Categorization of DSL substances under CEPA 1999: Application of rapid screening tools for categorized substances of low ecological concern

Submitted to:
Environment Canada

Prepared for:
Canadian Environmental Network Toxics Caucus

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INTRODUCTION

This correspondence is submitted as a follow-up to the letter submitted by the Canadian Environmental Law Association dated July 6, 2006 on this issue and also responds to the *Canada Gazette* posting of the document entitled *Technical Approach for "Rapid Screening" of Substances of Lower Ecological Concern* on December 9, 2006. Building on our earlier letter, we are detailing our ongoing concerns with the government's decision to apply the rapid screening methodology to approximately 1200 substances meeting the categorization criteria but considered to be of "low ecological concern" or "low priority" substances due to their *suspected* low volumes in commerce.

As noted in earlier communications, the undersigned groups maintain that, at this time, the proposal to apply the rapid screening tool to these substances is inappropriate for "setting aside" substances and deeming that no further work is required. Rather, the rapid screening tool should be used to provide additional information on the environmental fate and exposure of substances that are currently considered of low priority and determine if they require elevation to a higher priority. Therefore, we urge government to delay the release of the results from application of the rapid screening tool, expected shortly, until necessary modifications to the approach can be made.

At this stage in the process, the government's approach should not focus on attempting to reduce the number of substances that must be addressed in the Chemicals Management Plan, but on identifying and including in the assessment process all potentially hazardous substances. In this way, government can ensure that the protection of human health and the environment remains the priority focus of both Environment and Health Canada. Currently, the government approach falls short on this count.

Recommendation: **We urge government to delay the release of the results from application of the rapid screening tool. We believe that current application of the rapid tool inappropriately eliminates substances that are potentially of human and environmental health concern.**

***Recommendation*: We urge the government not to apply the rapid screening tool for "setting aside" substances considered of low ecological concerns and deeming that no further work is required. Rather, the application of the rapid screening tool should be focused on identifying substances that require elevation to higher priority levels for further work.**

***Recommendation*: Related to the concerns notes below, we strongly reject the suggestion that the rapid screening approach could be applied to higher priority substances.**

CONCERNS WITH THE GOVERNMENT'S RAPID SCREENING APPROACH

Our major concern is with the issue of volumes in commerce. Based on outdated information on low quantities in commerce, government has concluded that these chemicals have a "low probability of meeting the s. 64(a) criterion". To verify whether or not a chemical meets, or is likely to meet, the "inherently toxic" criteria under s. 64, a consideration of both hazard and exposure is required. With respect to hazard, these substances have already met the specific criteria for categorization - they are persistent and inherently toxic (PiT) or bioaccumulative and inherently toxic (BiT). However, exposure cannot be accurately assessed under the proposed tool, due to the reliance on quantity of use data gathered in 1986.

The usefulness of the rapid screening tool is predicated on the assumption that volumes in commerce are roughly similar to those reported at the time these substances were nominated for the DSL in 1986, over 20 years ago. This assumption is unjustified. Despite the department's claim that "conservative estimates of exposure" are being applied, the tool fails to address the likelihood that these volumes have increased over the last 20 years to the degree that the rapid screening approach is invalid. Drawing on other jurisdictions and databases to identify increases in use volumes is insufficient to identify volumes in use in Canada. **See Appendix I for a discussion of the use of the identified filters as tools for identifying chemicals which may be in use at higher levels than in 1986**.

***Recommendation*: Since the quantity data available for DSL substances is 20 years old, it is our view that industry should provide updated information on volumes in commerce for each of the 1200 substances. The application of surveys for this purpose would be both appropriate and timely.**

In the short term, a survey to collect current quantity and use information a survey should be conducted under Section 71 of the *Canadian Environmental Protection Act* (CEPA). Furthermore, in order to improve information collected on DSL substances on an ongoing basis, government should require mandatory reporting for range of uses and quantity by all facilities every two years. This reporting requirement should be made mandatory under section 70 of the

CEPA. We would propose that a new subsection be added to CEPA section. 70, that would require proponents to supply biennial information on their DSL substances' type and quantity of use. The results of this reporting should be made available to the public in a timely manner.

