FOR WHOSE FUTURE?

A RESPONSE TO THE GOVERNMENT OF CANADA'S PROPOSAL FOR THE REGULATION OF BIOTECHNOLOGY UNDER THE CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA)

PREPARED FOR:

BIOTECHNOLOGY CAUCUS,
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March 1996

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CANADIAN ENVIRONMENTAL NETWORK.
For whose future ? : a response
to the government of Canada's
proposal for the regula...RN18413

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THE FOLLOWING GROUPS SUPPORT THE RECOMMENDATIONS OUTLINED IN THIS REPORT:

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A Response to the Proposals of the Government of Canada on the Regulation of Biotechnology Products under the Canadian Environmental Protection Act (CEPA)

I. INTRODUCTION

In June 1994 the House of Commons Standing Committee on the Environment and Sustainable Development began its review of the *Canadian Environmental Protection Act* (CEPA). A parliamentary review of the Act was mandated when it was passed in 1988. The Standing Committee conducted cross-country public hearings of CEPA between June 1994 and May 1995, and delivered its report and recommendations, entitled It's About Our Health!, in June 1995.[1]

One of the areas in which the Standing Committee recommended major changes to CEPA was with respect to biotechnology. Partially in response to a proposal made by the Canadian Institute for Environmental Law and Policy (CIELAP),[2] the Committee recommended that a new biotechnology part for CEPA be established to provide standards and procedures for the assessment of the environmental and human health impacts of biotechnology products (Recommendations 68 and 69). The intention was that this part provide a benchmark for the evaluation of products of biotechnology, including genetically engineered plants, microorganisms, fish, and animals.

Unfortunately, the proposals regarding the regulation of biotechnology contained in the government's December 1995 response to the Standing Committee's report[3] would significantly weaken the existing regulatory framework for biotechnology products established by the Act. The government's response proposes a biotechnology part in CEPA, but its primary purpose would be to exempt from the requirements of CEPA products which are, or *may* be, regulated under other acts. The current minimum standard for notification and health and environment assessment of all biotechnology products established by s.26(3)(a) of CEPA would be eliminated.

The "safety net" provided by the current Act would also be weakened. Instead of the current situation, in which CEPA applies to a product if a regulation requiring notification and assessment of potential toxicity has not been made under another Act, CEPA would only apply where there is no *potential* to make a regulation related to biotechnology under another Act.

This proposal cannot be supported. Instead, in a manner consistent with the intent of the Standing Committee's recommendations, it is proposed that a new biotechnology part be established under CEPA, which would apply to *all* products of biotechnology which may enter the environment, including those currently proposed to regulated under other statutes, such as the *Seeds Act*, *Pest Control Products Act*, *Fertilizers Act*, and *Plant*

Protection Act. This new biotechnology part would establish assessment procedures and criteria for all products of biotechnology, and provide for public participation in decision-making regarding biotechnology products.

II. THE FRAMEWORK OF THE GOVERNMENT RESPONSE

1) The Protection of Public Health and The Environment vs. "Competitiveness"

The Government Response to the Standing Committee's recommendations on the regulation of biotechnology products is confusing and disturbing. On the one hand it states that "All Canadians have the right to a clean and safe environment, in order to protect their health."[4] On the other, it states that rules and regulations exist "to ensure a level playing field for business" and to "assure that our markets are competitive."[5]

Indeed, if the report of the Standing Committee was "About Our Health", the Government response seems in places more concerned about the health of biotechnology companies. The protection of public health and environmental protection appear to be secondary considerations. It is difficult to see how Canada will be able to fulfil its commitments under the *United Nations Convention on Biological Diversity*, soon to be headquartered in Montreal, if the government's position on biotechnology and environmental protection remains as articulated in the government response.

