Introduction

The Canadian Institute for Environmental Law and Policy (CIELAP) is an independent, not-for-profit environmental law and policy research and education organization, founded in 1970 as the Canadian Environmental Law Research Foundation (CELRF). The Institute is incorporated as a non-profit corporation under the laws of Ontario, and is recognized by Revenue Canada as a charitable organization.

The Institute has a long history of involvement with the Canadian Environmental Protection Act, (CEPA) beginning with the Act's inception in the mid 1980s. The Institute has authored or co-authored major briefs and submissions at each stage of the current review of the Act, which began, as required by the statute, in 1993. These have included the submission of a brief and five supporting research papers to the House of Commons Standing Committee on Environment and Sustainable Development in September 1994, 1 co-authorship of briefs on behalf of member organizations of the Toxics and Biotechnology Caucuses of the Canadian Environmental Network (CEN) in response to the government of Canada's December 1995 response to the Standing Committee's June 1995 report, 2 and co-authorship, with the Canadian Environmental Law Association (CELA) of an October 1998 brief to the House of Commons Standing Committee for the purposes of its clause by clause review of Bill C-32. 3

The primary focus of the Institute's work in the CEPA review process has been the Act's provisions regarding the regulation of products of biotechnology. These provisions are also the principle subject of this brief. However, the Institute wishes to highlight a number of the Bill's more general provisions as well.

General Comments Regarding Bill C-32

The Canadian Environmental Protection Act deals with a wide range of subjects, including toxic substances, the regulation of biotechnology, standards for vehicle emissions and fuels, and the ocean dumping of waste. As such, the Act should provide the foundation for the government of Canada's efforts to ensure the protection of the health and environment of Canadians.

Unfortunately, the Bill currently before the Senate, if enacted in its present form, will be unable to fulfil this promise. The new Canadian Environmental Protection Act contains a number of elements which would significantly constrain the ability of the Ministers of the Environment and of Health to ensure the protection of Canadians' health and environment. Indeed, when read together, these provisions would make it almost impossible for the Ministers to act to protect Canadians' health and environment. Specific concerns exist with respect to the following aspects of the Bill.

Harmonization

Bill C-32, as passed by the House of Commons, requires offers of consultation with the provinces and territories be made before virtually any substantive action can be taken by the Minister under the Act. Clauses requiring offers of consultation appear at least thirteen times within the Bill, including: s.47 (information gathering); s.54 (objectives, guidelines and codes of practice); s.62 (pollution prevention); s.69 (guidelines re: toxic substances); s.76 (priority substances); s.121 (land based sources of marine
pollution); s.140 (fuels); s.166 (international air pollution); s.176 (international water pollution); s.197 (emergencies); ss.208 & 209 (government operations and aboriginal lands); and s.323 (economic instruments).

These clauses were not present in Bill C-74, and no reference to such provisions was made in the government's December 1995 response to the Standing Committee's June 1995 report. The original provisions of Bill C-32 required that there be offers of consultation to the provinces and territories before action was taken. However, clauses added by the government to each section at report stage in the House of Commons appear to have elevated this requirement to a statutory duty to consult, which may also bar the Minister from acting if an offer to consult is accepted by a province.

Cost/Benefit Analysis

The Bill, as currently before the Senate, would introduce, for the first time in Canadian federal environmental, health or safety legislation, a requirement for cost/benefit analyses prior to the taking of precautionary action to protect human health, safety or the environment. Such requirements, which suffer from significant methodological weaknesses, will establish unnecessary barriers to the adoption of precautionary measures to protect these public goods.

Residualization

The Bill, as passed by the House of Commons, contains a number of clauses which state that action can only be taken under CEPA where the provisions of other Acts of Parliament do not apply. These include s.76 ('toxic' status of substances prohibited or substantially restricted by other jurisdictions); s.93(4) (regulation of 'toxic' substances); s.115(2) (regulation of transboundary movement of biotechnology products); s.118(2) (nutrients); s.200(2) (environmental emergencies); and s.210 (federal lands and operations). The Canadian Environmental Protection Act, as Canada's principle health and environmental protection legislation, typically contains stronger requirements than those of other Acts. The effect of these provisions would, therefore, be to diminish the protection of the health and environment of Canadians. Similar provisions related to the assessment of new substances and products of biotechnology are discussed in detail in the following section of this submission.

