CANADIAN ENVIRONMENTAL LAW ASSOCIATION
L'ASSOCIATION CANADIENNE DU DROIT DE L'ENVIRONNEMENT

Confidentiality and Burden of Proof under the *Canadian Environmental Protection Act* (CEPA)

Submission to the House of Commons Standing Committee on Environment and Sustainable Development

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November 20, 2006

Burden of Proof

The burden of proof issue is extremely important from a number of perspectives: historical, economic, and scientific. Historically, tens of thousands of substances were allowed to enter the Canadian market without any toxicological information or assessment. These substances, now known as "existing substances", may exhibit any number of hazardous properties, such as toxicity, persistence, and bioaccumulation. The burden was then placed on government to try to identify a limited number of substances to be added to the Priority Substances Lists and assessed. This process proved to be extremely inefficient, expensive, and ultimately ineffectual as there still has not been regulatory action taken to prohibit or eliminate these substances. This approach has lead to a backlog of substances in continued use and exposure to Canadians and its environment to toxic substances. The remaining backlog of substances has been studied to some extent through categorization, but this initiative is similarly hampered by the scarcity of available information and the lack of onus on industry to provide missing data. To ensure that action is taken to deal with the worst substances, the Act must provide for reverse onus and greater industry responsibility for its substances.

Although CEPA requires the federal government to apply the precautionary principle, more weight is given in practice to social, economic and legal considerations than to protecting health or the environment. The Act does not operationalize the principle by setting out how it shall be explicitly used at every stage of decision-making processes.

The task of putting the precautionary principle into effect is challenged by the fact that, in practice, the burden of proving chemical hazards rests largely with the government and by extension, the Canadian public. A key means of putting the precautionary principle into practice would be to reverse the burden of proof about chemical hazards, called a "reverse-onus" approach.

Currently in Canada, there is a distinct approach to dealing with existing and new substances. For example, during the categorization of existing substances, the burden of proof was on the government to show that existing substances meet the criteria for categorization. Similarly, the burden is also on government to conduct assessments in order to determine whether substances are toxic under CEPA before regulatory or other management actions are taken. While the government has the power under para. 71(1)(c) to require a proponent of a substance to conduct toxicological tests, this power is limited by the requirement that the Minister first have a "reason to suspect that the substance is toxic or capable of becoming toxic". There is a lack of clarity regarding the suspicion of toxicity threshold and the degree of certainty which is required in order to meet it. It is important to note that environmental exposures to these substances will continue while any evaluations occur.

In contrast to the situation with existing substances, the New Substances Notification program does require that a small data set be submitted before a chemical can be newly introduced to the Canadian market. However, as with the Existing Substances program, the Ministers may only request additional toxicological tests under section 84 where they "suspect that a substance is toxic or capable of becoming toxic". The Ministers' power to require industry to conduct toxicological testing and to submit the results (sections 71(1)(c) and 84(1)(c)), should be unconstrained by a prerequisite that the Ministers "suspect" a substance is toxic.

By contrast to the revised and soon to be promulgated *Pest Control Products Act* (PCPA), CEPA makes no explicit mention of where the burden of proof lies. The new PCPA places the onus on manufacturers to demonstrate acceptable risk of pesticide products before they can be put on the market.

The coming *Registration, Evaluation and Authorization of Chemicals* (REACH) Regulation in Europe will place the onus on manufacturers by requiring data for any chemical that is on the market. Since Europe is the largest chemicals market in the world, Canadian and other internationally-situated companies will be meeting this standard and could do the same for the Canadian market. It should not be considered onerous or unreasonable to modernize and harmonize toxic substances regulation under CEPA in a manner similar to that already done for pesticides in the revised PCPA.

In order to operationalize the precautionary principle and to facilitate decisions regarding the safety of substances in a manner which is consistent with other initiatives, it is imperative that Section 71 and 84 be strengthened. More generally, the parts of the Act dealing with data-gathering and assessment need to be restructured if the burden of proof is to be meaningfully shifted toward proponents of chemicals.