Rather than proposing standards which will permit the regulation of novel, risky, unpredictable and untested processes and products of biotechnology, in its response, the government states that it:

> "wants to ensure that we have a regulatory regime in place which promotes innovation, encourages investment in biotechnology, supports technology transfer and places Canadians at a competitive advantage."[6]

To achieve this, the Government recognizes that CEPA must be amended to "allow for the promotion of biotechnology as a "green" technology."[7]

The government's emphasis on "cost-effectiveness" and "environmental protection at least cost" further indicates its willingness place economic considerations ahead of the protection of human health and the environment. "Cost" is a highly subjective term, its meaning dependent on the outlook and commitment of those using it. The protection of the environmental and public health must not be contingent on its not being an excessive cost to business.

The government backs its argument for making environmental protection conditional on "cost-effectiveness" by referring to "diminishing government resources".

However, funds are apparently available to subsidize the biotechnology industry through such programs as the $50 million Industrial Research Assistance Program (IRAP) of the National Research Council and the $29 million allocation for the National Biotechnology Strategy.

Recommendation:

1) *The protection of human health, safety and the environment should be the overriding priorities in the regulation of biotechnology by the government of Canada.*

2) The Stated Goals of Government Policy Regarding Environmental Protection and CEPA

The government states its objectives in the executive summary of Chapter One of its response to the Standing Committee's report:

> "Our goal is that a renewed CEPA would: contribute to the goal of sustainable development through pollution prevention, and establish pollution prevention as the priority approach for environmental protection; use the ecosystem approach; contribute to meeting Canada's obligations under the international Convention on Biological Diversity; affirm that science is an integral part of decision-making; use the precautionary principle; apply the concept of user/producer responsibility; [and then...] acknowledge the interrelationship of economic and environmental principles..."[8]

Chapter Two states that these goals are to be achieved "at the lowest possible cost to all Canadians, including Canadian businesses."

Chapter Three, on the role of public participation in CEPA, calls for providing Canadians with "better access to information and better legislative means to take action against polluters," including the right to sue if the government does not take action. It is notable that the government calls for public action only after the fact. Despite the rhetoric about prevention, there is no mention of any democratic participation in the decision-making process, public or private, concerning activities that might lead to pollution.

The summary of Chapter Seven on biotechnology explicitly states that CEPA should address the "products" of biotechnology, calling for:

"a strong federal presence to ensure the safe and effective use of products of biotechnology and to maintain their economic potential. CEPA would continue to act as the 'safety net' for those areas not covered by other federal Acts."

There are four crucial points in this vague statement. According to the government position:

1) CEPA is not to have any role in determining the allocation of resources, what kind of research is undertaken or what products are produced by biotechnology. CEPA is to deal only with the consequences of what industry chooses to put on the market.

2) CEPA is to deal only with the products of biotechnology and not with the processes of biotechnology;

3) CEPA is to balance off any question of the safety of the products of biotechnology with their economic potential; and

4) CEPA is only to provide minimum standards and to cover only what is not already covered, [however inadequately] under existing acts [or, it must be added, ministerial jurisdictions where there are no Acts].

In order to fully understand the government's suggested approach to biotechnology, one must first look at what it refers to as the "guiding principles for an effective CEPA". The first of these principles is not environmental protection, but economic growth in the name of "sustainable development". The second principle is that CEPA "contribute to the goal of sustainable development through pollution prevention."

The document as a whole appears to define "pollution" in a narrow sense, as contamination of the environment by inert toxic (chemical) substances. There is no recognition that the environment could be also be polluted, that is, be degraded or become toxic and disease- or ill health-causing, as a result of the deliberate or accidental release of the products of biotechnology, such as genetically modified organisms. Such organisms could well be, unexpectedly, capable of destroying plant or animal food sources in addition to being directly harmful to humans and the environment.

