverse neuro-behavioural effects in offspring.[2] [3]

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[1] Please note our fundamental opposition to uncertain substances being "categorized out", as formulated in Recommendation #12 of the "ENGOs' Comments on the Categorization Process and Environment Canada's Proposal on Polymers and UVCBs" (July 5, 2005):

> 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.

[2] Laslo-Baker D, Barrera M, Knittel-Keren D, Kozer E, Wolpin J, Khattak S, Hackman R, Rovet J, Koren G. "Child developmental outcome and maternal exposure to solvents" (July 2005) Arch Pediatr Adolesc

We emphasize, in particular, the usefulness of surveys in providing additional information at the SA phase. Through screening assessments, government has the opportunity to examine broad chemical characteristics extending beyond the basic PBiT criteria. Survey information could play a critical role in determining which chemicals should proceed to full risk assessment.

Position: Surveys should not be limited to PBiTs alone, but should be broadly applied to low confidence and uncertain substances as well.

Position: Government also should not import an explicit or implicit volume threshold into their use of surveys. Efforts should be made to administer surveys in a comprehensive manner to both high- and low-volume users, including research facilities.

Timing and Process

We foresee several ways in which the application of survey and SNAc provisions could be derailed, or lose effectiveness, as the prioritization and assessment of substances proceeds. First, surveys and SNAcs should be used early in the process to ensure that time and resources are not wasted on circuitous or incomplete information-gathering exercises. While it is acknowledged that there are several good preliminary sources of information, including internet data searches and industry meetings, we hope that reliance on these approaches does not eclipse the need for comprehensive, mandatory feedback, and concrete action through the use of SNAcs. It is noted that interested industries have been given ample opportunity to provide voluntary information throughout the categorization process.

Once the choice is made to issue a survey, it is important that appropriate and proactive deadlines are set for industry response, and predictable government responses are communicated. For instance, where surveys are required to identify stakeholders and use patterns, it should be clearly conveyed that SNAc provisions will be applied if industry does not respond in a timely manner. It should also be evident that any new use of these substances would be subject to the New Substances Notification Regulations, and that the substances could potentially be deleted from the DSL.[4] Where surveys are intended to fill information gaps in screening assessments, the consequence of industry inaction should be immediate precautionary risk mitigation, mandatory data production under section 71(1)(c), and/or sending the substance for a full assessment. There is also the question of what enforcement measures will be directed towards those facilities which fail to respond to the survey or to the SNAc provisions, despite the fact that they use the

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Med. 159(7): 956-961.

[3] Alonso-Magdalena, P, S Morimoto, C Ripoll, E Fuentes and A Nadal. 2006. **"**The Estrogenic Effect of Bisphenol-A Disrupts the Pancreatic ß-Cell Function ***in vivo*** and Induces Insulin Resistance" (2006) Environmental Health Perspectives 114: 106-112.

[4] We are aware that delisting substances from the DSL may require amendments to CEPA. NGOs have identified this matter as an issue for the CEPA legislative review.

substances specified. Government's strong and clear communication on these issues would help promote transparency, a desirable goal for the NGO community.

Finally, we reiterate the need to maintain transparency in the use of surveys and SNAcs. The NGO community is capable of, and interested in, providing useful input at the survey development stage. Additionally, the results of the surveys and the ensuing decisions by government should be made publicly available through an on-line electronic means, and there should be a open review process through which the adequacy of the data may be validated.

Position: Surveys and SNAcs should be used early in the process, with appropriate and timely deadlines set for industry feedback.

Position: Government should communicate the process it will follow in response to industry's feedback (or lack thereof).

Position: The development and use of surveys should take place in a transparent and inclusive manner, and include participation by NGOs. The results of the surveys and the ensuing decisions by government should be made publicly available through an on-line electronic means, and there should be a open review process through which the adequacy of the data may be validated.

Screening Assessments

Our comments on the SA phase are premised on the understanding that government is required to undertake SAs for human health and the environment on all substances found to meet the Section 73 (1)(a) and (b) criteria as of September 14, 2006. Should government permit certain substances to circumvent the section 74 SA requirements on the basis of data submitted after September 14, 2006, we are concerned that regulators could fail to assess or manage large numbers of potentially hazardous substances, and the transparency of the decision-making process would be weakened.

