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Comments on the
Review of the *Canadian Environmental Protection Act 1999*
From the Canadian Institute for Environmental Law and Policy

February 26, 2007

The Canadian Institute for Environmental Law and Policy, also known as CIELAP, is an independent think tank which has been providing advice to the federal government for over 35 years. CIELAP has had a long history of involvement with the *Canadian Environmental Protection Act* (CEPA) from the time of the Act's inception in the mid 1980s. The Institute has authored or co-authored major briefs and made submissions in past reviews of CEPA, as well as participating in the current review.

CIELAP has particular concerns on the issue of how assessments under CEPA should take into account vulnerable populations and ecosystems. Our comments focus on two of CIELAP's current areas of research: the impacts of pharmaceuticals in water and of innovative technologies such as biotechnologies and nanotechnology.

The Impacts of Pharmaceuticals and Personal Care Products in Water

In considering how CEPA can most effectively protect the health of children and other vulnerable populations, the precautionary principle is fundamental.

CEPA requires the federal government to apply the precautionary principle by ensuring that "… where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." While it is laudable that CEPA states this principle, it is even more important that the principle be implemented in a meaningful way. If the precautionary principle is not made operational, vulnerable populations and ecosystems are the most likely to be adversely impacted in a significant way.

Earlier this year, CIELAP released a report entitled *There is no "Away" - Pharmaceuticals, Personal Care Products, and Endocrine-Disrupting Substances: Emerging Contaminants Detected in Water*. The report notes that pharmaceuticals or chemical substances which alter the physiological state of living organisms are being used increasingly not only in human medicine but also for disease prevention and as growth promotion in veterinary medicine. These contaminants find their way into water in four main ways:

1. substances used in manufacturing are discharged into wastewater;
2. unused medications and cleansers and personal care products like shampoos are discarded into or washed away with wastewater;

3. drugs and their metabolites as well as bioactive substances like caffeine are excreted in the user's urine and feces and enter the wastewater stream directly; and
4. discarded or excreted substances are carried in run-off from private septic systems, treatment facilities for livestock waste and aquaculture operations, and from animal waste and sewage sludge spread on farm fields.

Testing in the US has found emerging contaminants virtually everywhere – in surface water, groundwater, and streambed sediments. For instance, one program sampled source water in 25 groundwater and 49 surface water supplies, testing for 124 different chemicals. At least one of the chemicals tested for was found in 96% of the samples, with most sites having a number of different contaminants present. Testing in Canada has been much more limited: however, one study of samples near sewage treatment plants in 14 Canadian cities found a number of pharmaceutical products present. It must be emphasized that concentrations found are very low.

The increased human use of antibiotics and the sub-therapeutic use of antibiotics as growth promoters in farm animals have led to increased concerns about drug-resistant strains of pathogens leading to antimicrobial resistance.

There is concern that exposure to certain environmental contaminants may interfere with the human endocrine system. The endocrine glands produce chemical messengers, called hormones, which are transported to various sites in the body through the bloodstream. Endocrine-disrupting substances (EDSs) can: block hormones, decreasing hormonal activity; mimic hormones, increasing hormonal activity; or affect the production, transport, action and removal of hormones. These hormones control many of the body's functions, including growth, development, and reproduction.

EDSs include pharmaceuticals such as birth control pills and synthetic hormones. Other products also incorporate or are themselves EDSs: industrial chemicals such as PCBs, metals, and plasticizers; various fragrances, and preservatives in cleaning and personal care products; contaminants like dioxins; and pesticides such as the insect repellent DEET.

Evidence so far comes from studies of laboratory animals and some wildlife studies. In humans and other large mammals the health effects of EDSs are not well understood. In fish, birds, and other wildlife, effects have included reproductive impairment or failure, deformities, and feminization. One study has shown a long-term intergenerational effect of EDS on lower sperm count and reduced fertility in four generations of male rats.

Some evidence suggests that the human health effects of EDSs include the incidence of disease and abnormalities clearly linked to the endocrine system. Recently, the incidence of breast, testicular, and prostate cancers has risen at a time when the overall cancer rates have been declining. All three of these cancers are linked to the presence of excess hormones.