Recommendations

1. The Ministers' power to require industry to conduct toxicological testing and to submit the results (sections 71(1)(c) and 84(1)(c)), should be unconstrained by a prerequisite that the Ministers "suspect" a substance is toxic. Such a prerequisite weakens the Ministers' ability to shift the burden of proof onto the proponent of a substance.
2. When categorization indicates that a substance is Persistent, Bioaccumulative and inherently Toxic (PBiT), industry should be required to demonstrate why the substance should not be considered CEPA-toxic, thus reversing the onus.
3. Substances other than PBiTs that are identified as priorities through the categorization process should be considered CEPA-toxic unless data demonstrating otherwise are provided by the proponent.
4. When a Priority Substance is deemed to require a full assessment under section 76 following its categorization and screening assessment, reverse onus should apply.
5. An explicit onus should be placed on proponents of substances that are prohibited or severely restricted in other jurisdictions. This could require that section 75 be revised.
6. CEPA needs stronger authority to use the precautionary principle to ban or significantly reduce the most dangerous substances. Such authority would better enable the departments to eliminate or reduce dangerous risks in the absence of full scientific certainty about toxic substances. Explicit precautionary language and obligations should be added at key stages of the CEPA toxic substance management process.
7. The burden of demonstrating safety should be on those wishing to introduce new chemicals or to re-introduce banned chemicals. The Authorization process under REACH, and portions of the revised registration regime of the *Pest Control Products Act*, offer examples of this approach.
8. Existing language that limits actions only to those that are "cost-effective" should be removed from the definition of the precautionary principle (see Preamble), in order to better place the emphasis on protecting the environment and human health.
9. The committee should also review overarching federal government policies that deal with risk management and regulation-making and their impact on CEPA implementation.
10. Section 73(2) currently provides the Ministers with the authority to cooperate with other governments and "any interested persons" to acquire information required for categorization decisions. This section should be strengthened to provide the Ministers with more direct and explicit authority to require industry to produce such information.
11. Section 74 should be revised, placing an onus on industry to provide the information necessary for the Ministers to conduct the screening assessments. There should be a specified time limitation to ensure that this information is provided promptly upon request.

Confidentiality

The issue of confidentiality has far-ranging implications for transparency, precautionary action, and the public's right to know about substances that may have an impact on their health or their environment. The public's right to know must take precedence over industry claims that "competitiveness" requires confidentiality. Notifiers should be required to *demonstrate* the validity of their confidentiality claims and unless this onus is met, a presumption of public disclosure should prevail.

Currently, confidentiality requests are not dealt with in a uniform manner across government departments. Departments also have different policies regarding how much information to disclose about the notification and assessment of substances.

The main provisions in CEPA concerning confidentiality of business information are found in sections 51-53 and 313-321. Sections 313-321 apply to a broader range of circumstances under CEPA, therefore we will focus our comments on these provisions. They hold that a person who provides information to the Minister under this Act may request in writing that the information be kept confidential. Section 314 specifies that the Minister will not disclose the information unless a legal test is met, as set out in sections 315-317. Section 315 provides that the Minister *may* disclose the information where:

> (*a*) the disclosure is in the interest of public health, public safety or the protection of the environment; and
> (*b*) the public interest in the disclosure clearly outweighs in importance
>
> (i) any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided, and
>
> (ii) any damage to the privacy, reputation or human dignity of any individual that may result from the disclosure.

The Minister may also disclose the information for a number of other reasons, including "as may be necessary for the purposes of the administration or enforcement of this Act", or under an agreement between the Minister and any other Canadian minister where the other minister undertakes to keep the information confidential.

The Guidelines for the Notification and Testing of New Substances (one set of Guidelines for Chemicals and Polymers, and one for Organisms) provide additional detail. The Guidelines for Chemicals and Polymers specify that even if the substance is already listed on a public inventory such as the United States Environmental Protection Agency's *Toxic Substances Control Act* (TSCA), confidentiality may still be maintained in Canada if further substantiation is provided. If the substance is not already listed on a public inventory, the notifier need only sign a Certification Statement attesting to the accuracy of the claim, and indicate that the following six criteria are met:

a. the information is confidential to the notifier;
b. the notifier has taken, and intends to continue to take, measures that are reasonable in the circumstances to maintain the confidentiality of the information;

c. the information is not, and has not been, reasonably obtainable by third persons by use of legitimate means except with the consent of the company;
d. the information is not available to the public;
e. disclosure of the information may reasonably be expected to cause substantial harm to the competitive position of the notifier; and
f. disclosure of the information may reasonably be expected to result in a material financial loss to the company or a material financial gain to its competitors.