Another important aspect of the SA phase is government's communication of the results. As with categorization, we recognize that the results of screening assessments are neither exhaustive nor incontrovertible. It is critical that limitations in the science and the process be articulated, and sources of error or uncertainty identified. For instance, government should explicitly recognize the major data gaps which exist for exposure and toxicity endpoints. Government should also clarify that the categorization and screening tools **do not provide comprehensive risk assessments**, but rather identify and prioritize substances for further assessment and action.

It is both disturbing and irrational that CEPA allows chemicals which are recognized world-wide as toxic to be designated as non-toxic under CEPA, based on the probability of exposure, bioacccumulation or persistence. This can create serious misunderstandings, both politically and scientifically, regarding the potential for harmful impacts to be felt in Canada as well as internationally (particularly in relation to persistent organic pollutants,

which can travel long distances from the original source). The term "non-toxic" implies that the substance is not toxic regardless of the exposure. Clarification of the term "CEPA non-toxic" is required in all screening assessments and State of the Science reports where such a finding occurs.

Position: Government is required to undertake screening assessments for human health and the environment on all substances found to meet the Section 73 (1)(a) and (b) criteria as of September 14, 2006.

Position: The limitations of the categorization and screening assessment frameworks should be openly communicated, and SAs should specify areas of uncertainty and levels of confidence.

Data Poor Substances and the Application of the Precautionary Principle in SAs
As we discussed in our presentation at the September 8, 2005 meeting, the paucity of data available for many "categorized in" substances creates the worrisome possibility that these substances may be stuck on the list in a state of limbo for many years or decades to come. This is an unpalatable prospect for all involved.

Once a substance is scheduled to receive its SA, it is incumbent upon government to publish the assessment report in a timely fashion, even if some of the underlying data remains of low certainty. Specific areas of uncertainty in the data set should be noted in the assessment report, as underscored by Health Canada's presentation on the Margin of Exposure (MOE). As was noted at previous stakeholder meetings, it would be impractical and unworkable to expect the same level of certainty as was sought prior to the release of the PSL assessments. Not only would this cause the assessment process to grind to a virtual standstill, it would be difficult if not impossible to obtain such in-depth information for many of the substances. Accordingly, it would assist the transparency of the process if government would clarify what data or information is required in order to complete the SAs. There has been very little feedback provided thus far on what would constitute an adequate SA, despite the various examples of assessments provided. Both Environment Canada and Health Canada should delineate a transparent assessment process through which substances will be declared as either "CEPA-toxic", subject to no further action, or subject to the in-depth assessment phase, at the completion of the screening assessments.

In reaching its determination on a substance's CEPA-toxicity, CEPA requires government to respond to information gaps in a precautionary manner. If there is insufficient information at the screening stage to demonstrate that a substance will not harm the environment or human health, we expect government to apply the precautionary principle by, for example, adopting immediate risk mitigation measures (that include consideration of elimination and phase out of the substance), sending the substance for a full assessment, or issuing a notice requiring additional data under section 71(1)(c). Government should also consider and assess the viability of safe alternatives at this stage of the process, if not sooner. The precautionary approach should be the guiding principle for these potentially harmful substances, especially given that they have already been

"categorized in" on the basis of their exposure or inherent toxicity, persistence, and/or bioaccumulation. Section 76.1(a) explicitly requires the Ministers to apply the precautionary principle in conducting and interpreting the results of a screening assessment under section 74.[5]

Position: It would assist the transparency of the process if government would clarify what data or information is required in order to complete the SAs.

Position: Government should delineate the transparent thresholds which must be met in the SA to indicate a substance is either "CEPA-toxic", subject to no further action, or subject to the in-depth assessment phase.

Position: Government should respond to information gaps in a precautionary manner, and clearly communicate what steps it will take in response to ambiguous screening assessments. The application of the precautionary principle may include: adopting immediate risk mitigation measures (that include consideration of elimination and phase out of the substance), sending the substance for a full assessment, or issuing a notice requiring additional data under section 71(1)(c).

Accounting for safe alternatives

It is our position that government should require an inventory of safe alternatives to be taken at the SA phase, if not sooner. Government has yet to review how it proposes to integrate this important precautionary feature into its post-2006 activities. There has been virtually no discussion on the value of collecting information about safe alternatives which are currently in use, being developed, or which could be developed in a reasonable timeframe. Rather, the focus at recent meetings has been on evaluating the adequacy of existing risk management measures being used by companies. Health Canada has indicated a particular interest in discovering what measures are being taken on their priority substances (i.e., the "301 substances"), so as to assist the department in deciding which substances should be "set aside" and which should be the focus of further work.