Much of the scientific work on EDSs has linked effects on fish and wildlife with exposure to EDSs in water. Such research cannot tell us with certainty about effects on people. Many more animal studies, along with clinical research and statistical trends and patterns will be needed before there is a widely accepted consensus about human health impacts.

History has shown that the potential hazards from emerging contaminants are not always initially clear. In 1962, it was discovered that thalidomide, which had been prescribed as a tranquilizer or sleeping pill during pregnancy, had caused dramatic birth defects in babies such as missing or truncated limbs. And in 1971, a link was established between the synthetic estrogen diethylstilbestrol (DES) taken during pregnancy to prevent miscarriage and its terrible effects on the female children of those mothers who had taken it.

These examples teach important lessons related to endocrine disruption and the issue of emerging contaminants. Researchers were aware that it was the rare or dramatic nature of the consequences of thalidomide and DES that had attracted scientific attention relatively early. They recognized that there might well be more subtle effects of chemicals and drugs that had so far gone unnoticed. Scientists also realized that some effects of these exposures were delayed and would not show any consequences until that fetus was a young adult. It was also noteworthy that some extremely small doses of hormones had devastating impacts.

A June 2006 study conducted by Environmental Defence, *Polluted Children, Toxic Nation,* tested seven children and six adults – children, parents and grandparents from five Canadian families – for 68 toxic chemicals. They found 46 of the 68 chemicals tested for, including 38 chemicals that can cause reproductive disorders and harm the development of children, 38 suspected cancer-causing chemicals and 23 chemicals that can disrupt the hormone system.

CIELAP supports recommendations made by Pollution Watch in their June 2006 submission on CEPA.

The categorization criteria in Section 73(1) of CEPA needs to be updated to require that Domestic Substances List substances be considered inherently toxic and identified for further action if they are known to be carcinogenic and/or known to be capable of reproductive or neuro-developmental toxicity. The provisions could be similar to those of Proposition 65 in California that require the Governor to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity.

Once identified, these substances should be targeted for virtual elimination.

CEPA also should be amended to require consumer product warning labels notifying the public if a product contains substances that are known to be carcinogenic or toxic to human reproduction and development.

The assessment provisions in CEPA should require consideration of the protection of children and other vulnerable populations. CEPA should include explicit language directing that vulnerable populations be taken into account in identifying substances for assessment, in conducting assessments and in undertaking management activities of substances including requirements to aggregate exposures to substances, to assess groups of chemicals with common mechanisms of toxicity, and to require an extra 10-fold child-protective safety factor in all risk assessment calculations. The new *Pest Control Products Ac*t should be consulted as it contains specific language requiring the use of additional safety factors to ensure that risk assessments are protective of the most vulnerable populations.

The government should also phase out antibiotics and hormones as growth promoters for farm animals in accordance with a precautionary approach to health and ecological concerns about antimicrobial resistance and EDSs.

The Impacts of Innovative Technologies

In 1994, CIELAP proposed that CEPA include a separate part on biotechnology to provide a basis for regulating biotechnology products that would ensure the protection of environmental integrity and human health, and strengthen public confidence in how the federal government evaluates and regulates these products. In response, the government included Part 6 of CEPA – Animate Products of Biotechnology to address this recommendation.

Unfortunately, this part of CEPA has been underused. Environment Canada has not been using its powers under CEPA to issue notices for information or take control actions on biotechnologies. The current government should act to better utilize the powers that already do exist in CEPA. CEPA is the only federal legislation that provides clear authority for regulation of biotechnologies. The government should use CEPA to set baseline standards for assessment of new products and ensure coverage for products that are not controlled under other acts.

CEPA defines biotechnology as: "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms." Biotechnology, as defined by CEPA, covers a wide range of processes, from fermentation to such modern technologies as cloning and genetic engineering.

Modern biotechnology can involve the transfer of genetic materials between species, a process that does not occur routinely in nature. Specifically, modern biotechnology involves recombinant-DNA technology (rDNA-also known as genetic engineering).
The past few years have witnessed the rapid commercialization of agricultural biotechnology in Canada. Significant portions of Canadian crops now include canola and soya genetically engineered to resist specific herbicides, and corn and potatoes engineered to produce their own pesticides. Modern biotechnology is also moving quickly into new fields, most notably the production of genetically engineered
fish, animals, and trees.