Virtual Elimination and Toxic Substances

Bill C-32's approach to the question of how to deal with the substances that present the most serious threats to the health and environment of Canadians is also a source of major concern. The 1993 'Red Book,' reflecting the provisions of the Canada-United States Great Lakes Water Quality Agreement, and the recommendations of the International Joint Commission, stated that the use of such substances should be phased-out. However, Bill C-32 takes a different approach, providing that such substances can continue to be used and generated as waste, with the implication that they will continue to enter the environment, and threaten the health of Canadians.

Bill C-32 and Biotechnology

The Canadian Environmental Protection Act defines biotechnology as: "the application of science and engineering in the direct 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. Biotechnology may be broken down into two categories: traditional biotechnology, and modern biotechnology.
Examples of traditional biotechnology include plant cultivation, animal husbandry, and the selective breeding of plants and animals. In these processes, "human intervention appears as the manipulation of processes that are otherwise occurring in nature routinely."

Modern biotechnology, however, is distinct from these traditional practices in that it 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). This is "the process of artificially moving genes among unrelated organisms, across normally impenetrable species barriers, which specifically excludes conventional plant breeding or genetic improvement within a species."

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 which 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 the likely rapid emergence of pest populations resistant to Bt toxin. The possibility of allergic responses to foods engineered to contain new proteins has also been demonstrated.

In addition, there are growing concerns regarding the socio-economic impacts of these products. Many, such as crops engineered to be resistant to specific brands of herbicide, appear as much intended to secure the market position of agricultural supply firms, as meet any needs identified by farmers or consumers.

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 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 recently moved to impose new conditions on Bt crops, and conduct research on their potential ecological impacts, several years after approval was granted for their commercialization.

A significant range of emerging applications of the technology remains unregulated in Canada, including genetically modified fish and animals. Health Canada has yet to promulgate regulations regarding the assessment of novel foods, including genetically engineered foods, prior to their entry into the marketplace.

At the same time, the controversies over the acceptability of biotechnology products, particularly genetically engineered foods, continue to grow. In Western Europe, a number of major food retailers, processors and distributors have responded to public concerns by making commitments not to sell genetically engineered foods to their customers. Canadian governments have consistently sought to avoid any significant societal debate about the value, purpose and acceptability of applications of biotechnology, particularly with respect to agriculture and food. The government of Canada has also maintained a policy of denying consumers the right to choose in the marketplace, by opposing the mandatory labelling of genetically engineered foods.
These development imply that Canada should be looking to strengthen, not weaken its regulatory oversight of biotechnology products. However, a weakening of the existing legal framework for biotechnology products, established by Parliament when it passed CEPA in 1988, has been precisely what the government of Canada has sought to do throughout the CEPA review process.

CEPA’s provisions related to the regulation of products of biotechnology have been the primary focus of CIELAP’s work throughout the CEPA review. CEPA was the first, and to date, only time Parliament has spoken directly to the question of how products of biotechnology are to be regulated. Under the original Act, passed in 1988, biotechnology products were explicitly included under the Act’s provisions dealing with new substances. These required that any substance ‘new’ to Canada, including products of biotechnology, be subject to notification of Environmental Canada and Health Canada, and an evaluation of their potential ‘toxicity,’ as defined by section 11 the Act, before they can be imported or manufactured. The Act provided authority to the Minister of the Environment to prohibit or impose controls on the manufacturing, import or use new substances that are found to be ‘toxic’ or are suspected of being ‘toxic.’