3) Environmental Problems with Applications of Biotechnology

The specific environmental risks which have been identified in relation to biotechnology products include:

* the creation of new pests, such as the escape of a transgenic salt tolerant rice

from cultivated fields into estuaries;

* the enhancement of the effects of existing pests or creation of new pests through hybridization or gene transfer to related plants or microorganisms;
* the enhancement of the effects of existing pests as a result of the selective pressures provided by plants modified for pest resistance or intensified pesticide arising in conjunction with the modification of plants for pesticide resistance;
* infectivity, pathogenicity, toxicity or other harm to non-target species, including humans;
* disruptive effects on biotic communities, resulting in the elimination of wild or desirable natural species through competition or interference;
* adverse effects on ecosystem processes and functions, such as nutrient cycling;
* incomplete degradation of hazardous chemicals by microorganisms employed in bioremediation, and waste water treatment, leading to the production of even more toxic by-products.[9]

These specific risks sometimes overshadow the more general risk of reducing biological diversity in any given ecosystem. Introduced species may, for example, disturb food-chains or habitats, which in turn will affect biodiversity.[10] Biotechnology can also threaten the biodiversity through its implicit drive to breed uniformity in plants and animals, and by furthering and encouraging monocultures. These potential consequences, and the more subtle and perhaps even far more drastic environmental destruction that could be caused by slow but persistent genetic changes, induced unwittingly in the pursuit of commercial biotechnology products, do not appear to have been considered in the government's approach to the regulation of biotechnology products.

It is also important to note that these environmental and health risks are not limited to the introduction of genetically engineered or modified organisms. Naturally occurring organisms can behave as "exotic" species when introduced into ecosystems of which they are not native inhabitants as well. In addition, the introduction of a naturally occurring species into a natural habitat can have disruptive effects if the species is introduced in very high concentrations or quantities. It has also been argued that certain naturally occurring species of microorganisms that have potential to be used in bioremediation may be opportunistic human pathogens.[11]

A dramatic illustration of the potential environmental problems associated with applications of biotechnology is currently being played out in Australia, where, in the words of the journal *New Scientist*, "an experiment involving the release of a lethal rabbit virus on an island off South Australia has gone dramatically wrong. The virus has escaped from a high-security quarantined area and reached the mainland."[12]

Australia has been fighting to control the European rabbit ever since it was introduced into Australia in 1859 to satisfy the hunting desires of Thomas Austin. Since then it has multiplied out of control and its population is now estimated at 200 to 300

million, despite all efforts to contain it.

Scientists believed the rabbit calicivirus, first seen in China in 1984, could be used to control the European rabbit and were conducting experiments under confined conditions on a small island to see if the virus could spread to domestic or native animals. When rabbits started dying on the mainland the scientists were surprised, not having any idea of how it got there. Nevertheless, they thought they could confine the virus to a small area until they found rabbits 300 km away also dying from the virus. Within a month it was reported that the escape of the deadly virus had wiped out Australia's rabbit industry because no other country would import rabbit meat from Australia, fearing further spread of the virus. One company alone had been exporting 32 tonnes of rabbit a week.

The next concern to surface was the development of an immunity to the virus by newborn rabbits that are not killed by it.[13] Now there is concern at the impact the sudden death of the rabbits will have on the entire ecosystem of Australia. The rabbit calicivirus was not even a genetically modified organism.

The potential impacts of other applications of biotechnology also appear to have been underestimated. Researchers at the Scottish Crop Research Institute have recently discovered, for example, that "much more pollen escapes from large fields of genetically engineered oilseed rape [canola] than was predicted from earlier experiments on smaller plots. They also found that escaping pollen fertilized plants up to 2.5 km away. "We've shown that there will be gene flow further, and in much larger quantities, than was predicted."[14]

4) Risk Assessment and the Precautionary Principle

Having stated that it intends to protect the environment on a "least cost" basis, the government states, under the heading "Science and the Precautionary Principle", that "science is an integral part of decision making under CEPA."[15] To say that "science is an integral part", however, is not the same as saying that the decision making will be based on science, and the very next sentence states that "the government is committed to a risk-based approach to decision-making." A "risk-based" approach is based on subjective and essentially comparative analyses and evaluations. Indeed, risk-based approaches to the evaluation of potential hazards have been strongly criticized as incorporating value assumptions in favour of the use of new technologies, such as biotechnology.[16]

