SUBMISSION TO THE HOUSE OF COMMONS STANDING COMMITTEEE ON ENVIRONMENT AND SUSTAINABLE DEVELOPMENT

REVIEW OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT (1999)

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Moving Beyond "No Evidence of Harm"

To: <u>The Chair and Members of the Committee</u>

Pollution Probe and Environmental Defense (USA) are pleased to make this submission on the review of CEPA (1999) to the Standing Committee on Environment and Sustainable Development. As long-standing champions for a cleaner and healthier environment, both organizations welcome the opportunity presented by the review of CEPA to convey our recommendations on how to build on the progressive elements of Canadian chemicals legislation by incorporating best practices from analogous U.S. and European chemicals legislation and policy.

With the recent announcement by the Canadian government of a new chemicals management plan, Canada has established itself as a leading nation in the move towards reducing the burden of toxic substances on humans and the environment. The recommendations made in this submission, if implemented, would help to position Canada to lead the world for years to come, both in concept and in substance.

We have titled our submission *Moving Beyond "No Evidence of Harm"* since we believe that this is the basic concept that needs to pervade chemicals legislation if we are to create a clean and healthy environment. The recommendations made in this submission are based on a research study that is in the final stages of completion by Dr. Denison of Environmental Defense (USA) in cooperation with Pollution Probe. The study involves a comparative analysis of

European Union, Canadian and U.S. chemicals legislation and policy and identifies practices that draw upon the best features of each regime. Where appropriate below, we specifically highlight those aspects of a given regime that we believe qualify as a "best practice."

The recommendations made in this submission were verbally presented by Dr. Denison to the House Standing Committee on October 19, 2006. The final report is expected to be available in February 2007 and will be forwarded to the Clerk of the Committee at that time.

Recommendations on key areas for enhancement of CEPA 1999, Part 5: Controlling Toxic Substances

1. Ensure that Canadian agencies can obtain and utilize REACH data: As the EU's REACH[1] system is implemented, considerable amounts of hazard data, information on use and exposure, and other information will become available through its registration process. The first registration deadlines will come three and one-half years after enactment, for high volume chemicals and lower-volume chemicals deemed "substances of very high concern" (SVHCs).[2] While many of the results will be made public through REACH's databases, it is critical that Canadian agencies have access to the underlying studies, including information that will be classified as confidential business information (CBI). Among other uses, these data will greatly facilitate and expedite the conduct of screening-level assessments of chemicals identified through the recently completed Domestic Substances List (DSL) Categorization process.

Canada should take steps now to prepare itself to receive and utilize REACH data. CEPA's provisions governing the ability of Canadian agencies to receive and use CBI from other countries/regions[3] should be carefully examined to ensure full access. Needed steps include the following:

- CEPA should be amended to require that companies submit to Canadian officials any risk-related information they submit under REACH for chemicals they produce in or import into Canada.
- If necessary, CEPA should authorize Canadian officials to negotiate with their counterparts in the European Commission or the new REACH agency, full access to REACH data, including CBI. Such access will be especially important for two groups of chemicals addressed in the recently completed DSL Categorization: those identified as meeting one or more of the categorization criteria, and those for which insufficient information was available to make such a determination.
- Canadian agencies should be empowered and sufficiently resourced to establish or enhance existing information technology infrastructure so that it is capable of receiving, processing and utilizing the large volumes of data REACH will yield.

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[1] REACH stands for Registration, Evaluation and Authorization of Chemicals. Adoption by the European Parliament and the Council of Ministers is now expected in December, with REACH taking effect in mid-2007.

[2] SVHCs include chemicals classified as carcinogens, mutagens or reproductive toxicants (CMRs) and certain persistent, bioaccumulative and toxic chemicals (PBTs).

[3] CEPA Sections 44(3) and 75(2) already authorize cooperation with foreign governments with respect to certain activities. However, the former section appears primarily to address environmental quality research and pollution prevention planning, while the latter appears to be limited to substances that have already been prohibited or restricted. Neither would seem to provide the direct authority recommended here.