Section 26(3)(a) of CEPA permitted new substances to be regulated under other Acts of Parliament, which are administered by agencies other than Environment Canada and Health Canada, provided that notification and an assessment of whether the substance was ‘toxic’ or capable of becoming ‘toxic’ took place under those statutes instead. The notification and assessment process which took place under other Acts of Parliament was required to be as stringent as that which would have taken place under CEPA.

The 1990 federal Green Plan included a commitment to enact regulations to operationalize the Biotechnology aspects of the new substances provisions of CEPA by 1995. Regulations made under CEPA for the assessment of microorganisms and “other organisms” not regulated under Acts of Parliament came into force in September 1997. Regulations regarding the notification and assessment of seeds, fertilizers and animal feeds came into force under the Seeds Act, Fertilizers Act, and Feeds Act in April 1997. It is comments on the proposed agricultural regulations, CIELAP noted that they were not as stringent as the proposed regulations for microorganisms under CEPA, particularly with respect to the evaluation of potential impacts on human health.

The CEPA review was initiated in 1993 under a provision of the Act requiring that a Committee of Parliament review the Act five years after its coming into force. The House of Commons Standing Committee on Environment and Sustainable Development tabled its report on the review of CEPA entitled Its About Our Health! in June 1995. The Committee recommended that a new part of CEPA be established to deal specifically with biotechnology, and that the part provide strengthened minimum notification and assessment standards for all products of biotechnology, including those regulated under other federal acts.

In December 1995 the government tabled its response to the Standing Committee’s report. The government’s response proposed to eliminate the requirements from the existing Act that all products of biotechnology be assessed for their potential ‘toxicity’ before they could be imported or manufactured, and that where products are regulated under other Acts of Parliament, the notification and assessment process be at least as stringent as that which would occur under CEPA.

The provisions of the government response regarding biotechnology were the result of lobbying within the government by Agriculture Canada and Industry Canada. There have been indications that Agriculture Canada threatened to block approval of the government response at the cabinet table unless it included these provisions, significantly weakening the new substances provisions of CEPA as they applied to biotechnology products.

A March 1996 submission in reply to the government’s response to the Committee’s report prepared by the CEN Biotechnology Caucus rejected the government’s proposal and called for all products of biotechnology that may be released into the environment to be regulated by Environment Canada and
Health Canada under CEPA. The submission was endorsed by 96 environmental, consumers, health, labour, farm, church and social justice organizations from across Canada.27

In May 1996, the House of Commons Standing Committee on Environment and Sustainable Development initiated a study of the regulation of biotechnology in Canada. The Committee tabled an interim report in June 1996, recommending that no action be taken to alter the provisions of CEPA as they affected biotechnology until the Committee could complete a more detailed study.28

The Standing Committee tabled its final report on biotechnology in November 1996, calling for a strengthening of the biotechnology provisions of CEPA, and the establishment of an independent commission to investigate the long-term environmental, health, social, economic and ethical implications of biotechnology.29

The government introduced Bill C-74, the new CEPA, the following month. Consistent with the direction government's response to the Standing Committee's June 1995 report, the Bill included a new part of biotechnology, but its key provision permitted Ministers responsible for the administration of other Acts of Parliament to determine for themselves whether the requirements of CEPA regarding the notification and assessment of biotechnology products were met.30 This meant, for example, that the Minister of Agriculture would determine whether his or her department's approach to the regulation of biotechnology products met the requirement of CEPA for notification and an assessment of potential 'toxicity,' as opposed to the objective test for 'equivalency' of regulation under another Act of Parliament established through section 26(3)(a) of the existing Act.

Bill C-74 also proposed similar changes to CEPA's general new substances provisions. This would mean that other new substances regulated under other Acts of Parliament, such as pesticides under the Pest Control Products Act, would no longer be required to be assessed in a manner as stringent as that which would occur if they were being regulated under CEPA. No reference to changes to CEPA's general new substances provisions had been made in the government's December 1995 response to the Committee's June 1995 report.

Bill C-74 died on the Order Paper with the call of the June 1997 election.