***Recommendation*: We recommend that further efforts be undertaken by government to gather data on quantities in use and exposure. Such efforts should include expansion and enhancement of the National Pollutant Release Inventory (NPRI) program to track releases and transfer of all substances identified through the categorization process.**

***Recommendation:* Initially, government should also collect data on quantity and range of use for all DSL substances through surveys under section 71 of CEPA. Mandatory updates of such information should be required through Section 70 of CEPA. To facilitate this recommendation, we propose that a new subsection be added to CEPA section 70, that requires proponents to supply biennial information on their DSL substances' type and quantity of use.**

***Recommendation*: Since the government's prioritization of work on DSL chemicals is strongly linked to the quantities in commerce, it is imperative that EC obtain accurate quantity in use data prior to "setting aside" any of these "low concern" substances.**

Furthermore, since the PiT and BiT results reflect only the ecological properties of these substances, a more appropriate and precautionary approach would be to review and consider any available toxicity data on these substances related to human health. This approach should not be limited to the definition of inherent toxicity outlined by the Departments of Environment and Health in the categorization process. Rather, health endpoints should be expanded to include chronic toxicity, endocrine disruption, and developmental neurotoxicity.

***Recommendation*: It should not be assumed that the hazard properties of these substances are of relatively less concern on the basis of their PiT or BiT profiles alone. Health Canada should consider human toxicity data related to a range of health endpoints before determining that these substances require no further work.**

EC has suggested a series of "mechanical filters" to assist in verifying current volumes and hazard properties of greater concern. This method involves flagging substances which appear on international HPV lists and various pollutant release inventories. We have a number of concerns regarding the use of these lists and inventories. First, it is unclear how accurately international HPV lists reflect quantities in use in Canada.

Second, substances are only included on such lists once they exceed high volume thresholds. Similarly, many substances covered by pollutant release inventories are required to meet specific reporting thresholds (including a quantity threshold) before reporting is made mandatory. The existence of such thresholds means that facilities reporting to these inventories generally have very high-volume emissions. Thus, it is reasonable to conclude that HPV lists and inventories may identify some substances in use at very high volumes, but not those in the middle volume ranges. For instance, the US HPV program identifies substances that are manufactured or produced at amounts equal to, or greater than, one million pounds per year (over 454,000 kg/yr).

The cut-off for "low concern" substances is 1000 kg. Obviously, there is a huge middle range between 1000 kg and 454,000 kg that cannot be captured by the HPV lists.

Third, the volume thresholds that are used for the lists and inventories focus on single-source releases, and do not account for situations in which high volumes are created cumulatively by numerous smaller facilities. Failing to include cumulative sources falsely supports the notion that these substances are indeed low volume. For example, mainly due to reporting thresholds, the NPRI does not require reporting by a number of sectors that release NPRI pollutants (such as auto body shops, drycleaners, etc.).

Fourth, the pollutant release inventories focus only on releases and do not account for amounts used in commerce. This is a significant gap in the approach, despite government's rationale that emphasis should be placed primarily on exposure to substances through releases. Exposure may occur at multiple points during the lifetime of a substance, including its manufacture, use, generation, release or disposal.

Fifth, pollutant release inventories, including the NRPI, do not track all substances. Only a very small portion of the 1200 chemicals proposed for rapid screening could be tracked using this approach.

Contrary to government's claim that few of these substances will have undergone dramatic volume increases since 1986 or will possess hazard properties of concern, the mechanical filters employed by the government have already identified approximately 600 of these so-called "low concern" substances that appear on international HPV lists and/or pollutant release inventories. How many others are used in high volumes today, but have not been captured by these filters for the reasons noted above?

For each substance flagged by one of these mechanical filters, government will "evaluate [the] basis of each information source and determine significance in identifying substances for further evaluation," and apply a manual information search for "more detailed information collection" as is suitable.[1] This type of discretionary approach lacks transparency and predictability. Rather, government should commit to assigning all flagged substances to a higher priority stream and conducting more in-depth assessments in every case.

***Recommendation*: If a substance is flagged by a mechanical filter, it should automatically receive a higher prioritization and more in-depth assessment.**

For each substance not flagged by appearance on an HPV list or a pollutant release inventory, government proceeds with its assessment under the assumption that its volume in use is no larger than 1000 kg. As indicated above, the rapid screening approach does not take into account the reality that more companies could have begun using the substance after it was added to the DSL in 1986.