2. Authorize and require Environment Canada and Health Canada to require chemical producers and importers to submit up-to-date information on the quantities, production facility locations and use patterns for each of their DSL and NDSL chemicals: A combination of mandatory frequent regular reporting of chemical manufacture/import and use information, and a requirement to report at once any significant changes in manufacture or use (as will be required under REACH), would provide the best means for government to effectively track chemicals in commerce. Ideally, annual reporting should be required; if actual reporting is done less frequently, annualized quantities and use patterns should still be reported for each year in the reporting cycle. This recommendation draws from the best of the US and EU approaches:

- The US Toxics Substances Control Act (TSCA) imposes has regular reporting, but only every five years and only for chemicals above a too-high threshold of 25,000 pounds/year. It has no generally applicable requirement to report significant changes.
- REACH will have no regular reporting beyond that required as production or import quantities reach the next highest registration tiers. But it will require immediate reporting of any significant changes in production and use.
- In contrast, CEPA currently lacks any requirement for regular or significant-change reporting, beyond its tiered notifications applicable to new chemicals, which generally extend only up to 10,000 kg/year. The DSL Categorization process was severely hampered by its forced reliance on 20-year old production and use data dating back to the original formation of the DSL.

Under the recently announced Chemicals Management Plan, Environment Canada and Health Canada intend to request, through a Challenge to Industry, one-time reporting of available information for about 200 chemicals. While this is an appropriate and needed immediate step, in the longer term it is insufficient to reflect the reality that chemical production and use patterns are highly dynamic, with the result that information collected today will become rapidly outdated. This problem plagued the DSL Categorization process. Health Canada was generally forced to rely on 20-year-old data in its effort to identify DSL chemicals posing the Greatest Potential for Exposure (GPE) to Humans. Not surprisingly, it is now finding that many chemicals tentatively identified as of high or intermediate exposure concern based on manufactured quantity and use pattern are no longer manufactured or used in Canada. Unfortunately, the same data gap raises the converse, unanswered, and critical question: *How many chemicals that were not manufactured or used in significant quantities in the mid-1980s, are today, and hence pose a risk of significant exposure not captured through the DSL Categorization?* The Canadian Government needs to have ongoing authority and a mandate to routinely collect such information on all or most chemicals in commerce.

3. Reduce the burden on government to require industry to test its chemicals: REACH's greatest leap forward lies in its bold effort to finally address the legacy left by the tens of thousands of unassessed chemicals that were grandfathered into chemicals policies adopted in the 1970s and 1980s, based on the questionable assumption that they all must be safe. Canada's DSL and NDSL are largely composed of such chemicals. REACH acts on the common-sense proposition that we simply ought to know whether and under what conditions all (or at least most) of the chemicals we produce and use, are safe – rather than continue what amounts to a large-scale, uncontrolled experiment. Current policies reward ignorance rather than knowledge. A key means by which they do so is by placing significant burdens on governments that must be met even before they can request more information from industry: In what amounts to a classic

Catch 22, *government must already have information sufficient to document potential risk in order to ask for information sufficient to determine whether there is actual risk.* And that hampers our ability not only to determine which chemicals may pose risks before widespread exposure has occurred, but also to identify those chemicals that pose little or no risk, and hence may be good replacements for riskier chemicals.

Under CEPA 1999, this burden is most vividly embodied in Section 72, which directly limits the ability of the Minister to require chemical producers to conduct testing to better understand chemical risks only when "the Ministers have reason to suspect that the substance is toxic or capable of becoming toxic or it has been determined under this Act that the substance is toxic or capable of becoming toxic." CEPA should be amended to reduce this burden – or better yet, to reverse it: For chemicals of interest, Environment Canada and Health Canada should be authorized to require testing they deem needed unless their producers or importers can provide information sufficient to obviate the need for testing. At the very least, such authority should be provided for two groups of chemicals:

- those chemicals that have been categorized in through the DSL Categorization process, where more or more definitive information is needed to properly assess them; and
- those chemicals that were not categorized in due to lack of sufficient information.