In March 1998 Bill C-32 was introduced into the House of Commons. The Bill's provisions regarding Biotechnology products and new substances were unchanged from Bill C-74.

The House of Commons Standing Committee on Environment and Sustainable Development considered Bill C-32 for nearly a year after the Bill was referred to committee following second reading. The Standing Committee reported the Bill out of Committee in April 1999. In the course of its clause by clause review, Committee amended the biotechnology part of the Bill so that the Ministers of the Environment and Health would determine whether regulations proposed by other Ministers for biotechnology products meet CEPA's requirements regarding notification and an assessment of 'toxicity' prior to import on manufacture. If the regulations were not equivalent, then the products would be assessed by Health Canada and Environment Canada under CEPA.31

A government amendment that would have made determinations of 'equivalency' of regulation under other Acts of Parliament a decision of the cabinet was defeated in Committee.32

The Committee also amended the preamble and administrative duties sections of the Bill to explicitly identify biotechnology as a threat to biological diversity, along with the use and release of toxic substances, pollutants, and other wastes. This is consistent with the provisions of Art. 8(g) of the United Nations Convention on Biological Diversity, which obligates parties to the Convention to establish or maintain means to protect biodiversity from the use and release of products of biotechnology.
Bill C-32 passed third reading in the House of Commons on June 1, 1999. At report stage the government introduced amendments to reverse the Committee's amendments regarding biotechnology. The government's amendments state that the Governor in Council (i.e. Cabinet) has "exclusive" responsibility for determining if CEPA's requirements for notification and assessment of potential 'toxicity' prior to import or manufacture are met by a regulation made under another Act of Parliament. The cabinet's decision is to be "conclusive proof" that CEPA's requirements are met. Similar amendments were made to the Bill's general new substances provisions.

Government amendments also removed the references to biotechnology as a threat to biological diversity in the preamble and administrative duties section of the Bill added by the Standing Committee, and replaced them with clauses recognizing "the need to protect the environment, including its biological diversity and human health, by ensuring the safe and effective use of biotechnology."

Summary and Conclusions

CEPA is currently the only place in Canadian federal law where Parliament has spoken directly to how products of biotechnology are to be regulated from an environmental and human health perspective.

CEPA, as enacted in 1988, required that all new biotechnology products be subject to notification and an assessment of their potential toxicity (i.e. potential to cause immediate or long-term harm to human health or the environment) before they could be imported into Canada or manufactured in Canada. The Act permitted biotechnology products to be regulated under legislation other than CEPA, by agencies other than Health Canada and Environment Canada, provided that the notification and assessment process is at least as stringent as that which would occur under CEPA.

The House of Common's Standing Committee on the Environment and Sustainable Development has consistently recommended that this basic framework be strengthened. This was reflected in the Committee's original review of CEPA, its November 1996 report on the regulation of biotechnology, and the amendments which the Committee made to Bill C-32 in clause by clause review.

Throughout the CEPA review the government has sought to remove this one basic rule established by Parliament about the regulation of biotechnology in Canada. The current version of the Bill would place the requirements for the evaluation of biotechnology products, including genetically engineered microorganisms, plants, fish, animals, foods and drugs, entirely at the discretion of the cabinet. In effect, this would permit the cabinet to exempt whole classes of biotechnology products from the need for evaluations of their potential effects on human health or the environment before they are introduced into Canada.

These provisions are the result of intensive behind-the-scenes activities by agencies and departments that are strongly committed to the promotion of biotechnology, particularly Agriculture Canada and Industry Canada. Similar changes have been made to the Act's general provisions regarding new substances, even though no reference to such changes was made in the government's December 1995 response to the Standing Committee's June 1995 report.

Summary of Recommendations

Harmonization
1. Replace the word "shall" with the word "may" in the second line of sections 47(2); 54(3); 62(2); 69(2); 76(2); 121(2)(a); 140(4); 166(2); 176(2) 197(1); 208(2)(a)(first line); 209(3)(a)(first line); and 323(1).