By identifying non-hazardous alternatives at an early stage of work, the assessment and management phases will not simply be limited to existing measures and inside-the-box thinking. This has the added advantage of promoting those green industries involved in the development and application of safe alternatives. It is arguably in the best interests of both government and industry to identify and adopt safe alternatives early on, and avoid the time-consuming, expensive information-gathering process needed for many of the "categorized in" substances. Moreover, assessments which compare existing substances with alternatives need not be resource-intensive, and may prove to be more cost-effective and protective of human and environmental health. If industries have an incentive to identify and adopt alternatives, they may well opt for the substitution route rather than the

[5] An example of a precautionary assessment is the EU's treatment of PBDEs. A population approach was used, which considered actions needed to protect those most at risk in their workplaces and homes, and those most vulnerable, such as breast-feeding infants.

onerous data generation route.[6] The option presented to industry should be as follows: either produce the toxicity information needed to demonstrate that the substances will not harm the environment, or identify viable and safe alternatives to the substances. This approach is necessary to ensure that proactive steps can be taken to advance the assessment and management of these substances.

Position: Government should require an inventory of safe alternatives to be taken at the SA phase, if not sooner. Such an inventory should include not only existing alternatives, but also alternatives in development and those which could be developed within a reasonable timeframe.

Position: There should be an onus on industry either to produce the toxicity information needed to show that a substance will not cause harm, or to adopt safe alternatives.

Timing and Process

It is critically important to impose a reasonable timeframe for industry's involvement, and to clearly communicate the implications for industry if deadlines are not met. While we encourage industries to continue to provide relevant information, government's treatment of the information should be governed by the phase of work then underway. For instance, after September 14, 2006, newly submitted industry information should be incorporated into SA decisions, *not categorization decisions*. The alternative is a time- and resource-intensive process whereby industry can challenge each level of government decision for an unlimited period of time. Additionally, the transparency of the assessment process is eroded if the criteria and science underlying government's decisions are not clearly communicated.

Government should also establish a timeframe for the completion of its work on SAs. This timeframe needs to be set jointly between Environment and Health Canada on the basis of their combined workplan. It should accommodate new input from the other feeders, and provide for periodic re-prioritization of the "categorized in" list on the basis of new information. Clear guidance is needed on the type of information which will be viewed as sufficient to warrant the further assessment of a substance nominated through one of the other feeders. Similarly, government should clarify under what circumstances nominated substances will be elevated above "categorized in" substances in the prioritization scheme.

As mentioned above, the timeliness of government's response will be affected by the level of certainty which is sought prior to the release of the SAs. Since it would be impractical to seek the same degree of detail as was available for the PSL assessments, government needs to specify the level of data which is required for the SA process, and how information gaps will be reflected and communicated in the assessment outcomes and measures proposed.

[6] Koch, L., Ashford, N. A. "Rethinking the role of information in chemicals policy: implications for TSCA and REACH" (2005) 14 Journal of Cleaner Production, 31 – 46.

Finally, it is important that the departments provide transparent progress reports to the public on their data collection, re-prioritization, assessment, and management activities. These progress reports should be combined with mechanisms to measure the effectiveness of the approaches adopted.

Position: Post-September 14, 2006, newly submitted industry information should be incorporated into SA decisions*, not categorization decisions.*

Position: It is critically important for government to impose a reasonable timeframe for industry's involvement, and to clearly communicate the implications for industry if deadlines are not met.

Position: EC's and HC's joint timeline should provide for input from the other feeders and periodic re-prioritization on the basis on new information.

Position: Government should provide public progress reports and performance indicators.

State of the Science Reports

We appreciate having the opportunity to participate significantly in recent meetings regarding each department's proposals for the SA phase. Health Canada has indicated an intention to release State of the Science reports as a preliminary means of making the science supporting the SAs publicly available. Nine such reports have been released to date.