The government's proposal also significantly distorts "the precautionary principle" by defining it to mean 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."[17] This is a deliberate reversal of the essential intent of the precautionary principle, that calls for not proceeding with an action

or project if there is reason to believe the consequences might be damaging. The precautionary principle, correctly applied, also shifts the burden of proof from the potential victim to the advocate of a technology or practice.

The government, however, states that "where an activity or substance poses a serious threat or is likely to pose a serious threat . . . precautionary measures should be taken even in the face of scientific uncertainty."[18] In other words, once a serious threat has been established, then, and only then, are some "precautionary measures" to be taken. Clearly such wording does not shift the burden of proof. On the contrary, it implies that as long as some unstated "precautionary measures" are taken, the project can proceed.

It might be possible to be more sympathetic to the government's approach were it not continually stated that environmental protection is to be qualified by extrinsic economic factors, such as stating that environmental protection must be ensured "in the most efficient way". Here, again, there is a subjective qualification: the measurement of "efficiency" is entirely contingent on the values and purposes of the accounting process. Are the environment and human health to be protected, or is this protection entirely contingent on it not being a business cost?

Recommendations:

Precautionary Principle

2) Where there is uncertainty regarding the likely environmental or health effects of a biotechnology product, field trials and other activities which may result in the product entering the environment should not be approved.

Reverse Onus

3) The onus of proof should be on proponents of biotechnology products to prove that their products are safe and will not harm the environment or human life or health, rather than on governments and the public to demonstrate the existence of potential hazards.

5) Pollution Prevention and Biotechnology

The Government Response also elaborates on the meaning of 'pollution prevention', saying that the government wants to shift environmental activities "towards avoiding or minimizing the creation of pollutants and wastes rather than trying to manage them or clean them up after they have been created."[19] This is a commendable position -- depending, however, on what is defined as "pollutants and waste". Since the document

speaks of "toxic substances" that can be identified and labelled, it is clear again that the government definition of "pollution" does not include the processes and products of biotechnology. This is an important exclusion, and one in keeping with industry insistence that there is nothing novel about modern genetic engineering. It is also an exclusion that encourages corporations to shift their emphasis from the production of chemical substances to biological products.

Unfortunately, it does not recognize that the processes and products of biotechnology might well be causes of pollution themselves. In fact, unlike chemical pollutants, genetically-engineered life-forms are self-replicating, and able to mutate and adopt to new environments. In the long-term, the may present a greater danger to the environment and human health and conventional "toxic" substances.

6) The Role of Governments in the Promotion and Regulation of Biotechnology

Perhaps the most shocking aspect of the government's proposed approach, however, is the role it assigns to the regulatory system. This seems to have little or nothing to do with public health and environmental protection and everything to do with the promotion of commercial interests. It is not "Canadians" who will gain a "competitive advantage" from the approach which the government proposes; it is a limited number of business interests, a large percentage of which are subsidiaries of transnational corporations. But it is Canadians whose health and environment will be put at risk.

In place of a rigorous regulatory regime designed to ensure that unnecessary risks are not taken in the name of competitiveness and progress, or even in the name of "sustainable development", what is being offered is a piecemeal compilation of standards and programs inherited from a pre-biotechnological age and administered by a number of departments engaged in jurisdictional conflicts.[20]

In shifting away from the role of regulator in the public interest to the role of business promoter, the government is not calling for the enforcement of safety standards or the exercise of the precautionary principle, but for a policy of caveat emptor, buyer beware. Such an approach is likely to be unacceptable to Canadians.