Sections 47(3) 54(3.1); 62(3); 69(3); 76(2.1); 121(3); 140(5); 197(2); 208(3); 209(4); and 323(2) should be deleted from Bill C-32.

Cost/Benefit Analysis
2. The word "cost" should be deleted from paragraph 6 of the preamble and s.2(1)(a) of Bill C-32.

**Residualization**

3. Sections 76; 94(3); 115(2); 118(2); 200(2) and 210 of Bill C-32 should be amended so that regulation or possibility of regulation of a substance or activity under another Act of Parliament does not preclude the regulation of the substance or activity under CEPA for the purposes of the protection of human health and the environment, and that in the event of a conflict between a regulation made under CEPA and a regulation made under another Act of Parliament, the more stringent of the two regulations prevails.

**Virtual Elimination**

4. Section 65(1) of Bill C-32 should be amended to define "virtual elimination" as the cessation of the intentional manufacture, import, use or sale of a substance, and the reduction of the generation or release into the environment of the substance as a result of the manufacture, use or processing of another substance or substances below the level of quantification specified by the Ministers in the List referred to in subsection (65)(2).

**Biotechnology**

5. Restore the provisions of the existing CEPA requiring that all biotechnology products undergo an evaluation of the impacts on human health and the environment before they are introduced into Canada. Specifically section 106(7) of Bill C-32, as passed by the House of Commons on June 1, 1999, should be deleted. Section 81(7), regarding substances and activities new to Canada should also be deleted.

In the alternative, section 106(7) as amended by the Standing Committee on Environment and Sustainable Development and reported to the House of Commons on April 15, 1999, should be restored to Bill C-32.

6. Consistent with Canada's obligations under the United Nations Convention on Biological Diversity, Bill C-32 should be amended to recognize products of biotechnology as a potential threat to biological diversity. Specifically paragraph 14 of the preamble, and section 2(j.1) should be deleted from Bill C-32, as passed by the House of Commons on June 1, 1999. The words "products of biotechnology" should be added to paragraph 13 of the preamble and section 2(j) of Bill C-32.

**Endnotes**


4. Bill C-32, *The Canadian Environmental Protection Act, 1999*, as passed by the House of Commons, June 1, 1999, s.2(1)(a).

5. Bill C-32, *The Canadian Environmental Protection Act, 1999*, as passed by the House of Commons, June 1, 1999, s.65.


9. As of July 1999, food safety approval had been granted for 36 'plants with novel traits' including corn, canola, tomato, potato, soybean, cottonseed and squash. General environmental releases have been granted for 31 'plants with novel traits' including canola, corn, potato, soybean, wheat and flax (http:www.cfia-acia.agr.ca/english/ppc/biotech.statuse.html).


13. See, for example, "In the Mill," *The Economist*, March 20, 1999, pp.64-65.


18. Draft regulations were published in the *Canada Gazette* in April 1995 (Food and Drug Regulations Amendment, Schedule 948).


21. Toxicity is defined by section of the Act as: where a substance "is entering or may enter the environment in a quantity or concentration or under conditions that:
   (a) have or may have an immediate or long-term harmful effect on the environment;
   (b) constitute or may constitute a danger to the environment or which human life depends; or
   (c) constitute or may constitute a danger to human life or health.

22. The might include, for example, genetically altered crops regulated by Agriculture Canada under the *Seeds Act*.

23. CEPA, s.26(3)(a).


32. Motion 97 to amend Clause 106 (moved by P.Torsney, M.P. in the name of the Minister of the Environment) March 16, 1999. The motion was defeated on a recorded division.


34. Ibid., s.2(j).
35. The government's amendments were similar to those defeated on March 16 in Committee. A Standing Order 76.1(5) states that "A motion previously defeated in Committee will only be selected if the Speaker judges it to be of such exceptional significance as to warrant a further consideration at report stage."

36. Bill C-32, *The Canadian Environmental Protection Act*, as passed by the House of Commons, June 1, 1999, s.106(7).


38. *Ibid.*, preamble, para 14, and s.2(j.1).