At the same time, a growing body of evidence has been emerging regarding the potential negative environmental and health impacts of these products. This work largely confirms ecological and health concerns that were predicted when biotechnology products first began to emerge in the late 1980's. Specific issues include the impact of pesticidal crops, such as corn and potato genetically modified to produce Bacillus Thuringiensis (Bt) toxin on non-target beneficial insects, and concerns about the emergence of pest populations resistant to Bt toxin. The possibility of allergic responses to foods engineered to contain new proteins has also been demonstrated.

The past few years have also seen a number of incidents that have raised serious questions about the ability of the current regulatory system, such as it exists, to protect the health and environment of Canadians. The most prominent of these events has been to controversy over the proposed approval of recombinant Bovine Growth Hormone (rBGH or rBST). However, there have also been recalls of genetically engineered crops by Agriculture Canada, after they had been planted by farmers. In addition, the Canadian Food Inspection Agency has had to impose new

conditions on Bt crops, and conduct research on their potential ecological impacts, several years after approval was first granted for their commercialization.

Genetically modified organisms used in the open field cannot effectively be contained and pose uncertain ecological risks and definite economic risks for nearby farmers who may be organic farmers or who did not plant genetically modified seed but could be sued for patent infringement if it infiltrates their crops, and for those who want to export their products to the EU or other countries with strict labelling and traceability regulations.

As noted in relation to emerging contaminants above, vulnerable populations and ecosystems have the most potential to be adversely affected in a significant way by negative environmental and health impacts of the products of biotechnology. CEPA must play a more effective role in the regulation of biotechnology products.

CIELAP has been calling for a comprehensive policy framework for biotechnologies since 1985. The opportunity exists for the government to show a leadership role in this regard and ensure that Environment Canada uses its powers under CEPA to establish a national regulatory regime to address the environmental risks of biotechnologies. Specifically, a regulatory regime for these processes and products should include:

- A statutory liability regime for environmental escape and damage of genetically modified organisms (GMOs);
- Systematic requirements for an assessment of the potential long-term impacts of products prior to authorization;
- Political willingness to implement the precautionary principle to deny and/or suspend authorization of environmental release of GMOs, even in the absence of conclusive scientific reports proving harm;
- Strong post assessment and approval monitoring of biotechnology products;
- Provision for public participation and external review and assessment of the information and evidence on which decisions are based; and
- Labelling of GMOs in food.

In addition, the government should pass the "Living Modified Organisms Regulations," proposed under CEPA in 2002, which provides a framework for the assessment and management of risks to the conservation and sustainable use of biodiversity from the transboundary movement of living modified organisms. As a result of our failure to pass these regulations, Canada has not been able to ratify the Cartagena Protocol, despite having signed it in 2001.

Also genetic use restriction technologies, also known as 'terminator' technology, which refers to plants that have been genetically engineered to restrict their ability to reproduce or to exhibit other specific traits, should be banned in Canada because the pollen from Terminator plants could contaminate and kill the seeds of other nearby plants.

Another innovative technology that is emerging quickly is nanotechnology, which refers to a variety of techniques used to manipulate materials at the scale of atoms and molecules. The building blocks for nanotechnology are simply the chemical elements and compounds that make up all materials. However, substances at the nanoscale have very different properties from those

they have in everyday human experience, such as changed strength, chemical reactivity, and electrical conductivity.

With the exploding growth of nanotechnology, exposures to synthetic nanomaterials for researchers, workers and consumers will increase, with as yet unknown results. In general, substances at the nanoscale are more reactive and toxic than at the micro- or macroscale. Tissue damage to lungs, brains, and hearts has been found in animal species exposed to carbon nanotubes and bucky-balls.

So far, Canada has taken the position that nanoscale materials are still the same substance as at the micro- and macroscales and do not need any additional regulation beyond what is required for ordinary uses of the substance.

CEPA should be used to regulate the development and use of nanotechnology. It would be appropriate to begin with a process with public and expert input to develop a regulatory and policy framework (or policy and regulatory approach) to nanotechnology, starting with a policy paper commissioned now on what a precautionary approach to ecological and human health hazards of nanotechnology would look like. Also, a strict liability regime entrenched in CEPA would hold producers of nanotechnology responsible for damage to human or environmental health.

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