The potential for adverse environmental and health effects arising from the manufacturing and use of products of biotechnology have been widely recognized within the scientific community.[21] The government's unwillingness to acknowledge the potential to cause harm of biotechnology products places the health, safety, and environment of Canadians as risk. In the results of public opinion research indicated that Canadians have place a much greater emphasis on the role of governments in the protection of health, safety and the environment in relation to biotechnology products than on the promotion of the industry (**See Table 1**).[22] The protection of human health and safety, and of environment of Canadians should be the overriding concern of the government of Canada in the regulation of products of biotechnology.

TABLE 1[1]

Table 14: LEVEL OF AGREEMENT WITH STATEMENTS REGARDING GOVERNMENT'S ROLE IN BIOTECHNOLOGY

	Agree	Neutral	Disagree
	%	%	%
Protect the safety of workers in biotech industries	87	8	5
Determine the safety of biotech products	87	8	4
Enforce regulations on activities in biotech	84	10	5
Consult the public on regulating biotech products and uses	81	13	5
Conduct a public information campaign about biotechnology	77	14	9
Assess the benefits of biotech	76	16	7
Be involved in the ethical aspects of biotechnology	75	16	8
Educate the public by offering seminars on biotechnology	74	16	9
Financially support biotech research in companies	37	33	29
Develop biotech products for commercial purposes	33	28	37

[1]. From: Optima Consultants, Understanding the Consumer Interest in the New Biotechnology (Ottawa: Industry Canada, November 1994).

III. THE EXISTING CEPA BIOTECHNOLOGY PROVISIONS

CEPA current only makes reference to biotechnology products in its definitions section and section 32, which provides authority to make a notification regulation for products of biotechnology. In effect, biotechnology products are treated as a category of new substances for the purposes of Part II of the CEPA. Section 26 of CEPA Part II, requires that notice be given to Environment Canada and Health Canada prior to the import, manufacture or sale of a new substance, and that it be assessed for whether the substance is capable for becoming "toxic," as defined for the purposes of CEPA.[23]

Conditions or prohibitions on the import, manufacture, use or sale of a new substance may be imposed by the Ministers of Environment and of Health on substances "suspected of being toxic," although prohibitions on manufacturing or importation are limited to not more than two years. [24] If a new substance is found to be "toxic" for the purposes of CEPA, its import, manufacture, use, or sale may be regulated or prohibited through section 34 of the Act.

One of the most important aspects of the existing structure of CEPA is that it provides that ***all*** new substances are subject to pre-manufacturing, import or sale notification and assessment of "toxicity." New substances, including all products of biotechnology, can only be exempted from the requirements of CEPA in this regard if they are regulated under another act of Parliament that provides for notice to be given prior to their manufacture, import or sale, and for an assessment of whether they are "toxic" as defined by CEPA.[25] In effect, CEPA is intended to ensure that all substances new to Canada, including products of biotechnology, are subject to notification and assessment requirements, and that a common minimum standard of assessment is used in all assessments.

IV. WEAKNESSES IN THE EXISTING BIOTECHNOLOGY PROVISIONS OF CEPA

The Standing Committee's recommendation that new biotechnology part be added to CEPA was based on a number of considerations. These included the following.

1) The Treatment of Biotechnology Products as a Adjunct to Chemical New Substances

CEPA currently deal with products of biotechnology as an add-on to the Act's provisions regarding chemical new substances. This approach fails to recognize the special environmental and human health risks posed by biotechnology products, which distinguish them from traditional chemical substances. Two major areas of concern have been identified in this regard:

(a) Many biotechnology products include life-forms which are self-replicating. Once released into the environment, they can reproduce, spread and mutate and transfer genetic material. The control of biotechnology products, and their genetic material, once in the environment, will therefore be difficult, if not impossible.