To facilitate the latter, CEPA should authorize and require Environment Canada and Health Canada to develop and make public lists of DSL chemicals for which categorization was either not possible or highly uncertain due to insufficient information.[4]

This recommendation goes beyond DSL Categorization and the Challenge to Industry under the Chemicals Management Plan in at least two respects. First, both of those processes are limited to collection and examination only of *pre-existing* information; yet a key finding of DSL categorization – one that confirms earlier studies of high-volume chemicals in the US and EU – is that the availability of data on most existing chemicals is exceedingly limited. Government needs unfettered authority to require industry to *generate new information* wherever it is needed to conduct thorough assessments. Second, that authority should not be restricted, as it is now under CEPA Section 72, to the small subset of cases where a Ministerial decision can be made that a chemical is, or is suspected, to be toxic; rather, CEPA should provide such authority for any substance that has been determined to meet the DSL Categorization criteria, or for which such determination could not be made.

4. Consider instituting a REACH-like registration system under CEPA: Registration under REACH provides a systematic means of collecting and compiling basic information about a large number of chemicals. Registration entails submission, by producers and importers of a chemical either collectively or individually, of a technical dossier containing information on the identity, manufacture and use of the substance, guidance on its safe use, and summaries of testing studies conducted and testing plans proposed to meet data requirements. Registration is also a condition of being able to initiate (for a new chemical) or continue (for an existing chemical) producing and marketing a substance.

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[4] Information provided by Environment Canada suggests that, based on its Categorization process, the number of such chemicals is at least 2,500; see www.ec.gc.ca/substances/ese/eng/dsl/cat_background.cfm. Health Canada does not appear to have indicated how many of the chemicals it reviewed lacked sufficient information to make a confident determination as to whether or not it meets the Categorization criteria. For chemicals examined by both agencies, the identity as well as the number of such chemicals should be made public.

The CEPA review should consider authorizing Environment Canada and Health Canada to establish a similar registration system for DSL chemicals. If registration for all DSL chemicals is deemed too ambitious, the focus might initially or primarily be on those chemicals that have been categorized in through the DSL Categorization process, with the aim of strengthening the accuracy and currency of information on such substances of potential concern. As already noted, because both DSL Categorization and the Chemicals Management Plan rely largely on available information, much of which is not current, a systematic approach is needed to collect and compile good and current information about these chemicals, especially to assist in carrying out the new Plan.

5. Take steps to ensure the integrity and credibility of industry-generated data and information developed using alternatives to direct testing: Where new data on chemicals are required to be generated, essentially all policies affecting chemicals worldwide – whether industrial chemicals or drugs, cosmetics ingredients, pesticides, or food additives – require and rely on chemical producers to generate and submit those data. REACH as well as existing US and Canadian approaches to assessing industrial chemicals rely extensively on such data. While the merits of this approach are subject to considerable debate in some circles, viable alternatives are difficult to imagine. It is critical, therefore, that every effort be made to ensure that industry-generated data used to formulate and support public policy are – and are seen as – credible. This need is even more pronounced when one considers the obvious financial incentives industry has in minimizing testing costs and being able to maintain that its products are safe.

Moreover, cost minimization and efficiency objectives are driving an increasing reliance by both industry and government on alternatives to direct *in vivo* testing, including use of *in vitro* assays, the use of various estimation and extrapolation methods and weight-of-evidence approaches. These methods have inherent limitations as well as legitimate uses. Both industry and regulatory agencies have less experience with them, and they often require different types of expertise both to properly use and to critically review. Finally, standardization of methodologies and guidance on their appropriate and inappropriate use are less well-developed than for standard testing methods. In carrying out the DSL Categorization process, because of the dearth of experimental data available for most DSL chemicals, Environment Canada and Health Canada relied heavily on data derived using some of these alternative methods, including through their own use of them.

To ensure a high degree of public trust in the Government's assessment and management of chemicals, steps are needed to ensure the integrity and appropriate use of industry data and these alternative information sources. Toward that end, CEPA review should consider requiring implementation of the types of measures indicated below.

- With respect to industry-generated data or other privately funded research, consider:[5]
    - Establishment of a registry of health and safety related studies, to ensure that results of all initiated studies are reported and made available, along with details of the method utilized in each study. This proposal is quite similar to practice already employed in the arena of pharmaceuticals regulation.

[5] These proposals are liberally adapted from a summary of Wagner, W. and Steinzor, R., eds. (2006) *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research*, Cambridge University Press, summary available at www.progressivereform.org/issue_science.cfm#rescue.

