

Burden of Proof – Reverse Onus CEPA 1999
ENGO Delegation to the Parliamentary Review of CEPA 1999
October 2005

Summary

- For many years, substances have entered into commerce without proof that they are safe despite increasing evidence of health problems, such as allergies, asthma-related conditions and cancer, associated with exposure to certain substances. Unless this pattern is altered, the harm from exposure to the multiplicity of chemicals in commerce is bound to escalate, with irretrievable consequences and costs on society.
- Currently the burden of proof that a substance is harmful has fallen to the public and to government, often in response to public pressure and emerging evidence questioning the safety of a substance. This needs to be reversed. The burden of proof must be shifted to industry to prove that a substance is safe before it is allowed to enter into or remain in commerce. It is an essential cost of doing business.
- Shifting the burden of proof to industry, i.e., the principle of *reverse onus* makes industry responsible for undertaking all necessary tests and studies to prove that a substance is safe and submitting all such information to government for evaluation.
- Where information is inconclusive, or lacking, or not forthcoming, the substance should not be allowed to enter into or remain in commerce.
- The government has too readily accepted the industry stance that having to collect and provide information represents an excessive “burden on industry”, rather than seeking to remove the burden of the harm done by many of these substances (e.g., flame retardants, chlorinated compounds) on the public and in the environment.
- CEPA does not provide the means to shift the burden of proof to industry. In fact, it does not really address this issue, other than its specific requirements regarding the notification for new substances. This is a grave omission that requires rectification.

Background – CEPA Provisions:

- There are no explicit statements in CEPA regarding “burden of proof”. Reference to responsibilities of industry is found in the preamble where the Government of Canada “recognizes the responsibilities of users and producers in relation to toxic substances, pollutants and waste and has adopted the “polluter pay” principle”.
- Part 5 (Sections 70 and 71) of the Act contains provisions for obtaining information from industry. Section 70 requires industry to provide data to government in a timely manner. Section 71(1)(c) “requires any one engaged in the importation or manufacturing of a substance under question to conduct toxicological and other tests.” Part 5 also contains notification requirements for new substances which provide a basis for burden of proof on industry.

Considerations:

- The government is not obligated to act on the information-gathering provisions of CEPA (Section 71) that allow government to request and/or require testing and other information from industry to determine whether an existing substance is toxic or capable of becoming toxic under the Act. In fact, the government has seldom acted on these provisions, and then, only on a *voluntary* basis.

- The nature and scope of the information requested under section 71 is not publicly available. Furthermore, claims of confidentiality by industry have been a barrier to the submission and/or publication of information.
- The criteria by which confidentiality is claimed are vague. Government does not appear to challenge these claims or have criteria in place to reject them.
- Section 71(1)(c), which *requires* testing by industry, has not been acted on at all. A barrier to implementing this section may be the Section 72 provision whereby the government cannot exercise their authority to act on Section 71 (1)(c) unless it has reason to suspect a substance is toxic or capable of becoming toxic under CEPA.
- Notification requirements from industry for new substances are not sufficient or adequate. They do not address the need for industry to prove that a substance is safe before allowing it to enter into commerce.
- Canada and other countries are facing an enormous backlog in assessing substances that have been in the market since the early eighties. The harm that many of these substances are doing have been accumulating for more than 20 years and continue to do so while industry's responsibility in this regard is lacking.

Recommendations:

- The principle of reverse onus i.e., requiring industry to prove that a substance is safe before it can enter and/or remain in commerce, should be an essential component of CEPA. Regulatory mechanisms to enforce such requirements on industry should be in place in the Act.
- The proof that a substance is safe should be based on precaution, valid for the long term, and show no potential for cumulative and synergistic effects. Where scientific and technical knowledge does not provide enough information on a substance to rule out any possibility that it has the potential to do harm, government should err on the side of caution and limit or ban its use until the substance can be shown to be safe beyond a reasonable doubt (i.e., applying the precautionary principle).
- Industry should be required to conduct the appropriate tests and provide all information to government for consideration and review in the categorization and assessment of existing substances. If a substance under question has not been proven safe within a reasonable time period, it should be removed from the market.
- Information-gathering provisions for both new and existing substances should be strengthened and made mandatory. Where information is withheld, or found to be inaccurate, the substance in question should be removed from the market.
- Industry should be required to follow a clearly articulated set of criteria before information on substances can be considered confidential. This calls for a review of the confidentiality provisions in CEPA.
- Clear penalties / accountability should be in place in the Act as a deterrent to unsafe products, process or practice.
- The CEPA review should examine cases where reverse onus is being applied or considered, for example;
 - Programs of other countries (for example, the European Registration, Evaluation and Authorization of Chemicals (REACH) program).
 - Requirements of the pharmaceutical industry in demonstrating safety.