(b) The technologies employed in the development of many new biotechnology products have only emerged over the past twenty years (especially recombinant DNA and cell fusion technologies). The evaluation of such products for potential environmental damage is surrounded by a great deal of uncertainty. Indeed, the scientific literature reflects wide concerns regarding the lack of adequate methodologies and data to properly assess the environmental and health effects of the products of biotechnology.[26]

These issues need to be recognized and addressed in the government's approach to the regulation of biotechnology under CEPA.

2) Biotechnology and the CEPA "Toxic" Test

The "toxicity" test forms the basis for CEPA's regulation of new substances. New substances must be found "toxic" under the definition employed by CEPA in order to be regulated under the Act. A number of problems have been identified with the definition and application of the concept of "toxicity" under CEPA in relation to chemical substances.[27]

Specifically with respect to products of biotechnology, the "toxicity" standard, which is rooted in chemical toxicology, provides too narrow an evaluative structure in relation to the potential scope of the effects of the use of biotechnology products. It also may be an excessively stringent test in relation to the level of uncertainty regarding the environmental and health effects of biotechnology products. This is especially true with respect to the potential long-term, indirect and cumulative environmental and health risks associated with biotechnology products, such as impacts on biodiversity.

The need to determine that a substance is "toxic" prior to its regulation under CEPA is related to particular constitutional concerns regarding the establishment of the jurisdiction of Parliament to regulate toxic chemicals. However, a strong case can be made that products of biotechnology constitute a unique and bounded subject of national concern, which cannot be dealt with effectively by the provinces acting individually or collectively. Consequently, Parliament may have the constitutional authority regulate biotechnology products through its power to legislate of the Peace, Order and Good Government of Canada, without having to establish that they are "toxic" for the purposes of CEPA. Federal jurisdiction over Agriculture,[28] Fisheries,[29] Trade and Commerce,[30] and Criminal Law in relation to public health,[31] provide additional bases for the establishment of federal regulatory authority over biotechnology products.[32]

3) Public Participation in Decision-Making

The existing provisions of CEPA regarding the notification and assessment of new substances, including products of biotechnology, make virtually no provision for public participation in decision-making. No notice is provided to the public when new substances enter the assessment process, or when field trials of new substances, including products of biotechnology, are conducted. Furthermore, there are no routes of appeal when a substance is added to the Domestic Substances List, when information requirements are waived, when conditions on substances "suspected of toxicity" are varied or rescinded, or when a field test of a new substance is approved. Public access to information regarding new substances, including products of biotechnology, is also extremely limited.

4) Regulation of Biotechnology Products not Regulated through CEPA

The problems related to the adequacy of the legislative framework for biotechnology products are not limited to CEPA. There are also continuing concerns over the scope of the legislative authority regarding environmental and human health evaluations of biotechnology products provided by the statutes under which Agriculture and Agri-Food Canada and other departments currently propose to regulate biotechnology products, using the CEPA section 26(3)(a) exemption through equivalent notification and assessment process mechanism. CEPA is presently the only federal regulatory statute which explicitly establishes regulatory authority in relation to biotechnology products.

In addition, many of the statutes under which it is proposed that biotechnology products be regulated contain no clear legislative authority for the evaluation of regulated products from an environmental or human health perspective. This is particularly true with respect to a number of the key agricultural statutes including the *Seeds Act*, the *Fertilizers Act*, and the *Feeds Act*. Indeed, an examination of the legislative record in relation to these statutes indicates that they were drafted primarily for the purpose of the prevention of fraud, and no reference was made to the conduct of evaluations for the purpose of the protection of the environment or human health.[33]

This situation leaves significant portions of the government's proposed regulatory framework vulnerable to legal challenge. At best, the proposal to establish regulations for the environmental and human health assessment of biotechnology products under statutes which make no reference to biotechnology, and which provide no explicit authority for such evaluations amounts to a form of legislative amendment through regulation. This practice has been strongly criticized on numerous occasions by Parliamentary Committees,[34] and by legal and constitutional scholars.[35]