[1] Gutzman, Don. Powerpoint Presentation: "Technical Approach for 'Rapid Screening' of Substances of Lower Ecological Concern" (Gatineau: 25 May 2006) at slides 11 and 32.

ISSUES RELATED TO THE RAIDAR MODEL

In addition to our objections regarding the outdated volumes in commerce, we have concerns about the use of the models involved in the rapid screening approach.

As noted above, we recognize that the rapid screening approach is useful for identifying chemicals which require further attention, but not for removing substances from further consideration. In the Technical Approach document, it is stated that: "RAIDAR can be applied to substances for which little or no empirical property data are available and emission rates are known only approximately. Although the uncertainties in output may be high, the results may be adequate to sort substances into groups of similar risk and thus compare lower and higher risk potential." Along with Arnot's *et al*[2] discussion on the use of the RAIDAR model, this passage raises two important points: first, uncertainties may be high in cases where there is little empirical property data, and second, the results are adequate for sorting purposes. Nowhere does this argument suggest or support the contention that the model's results are sufficient to "set aside" a categorized-in PiT or BiT, especially given CEPA's specific direction in s. 76.1 to use the precautionary principle in interpreting the results of s. 74 screening assessments. Indeed, the proposed approach is in contradiction to a precautionary approach for all of the reasons identified.

Jon Arnot with some help from Don Mackay were the scientists responsible for the creation of the RAIDAR model. Don Mackay indicated, (in a phone conversation on March 29, 2007), that he was in agreement with the concerns raised in the previous paragraph, and added that there are two uncertainties associated with the model:
1) there is considerable doubt regarding the accuracy of the chemical property data due to the lack of empirical data, and there is a need for better analytical information (lab-generated) rather than model generated data, and
2) due to the fact that ranking of chemicals is directly proportional to their quantities in use, and since we are dealing with uncertain use data, the model can be used only for ranking and grouping purposes. The model was never intended and is inappropriate for removing substances from further consideration.

The RAIDAR model can estimate how a substance is expected to be transported and transformed in the environment and how it will enter and accumulate in the food chain leading to wildlife and human exposure. As additional information becomes available, for example, through biomonitoring and through updated use and release data as noted above, the RAIDAR model could be reapplied to those substances that remain low priorities to determine if that level of prioritization is still appropriate. We strongly recommend that these substances be retained on the categorization list until the government has effectively completed its work on high and medium priority substances.

***Recommendation*: Before proceeding further with use of the RAIDAR model, government should require industry to provide robust experimental data on the chemical and physical**

[2] Arnot, Jon A., Don Mackay and Eva Webster. 2006. Screening Level Risk Assessment Model and Effects in the Environment. Environmental Science and Technology, 40, 2316-2323.

properties of the 1200 substances identified as candidates for the rapid screening tool, as this data is critical for proper functioning of the RAIDAR model.

***Recommendation*: With the exception of flagging substances as higher priorities, we recommend that no action be taken at this time on the 1200 substances considered to be of low ecological concern. These substances should be retained on the categorization list until work is completed on the high and medium priority substances.**

GENERAL CONCERNS WITH THE RAPID SCREENING APPROACH AND CATEGORIZATION RESULTS

We would like to take this opportunity to raise a number of remaining comments and questions regarding the rapid screening approach. Many of these comments have been previously submitted, but no adequate response was received from the department.