While we appreciate Health Canada's efforts to share information with interested stakeholders, we are still uncertain about several aspects of the process. For instance, does the release of the reports signal the completion of Health Canada's technical work on the SAs? When and how will Environment Canada's input be integrated into the assessments of these substances? What is the anticipated time interval between the distribution of the State of the Science reports and the publication of draft summary screening assessments? How will comments received after the release of the State of the Science report be addressed? What course of action will Health Canada pursue if the information available in the report and/or the draft summary screening assessment is not sufficient to reach a conclusion on CEPA toxicity? These and other questions have yet to be resolved in a policy statement.

Position: There should be further discussion on the scope of, and process for finalizing, the State of the Science reports, in the context of the questions raised above.

Content of SAs

1) Need to account for cumulative effects

Additional discussion is required concerning the factors that government assessors will consider in reaching their conclusions on CEPA-toxicity. In particular, neither the categorization approach nor the preliminary approach proposed for SAs accounts for the

cumulative effects of substances with a common mode of toxicity or for mixtures of chemicals. In our view, the absence of this discussion is a glaring omission. Chemicals are not found in isolation, and the lack of recognition of cumulative impacts further entrenches government's tendency to underestimate the real risks posed to humans and the environment. As a result, it becomes impossible to identify and implement the measures necessary to eliminate and reduce the impacts from such substances.

The importance of these cumulative assessments is highlighted by human impact studies, in particular. As humans are exposed to chemicals with similar modes of action through media such as food and water, their health risks are underestimated by substance-by-substance assessments. Findings from recent health studies should inform the departments on whether immediate control measures are necessary or if current industry measures can be strengthened further. [7]

We recommend that government incorporate cumulative effects considerations into the SA phase, where such information is available. A model to be considered is the Cumulative Risk Assessment (CRA), which was mandated in the United States under the *Food Quality Protection Act* for organophosphate and other classes of pesticides with similar modes of action. We understand that the PMRA is calculating CRAs in safety evaluations for some food-use pesticides. Two studies performed on farmed salmon illustrate the significance of CRAs: this salmon has been shown to contain a number of dioxin-like chemicals, mercury, and PCBs, that act synergistically on dopamine in neural systems and on thyroid.[8]

Position: In conducting SAs and any subsequent assessments, government should account for the cumulative effects of substances with a common mode of toxicity and for mixtures.

2) Margin of Exposure (MOE)

We recognize that the MOE calculation is useful in the prioritization of substances, but argue that it is not an appropriate tool to designate substances as either CEPA-toxic or non-toxic. Calculated MOE ratios have been found to vary widely, depending on what data were used, and what absorption and metabolic rates were considered (e.g. children vs. adults, animals vs. humans). For example, the MOE applied in Health Canada's assessment of seven brominated flame retardants continues to be of some interest and concern. A study by McDonald[9], referencing PBDE levels in human serum, breast milk, and fat, noted wide variations among individuals. A low MOE was observed in 8

[7] Henk J.M. Verhaar, Jenna R. Morroni, Kenneth F. Reardon, Sean M. Hays, Donald P. Gaver Jr., Robert L. Carpenter, and Raymond S.H. Yang. "A Proposed Approach to Study the Toxicology of Complex Mixtures of Petroleum Products: The Integrated Use of QSAR, Lumping Analysis and PBPK/PD Modeling" (1997) Environmental Health Perspectives, suppl. 105: Reproductive Toxicology.

[8] David O. Carpenter, Kathleen F. Arcaro, Brian Bush, William D. Niemi, Shaokun Pang, and Dilip D. Vakharia. "Human Health and Chemical Mixtures: An Overview" (Dec. 1998) Environmental Health Perspectives, vol. 106, s. 6.

[9] McDonald TA. "Distribution of PBDE Levels Among U.S. Women: Estimates of Daily Intake and Risk of Developmental Effects" (2004) Integrated Environmental Assessment and Management, vol. 1, no. 4, pp. 343-354.

out of 10 studies. For two studies, the MOE was 1 through 5, 6, 11, to 110, 170, 330, 33,000. Such a range of MOE values does not inspire confidence in the tool. Similarly, it is concerning that the MOE of 300 is the necessarily the most conservative value. Further discussion on this point is warranted, so as to ensure the transparency and supportability of the department's decisions in the public sphere as well as in the scientific community.

The MOE calculation implies that health effects in humans will be similar to health effects in animals at similar levels of exposure**.** This correlation is especially tenuous in the case of neuro-behavioural effects. A study by Rice[10] showed that experimental animal neurotoxicity data underestimated the effects in children for lead, methylmercury, and PCBs, in many cases by several orders of magnitude.