    - Requiring government access to all records of privately-sponsored research used in setting or implementing public policy. Such a requirement already exists for public-funded research.
    - Requiring the disclosure of funding sources and the extent of sponsor review/approval, as well as potential financial conflicts of interest, on the part of researchers who are privately funded and whose research is used in public policy settings. A growing number of scientific journals and organizations require such disclosures.
    - Requiring independent peer review or certification of studies submitted for use in public policy contexts, along with transparency safeguards to ensure disclosure of the identity of reviewers and any potential conflicts of interest, as well balanced representation of the scientific community among reviewers.
- With respect to alternatives to direct testing, consider steps to:
    - Avoid over-reliance through the creation of and adherence to clear, scientifically sound guidance on the appropriate and inappropriate uses of each alternative method.
    - Require justification and appropriate documentation by government or industry for both use of and decisions made based on information derived from alternative methods.
    - Ensure careful independent expert review.
    - Implement safeguards to prevent selective use and reporting, for example, by requiring that all results derived using all methods employed be reported to regulatory officials.
    - Require that any presentation or communication of both the data and conclusions or decisions based on data, derived using such methods clearly indicate the nature, source and specific means used to derive them.
    - Require that an assessment be made of the degree of confidence in or reliability of the data, and that any resulting uncertainty be communicated and reflected in appropriate qualifications of any conclusions or decisions based on such information.

6. Require improved flow of information along chemical supply chains. Another key innovation of REACH is its emphasis on ensuring the flow of risk-relevant information in both directions along the supply chain that connects producers, processors, distributors and downstream users of chemicals. Safe management of chemicals by all actors in the supply chain demands ready access to good information on how chemicals are being processed and used, the hazardous properties of chemicals and risk management practices that need to be implemented by each of the actors. The aim of mandating such information flow is to overcome disincentives such as competitive forces and confidentiality and liability concerns, and bottlenecks such as "middlemen" (i.e., distributors, brokers) that presently serve to block access to information needed to identify and mitigate risk. Suppliers typically have limited knowledge of how or even by whom their chemicals are used, while users have limited knowledge of the characteristics of the substances they receive or appropriate risk management measures recommended by the producers that know their substances best.[6]

[6] For more discussion of information flow in the context of improved chemicals assessment and management, see Denison, R.A., "Improving Information Flows – In Supply Chains and Beyond," presented at the North American Dialog on "Framing a Future Chemicals Policy," held in Boston, MA, April 2005, paper available at www.chemicalspolicy.org/downloads/W3-Informationflow.doc.

REACH induces information flow primarily by:

- requiring suppliers to communicate downstream, through safety data sheets or other means, hazard and risk-related information and other information about the substance "that is necessary to enable appropriate risk management measures to identified and applied;" and
- requiring downstream users to communicate upstream to their suppliers sufficient information on their use(s) of a substance to allow the supplier to develop exposure scenarios or assign the use(s) to exposure categories, so that needed risk management measures can be identified and in turn communicated back downstream.

CEPA review should examine these provisions of REACH and consider how they could be adapted for use in Canada, and should also consider authorizing Environment Canada and Health Canada to take steps to strengthen the two-way flow of information along supply chains both within Canada and between Canada and other jurisdictions.

7. Retain and strengthen the capability of Environment Canada and Health Canada to conduct risk assessments of chemicals and impose risk management requirements: It is clear is that establishment and retention of a strong capability – including the necessary resources – within government dedicated to chemical risk assessment and risk management is an essential element of any sound chemicals policy. The outcome of the recently completed DSL Categorization – with more than 4,000 DSL chemicals identified as needing further assessment – should provide ample motivation for CEPA review to recognize the need for sufficient resources to be devoted to the expeditious review of these chemicals and implementation of needed risk management controls on those found or suspected to be CEPA-toxic.

Pollution Probe and Environmental Defense respectfully submit these recommendations on enhancing CEPA 1999 and look forward to receiving the report of the House Committee upon its completion.

Pollution Probe is dedicated to achieving positive and tangible environmental change by defining environmental problems through research, promoting understanding through education; and pressing for practical solutions through advocacy.

Environmental Defense is dedicated to protecting the environmental rights of all people, including the right to clean air, clean water, healthy food and flourishing ecosystems. Guided by science, we work to create practical solutions that win lasting political, economic and social support because they are nonpartisan, cost-effective and fair.