There are also a number of additional gaps in the legislative authority provided by such statutes as the *Seeds Act*, the *Fertilizers Act* and the *Feeds Act*. These include:

* the absence of provisions establishing legislative authority for the evaluation of biotechnology products in terms of their likely impacts on biodiversity, or the regulation of the transboundary movement of biotechnology products, despite the likely establishment of such requirements through the proposed *Biodiversity Convention* Biosafety Protocol;

* the absence of any provisions regarding public participation in decision-making, such as notice and comment provisions regarding major decisions, or public access to information regarding new products;

* the absence of provisions establishing or designating appellate bodies for appeals of decisions made under these Acts, or regarding standing in, or outlining procedures for, such appeals;

* the absence of any provisions regarding civil liability for harm to the environment or human health by regulated products; and

* weak enforcement and penalty structures in comparison to CEPA.

Beyond these legal issues, consideration must be given to the multiple roles being played by Agriculture Canada in relation to agricultural biotechnology. The Department has acted simultaneously as the lead creator, tester, promoter and regulator of agricultural biotechnology products in Canada. The conflicts of interest inherent in these promotional and regulatory functions must be recognized and addressed.

V. THE STANDING COMMITTEE'S RECOMMENDATIONS REGARDING PRODUCTS OF BIOTECHNOLOGY

In its report, the Standing Committee recommended that CEPA be amended to include a new part to deal specifically with products of biotechnology. This Part was to include minimum notification and assessment standards for all products of biotechnology released into the environment, including those regulated under other Acts. Other federal statutes should only prevail over CEPA in regard to the assessment of the environmental impact assessment of biotechnology products, if their notification, assessment and regulatory standards are at least equivalent to those prescribed in CEPA.[36] The Committee also recommended that CEPA be amended to require the Governor-in-Council to publish a list of statutes considered to be at least equivalent to CEPA with respect to their assessment processes for products of biotechnology.[37]

VI. THE GOVERNMENT'S RESPONSE TO THE STANDING COMMITTEE'S PROPOSALS

The government's proposal regarding the regulation of biotechnology products under CEPA represents the most serious retrenchment contained in the government's response to the Standing Committee's report. It has the potential to endanger the health, safety and environment of Canadians by eliminating the minimum pre-manufacturing or importation environmental and health evaluation requirements for products of biotechnology currently provided by CEPA. In effect, the government is proposing to create a new biotechnology part for CEPA, but its primary purpose would be to exempt products of biotechnology from the Act's provisions. Specific comments on the government's proposals are as follows.

1) 7.1 Definition of Biotechnology

The government proposes to retain the current definition of biotechnology contained in CEPA. The current definition of biotechnology contained in CEPA is adequate and should be retained.

Recommendation:

4) The current definition of biotechnology contained in CEPA should be retained.

2) 7.2, 7.3, and 7.4 Separate Part for Live or Animate Products of Biotechnology

In these paragraphs, the government proposed to establish a new biotechnology part of CEPA, to apply to living products of biotechnology.

I) 7.2 Scope of the Proposed Biotechnology Part

The CEPA biotechnology part should be focussed on products of biotechnology which may enter the environment. In general, it should not apply to medical applications of biotechnology (i.e. diagnostic tools) except where these applications may have an impact on the environment or human health beyond the individuals to who have provided their informed consent to the application of the product.

Recommendation:

5) The proposed CEPA biotechnology part should apply to <u>all</u> products of biotechnology which may enter the environment.

ii) 7.3 Structure of the Proposed Biotechnology Part

The government proposes to use the existing CEPA section 11 criteria for "toxicity" and Canada's international commitments under the *United Nations Convention on the Conservation of Biological Diversity* to establish evaluative criteria for biotechnology products under the proposed CEPA biotechnology Part.