Little information has been reported about whether, and how, the confidentiality provisions have been applied. There is a general lack of clarity and understanding regarding the threshold to be met for a successful confidentiality claim. For instance, the Certification Statement is not applied uniformly, and at times the "and" is omitted from the list of six criteria, causing confusion regarding whether one or all of the criteria must be met. In some departments, *all* information received from a notifier is considered confidential unless the company provides explicit written consent for government to disclose it. Additionally, confidentiality is maintained between any government agencies which have not signed Information Sharing Agreements, so it is possible that notification packages may not be shared where the same substance is notified to different agencies under two or more Acts. As a result, public access to information is jeopardized, and consistency in government decision-making processes is eroded.

Recommendations

1. The committee should call and review evidence on the actual use of confidentiality claims under CEPA, in order to determine how and to what extent the provisions have been used to protect "the interest of public health, public safety or the protection of the environment."
2. The disclosure provisions should specify to whom disclosure will be made, i.e. to the public or to another Minister or government agency.
3. Notifiers should always be required to provide evidence substantiating their claim of confidentiality.
4. If the substance already appears on another public chemical inventory (such as the United States Environmental Protection Agency's *Toxic Substances Control Act* Chemical Substances Inventory, the Australian Inventory of Chemical Substances, the Korean Existing Chemicals List, and the European Inventory of Existing Commercial Substances) it should be automatically ineligible for confidential status in Canada.
5. Currently, under sections 313-321 there are no statutory conditions that the notifier must meet in order to claim confidentiality. However, the Minister must satisfy a number of legal conditions in order to reject the claim of confidentiality. Therefore, there is a legal presumption that the Minister will not disclose the information once confidentiality is claimed, unless certain conditions are met. This presumption should be reversed.
6. The criteria to be met in order to claim confidentiality should be removed from the guidance documents and added to the text of CEPA so that they are made mandatory. These criteria should be publicly reviewed to ensure that they continue to set an appropriate threshold.

7. Summaries of all notification packages with Confidential Business Information (CBI) claims should be made public prior to the final assessment decisions. The summaries should include a list of the information or studies submitted by industry in support of their applications.
8. Where confidentiality is claimed, the company's Chief Executive Officer (CEO) should be required to attest to the fact that the confidentiality criteria have been met. Currently, only the individual submitting the notification package is required to sign the Certification Statement.
9. A neutral ombudsperson should be appointed and empowered to review assessment documentation and verify the appropriateness of CBI claims. Its role would be akin to a neutral ombudsperson.
10. Ensure that CBI information can be shared freely among all government departments that are in a position to inform the assessments of new organisms. Formally negotiated Information Sharing Agreements should not be required between government departments which are involved in reviewing notification packages.
11. According to Canada's international commitments, CEPA provisions should ensure that information on chemicals relating to the health and safety of humans and the environment is not regarded as confidential. Accordingly, the public interest in receiving this type of information should automatically be deemed to outweigh any financial loss, prejudice to the competitive position, etc.
12. Under section 53(5), if the Minister rejects the request for confidentiality, the notifier may appeal the decision to the Federal Court. A comparable provision should be added to section 53 which would explicitly entrench the public's right to appeal if confidentiality is granted.

Note: Please see below for additional references.

"Reforming the *Canadian Environmental Protection Act*: Submission to the Parliamentary Review of CEPA, 1999"
http://www.cela.ca/publications/cardfile.shtml?x=2648

"Non-Governmental Organizations' Preliminary Comments on Path Forward Activities Post September 2006 for Substances Categorized under the *Canadian Environmental Protection Act* (CEPA) 1999"
http://www.cela.ca/publications/cardfile.shtml?x=2478

"NGO Submission on Proposed Amendments to the New Substances Notification Regulations (Organisms)"
http://62.44.8.131/publications/cardfile.shtml?x=2668

"Submissions on the Proposed New Substances Notification Regulations (Chemicals and Polymers)"
http://www.cela.ca/publications/cardfile.shtml?x=2127

CELA publication #551