



ASSESSING AND MANAGING THE HEALTH RISKS OF NEW SUBSTANCES UNDER THE CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA)

The Issue

About a thousand new chemicals, polymers and biotechnology products come onto the market in Canada every year. Health Canada examines these new substances for potential health risks before they are allowed to enter the marketplace.

Background

The Canadian Environmental Protection Act and Toxic Substances

Environment Canada and Health Canada share responsibility under the Canadian Environmental Protection Act (CEPA) to assess and manage threats posed by toxic substances. Environment Canada focuses on risks to the environment, while Health Canada focuses on risks to human health.

CEPA acts as a safety net by requiring health and environmental assessments for substances that are not regulated under other federal acts.

The CEPA Definition of Toxic

Under the Act, a substance is considered "CEPA-toxic" if it enters or may enter the environment in amounts that may pose a risk to:

- human health
- the environment (such as fish or wildlife)
- the environment upon which life depends (such as water, soil, and air)

Defining New Substances

Before CEPA was passed, the government took an inventory of substances that were already in use in consumer goods and manufacturing processes in Canada. These substances were classified as existing

substances. Any substance that was not added to the inventory is considered a new substance.

Examples of new chemical substances include ingredients used in dyes, adhesives, and laundry detergents. An example of a new biotechnology product would be genetically modified bacteria used to degrade oil.

The CEPA Approach to New Substances

Under CEPA, the government must use a preventative approach to manage the risks posed by new substances that may be toxic. This means that Health Canada and Environment Canada must examine new substances for potential risks before they enter the Canadian marketplace.

If a company intends to manufacture or import more than 20 kilograms per year of a new substance, it must notify the government. It must also submit information about the substance for review by government scientists. The amount of information required depends on how much of the substance a company plans to use on an annual basis, and could include the following:

- the chemical and physical properties of the substance
- the proposed use of the substance
- how easily the substance breaks down after it is released into the environment
- all adverse health effects that the substance is known to cause

Government scientists examine the information and decide whether action is needed to protect Canadians from potential risks. The CEPA deadlines for this work range from five to 120 days.



Assessing the Health Risks of New Substances

Health Canada scientists determine whether a new substance poses health risks by assessing the potential hazards and the potential for exposure. Among the factors they consider are:

- How will the substance be used?
- Does the substance cause health effects, and if so, how serious would these be?
- At what level of exposure are health effects likely to occur?
- Is the substance likely to get into food, drinking water, air, or soil?
- Does it break down easily once it gets into the environment?
- Does it have the potential to accumulate in the tissues of people, animals, or plants?

Potential exposure for children is assessed separately from exposure for adults, because their lower body weight puts them at greater risk for health effects. In addition, children are more likely than adults to put products into their mouths.

If Health Canada scientists conclude that a new substance poses no health risks to the public, and Environment Canada scientists conclude no risk to the environment, the import or manufacture of the substance can begin. If there is reason to suspect that a new substance may pose a health risk, Health Canada takes preventative action to manage the risks.

Managing the Health Risks of New Substances

Health Canada manages the health risks of new substances by imposing controls on the manufacture, import, use, release, and / or disposal of a substance. For example, Health Canada might allow the use of a chemical that softens plastic, as long as it is not used in products for children. Or, Health Canada might allow the use of a new substance in a factory as long as the amount released daily into the environment does not exceed a certain level. The controls could also include an outright ban, but this is rarely used.

Government of Canada's Role

Health Canada and Environment Canada's responsibility to protect Canadians and the environment from risks related to new substances does not end after the initial risk assessment and risk management phase. Companies are required under CEPA to report any new information, such as new findings about potential hazards, that may affect the original assessment. When this happens, Health Canada reassesses the health risks, and imposes controls, if necessary. This enables Health Canada to monitor the health effects of new substances on a continuing basis.

Need More Info?

For more on Health Canada's role under CEPA, see the following It's Your Health fact sheets:

Human Health and The Canadian Environmental Protection Act – An Overview

http://www.hc-sc.gc.ca/english/iyh/environment/cepa_overview.html

Assessing and Managing the Health Risks of Existing Substances Under CEPA

<http://www.hc-sc.gc.ca/english/iyh/environment/assessing.html>

Assessing and Managing the Health Risks of Living Biotechnology Products under (CEPA)

http://www.hc-sc.gc.ca/english/iyh/environment/cepa_biotech_products.html

For more information on New Substances and Products of Biotechnology, visit Health Canada's Web site at:

<http://www.hc-sc.gc.ca/hecs-sesc/nsac/index.htm>

For more information about the Canadian Environmental Protection Act, visit Environment Canada's Web site at

<http://www.ec.gc.ca/envhome.html>

Additional It's Your Health articles can be found at:

www.healthcanada.ca/iyh

You can also call (613) 957-2991