The HECS slide deck on the MOE states the following: "The MOE approach does not use default uncertainty factors or require the development of chemical-specific uncertainty factors, but similar information is taken into account in determining their adequacy [of the margins of exposure]"..."Requires explicit delineation of uncertainty." If this is the case, there needs to be a specific guideline on what constitutes cause for uncertainty.[11]

Position: We suggest that a science and toxicology panel be formed to discuss whether the use of the MOE is appropriate in screening assessments as a means of making decisions on toxicity and risk management . Other questions to be discussed should include whether other approaches will be applied in future screening assessments by Health Canada and Environment.

3) Consideration of endocrine disruptors and other low dose effects

The discussion to date on SAs has not addressed other types of relevant toxicity information. For example, we are concerned with the lack of consideration of endocrine disruptors in the SAs, as well as in Health Canada's explicit application of the ComHaz tool for substances on the Maximal List. The discussions on SAs provide an ideal opportunity to further Canada's work on endocrine disrupting substances and the development of models to identify these substances.

Position: Government should engage stakeholders in further discussions on the consideration and inclusion of endocrine disruptors in the SA process.

[10] Rice D. "Lessons from neurotoxiology from selected model compounds" (1996) Environmental Health Perspectives, vol. 104.

[11] Note: Data gaps exist and should be taken into account in discussions on establishing MOEs. There is a lack of data regarding impacts on children, chronic toxicity, animal to human extrapolations, and intraspecies differences (sensitive populations, varying rates of absorption, metabolic differences). The screening assessments should clearly articulate the areas of uncertainty and how factors are "taken into account in determining the adequacy of the MOE".

Risk Management

One of our most pressing concerns regarding the risk management phase is its positioning vis-a-vis the earlier phases. At the November 22 meeting, we heard that one of the intended purposes behind the surveys was to gather information about the existing management practices of selected companies, in order to determine if substances were already well-controlled. As noted above, we support the use of surveys as an information-gathering mechanism. Surveys may be appropriately used to determine if substances are no longer in commerce, to inform prioritization efforts, and to fill data gaps in assessment materials. However, surveys are not a replacement for section 74 screening assessments, nor should they purport to be. It is critical that survey information gathered on existing risk management measures not be used to replace SAs that are required for categorized substances or to conclude on the adequacy of those measures. Rather, the information should be used to inform the screening assessment and risk management phases. Additionally, for high priority substances (i.e., PBiTs) and those no longer in commerce, it is hoped that the survey information will prompt government to take immediate action (such as adopting pollution prevention measures) to mitigate the risks.

Part of the reason why it is so important for risk management decisions to be made in the proper sequence, i.e., after the screening assessment, is that, otherwise, discussions concerning safe alternatives and elimination / reduction strategies are undermined or even circumvented. Section 68(a) of CEPA provides that, when assessing whether a substance is toxic or capable of becoming toxic, or when assessing whether and how to control a substance, the Ministers may investigate "the development and use of alternatives to the substance" and "methods of reducing the quantity of the substance..." Simply noting and accepting existing risk management mechanisms in themselves achieves neither of these important goals, and does not support Canada's own policy on Pollution Prevention.

There is a need for open and transparent discussions on the consideration of safe alternatives and reduction/ elimination strategies in risk management decisions. These discussions should take place early in the process, and should not be pre-empted by confidential conversations with industry representatives on existing or planned management activities. We hope to be given the opportunity to participate in this dialogue, so that a common understanding may be developed of what constitutes a "sufficient" risk management response.

Position: Survey information gathered on existing risk management measures should not be used to replace SAs or to conclude on the adequacy of those measures. Rather, the information should be used to inform the screening assessment and risk management phases. For high priority substances (i.e., PBiTs) and those no longer in commerce, it is hoped that the survey information will prompt government to take immediate action (such as adopting pollution prevention measures) to mitigate the risks from these substances.

Conclusion

As mentioned in the opening paragraphs, the comments contained in this report reiterate some of the points that were raised in the meetings held between July-November, 2005. We hope that this document will provide additional guidance to Health Canada and Environment Canada as they develop the public consultation document on post-2006 path forward activities. We look forward to reviewing and commenting upon the consultation document once it is released.

If you have any further questions on these comments, please do not hesitate to contact us.

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