- We are concerned that the exposure assessment scenarios rely on the assumption that 70% of a substance is removed by secondary treatment systems. However, many wastewater treatment facilities in Canada are still limited to primary treatment systems and are only able to filter large objects. The model also assumes that secondary treatment systems will achieve the optimal level of removal of substances (i.e. 70%). However, there are several management and maintenance processes that must occur in order to achieve such a high level of performance. Currently, many secondary treatment facilities, where they exist at all, do not perform at such high efficiencies.
- For RAIDAR-unfriendly substances, e.g., inorganics, will only the two exposure modeling exercises be used, or will these substances not be subject to rapid screening?
- The Technical document states: "Application of this simplified approach is warranted, since it will accelerate the application of resources to issues that require more urgent attention." As stated earlier, we require further justification by government as to why there is a rush to complete work on lower-priority substances when the initial focus should be on the high and medium priority substances (i.e., PBiTs, and higher-volume, in commerce PiTs and BiTs).
- The Technical document further states: "Environment Canada recognizes that there is the potential for a limited number of cases where some level of risk is not identified, but is confident that other "feeders" will capture any significant cases." What is the basis for this confidence? How will the government review and respond to information submitted through the other "feeders" outlined in the *Canadian Environmental Protection Act*?
- Over the past year, NGOs have asked both EC and HC to articulate a priority-setting process for substances identified through other *CEPA* feeders (i.e., public nomination, emerging science, and decisions by other jurisdictions) relative to the priorities set for categorized-in substances. NGOs had hoped to see details on how and when substances identified through these other streams would be addressed in light of the concurrent categorization process. The process and criteria for establishing these priorities should be transparent; however, we have yet to receive feedback of this nature from either department.

- How many substances are currently expected to be routed through the rapid screening tools once the substances slated for group assessment are removed?
- EC has not discussed how human health toxicity data will be reviewed at the screening assessment phase for substances that are low priority. Despite the fact that Health Canada may not identify these substances as high priorities, there is nonetheless a need to consider toxicity data and exposure data from human health together with ecological data. For example, if a substance has been found to be inherently toxic to humans, this would suggest that additional attention is required at the assessment phase. We would like to see an assessment scheme that better integrates the consideration of available human health and ecological data.

To support the rapid screening approach, the government should immediately undertake the following:

- Enhance and expand the NPRI program to require reporting on all medium and low priority substances that meet the categorization criteria.
- Review and report on NPRI release and transfer data for these substances every two years to help in setting priorities for work on the remaining substances within the Chemicals Management Plan.
- In addition, issue a section 71 survey to gather information on the current uses and quantities for these substances from all facilities to confirm if these substances are indeed used in low volumes. Furthermore, add a subsection to section 70 of CEPA requiring information to be submitted biennially on quantity of use and range of uses for these substances.

CONCLUSIONS

In conclusion, we are reiterating our view that the rapid screening tool, including the RAIDAR model, is useful for *prioritizing* substances on the basis of their hazard profiles alone. This prioritization work would need to be undertaken in consideration of the comments provided above. We urge government to delay the release of results from the application of the rapid screening tool, expected in spring 2007. Since this tool cannot predict exposure with any degree of accuracy, it would be inappropriate to use it to assess "risk" levels from these substances. For the same reason, the rapid screening tool should not be used as a basis for determining inherent toxicity under s. 64 of *CEPA* for substances currently considered to be of "low ecological concern".

There are uncertainties and unjustified assumptions associated with the application of the rapid screening tool: most importantly, the model relies on outdated quantity in use data. Also, the RAIDAR model cannot be applied to all substances and bases its predictions on very little empirical data. Although the RAIDAR model can be a useful tool for grouping substances with similar characteristics, it is not a reliable way to prioritize work on substances of higher concern.

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Appendix I

Environment Canada (EC) has attempted to respond to anticipated concerns that the use of the rapid screening tool for this group of substances is based on outdated DSL quantity data. EC writes in the Technical Approach document:

> "… analysis of data collected under the US EPA Toxic Substances Control Act (TSCA) over the period from 1986 – 2002 for substances used at greater than 4540 kg (10 000 lbs) at one site shows that 77% of the high production volume (HPV) substances and 75% of the non-HPV substances in the US either decreased in quantity over this period or stayed within the same range. Furthermore, for those substances that experienced an increase in quantity over this period, 68% of HPV substances and 74% of non-HPV substances did not experience a change in quantity greater than one range category."

This argument does not provide much confidence in the implied assertion that few substances are in commerce at levels which are not greater than those in 1986. Reworded, this passage could read:

> "Analysis of data collected under US EPA TSCA over the period from 1986-2000 for substances used at greater than 4540 kg at one site shows that ***23%*** of the HPV substances and ***25%*** of the non-HPV substances in the US experienced an increase in quantity over this period. ***7.36%*** of HPV substances and ***6.5%*** of non-HPV substances experienced a change in quantity greater than one range."

As noted above, estimates based on the government's own work suggest that many "low concern" substances are now being used at higher volume levels.