As noted earlier, the CEPA section 11 "toxicity" concept may not capture the full range of potential human health and environmental effects of biotechnology products. The potential indirect and long-term cumulative environmental and health impacts of commercial scale uses of products of biotechnology must be considered. Particular attention should be given to the full range of impacts of the pest control and other "systems" of which biotechnology products are sometime integral parts. This must necessarily include an evaluation of the purposes of products, their efficacy, and the availability of potentially less harmful alternatives.

Recommendation:

6) The evaluative criteria established by the CEPA biotechnology Part should include:

- *potential immediate or long-term, direct or indirect, harmful effects on human life or health, including cumulative impacts and the effects of occupational exposure;*
- *potential immediate or long-term, direct or indirect, harmful effects on the environment, including cumulative impacts;*
- *potential immediate or long-term, direct or indirect, harmful effects on biological diversity, including cumulative impacts;*
- *the availability and likely effectiveness of monitoring control, waste treatment and emergency response plans with respect the product;*
- *the potential effectiveness of the product for its intended purpose; and*
- *the availability of alternative means of achieving the product's purpose which may present lower potential for harm to the environment and human health.*

The government's proposals make no provisions for public participation in decision-making regarding products of biotechnology.

Recommendation:

7) The new CEPA Biotechnology Part should make the following provisions for public participation in decision-making regarding biotechnology:

i) Public Notice:

(a) notification, in the Canada Gazette and/or on the proposed public registry, when applications for the approval of the manufacture, use, import or export of new biotechnology products, or products containing new biotechnology products are made, , followed by a public comment period of not less than ninety days;

(b) notification, in the Canada Gazette and/or on the proposed public registry, of the Ministers' decisions to approve, approve with conditions or prohibit, the import, manufacture, use, sale, export or discharge into the environment of biotechnology products, followed by a public comment period of not less than thirty days for decisions to approve or approve with conditions the import, manufacture, sale, export, or discharge into the environment of biotechnology products.

(c) notification, in the Canada Gazette and/or on the proposed public registry, of ministerial intentions to vary or rescind conditions or prohibitions imposed on the use, import, manufacturing, sale, export or discharge into the environment of biotechnology products, followed by a public comment period of not less than ninety days.

(d) notification, in newspapers of general circulation in vicinity of the test and on the proposed public registry, of proposals for field tests of products of biotechnology. Direct notification of the owners and occupiers of lands adjacent to the test site should also be required. A comment period of not less than sixty days should follow notice of a proposed field test.

ii) Notices of Objection

Members of the public should be permitted to file notices of objections under the following circumstances:

(a) following public notice of the Ministers' decisions to approve, approve with conditions or prohibit, the import, manufacture, use, sale, export or discharge into the environment biotechnology products;

(b) following public notice of the Ministers' intention to vary or rescind conditions or prohibitions imposed on the use, import, manufacturing, sale, export or discharge into the environment of a biotechnology product;

(c) following public notice of proposals for field tests of products of biotechnology.

Boards of Review should be required to be established unless the request is frivolous or vexatious, approvals should be suspended until any notice of objection is resolved, and intervenor funding should be provided for bona fide public interest intervenors.

iii) Access to Information

The public should be provided to the information submitted in response to the to the information requirements regarding new biotechnology products in a manner consistent with the following principles:

* *the definition of what can be kept confidential be narrowed to include only "trade secrets;"*

* *the claimant for confidentiality be required to provide supportive evidence of confidentiality when making a claim;*

* *requests for confidentiality on the identities of substances which will, or may, enter the environment, not be permitted;*

* *requests for confidentiality should not be permitted regarding information on toxicology, ecological effects, epidemiology or health and safety studies;[38] and*

* *there be a public appeal process regarding determinations that information is confidential.*

iv) Biotechnology Release Database

The biotechnology part of CEPA should also provide for the establishment of a data-base on the environmental release of all biotechnology products in Canada. Such a data base would be of assistance to governments, researchers, and other members of the public in assessing the overall use and effects of biotechnology products released into the Canadian environment. All environmental releases should be required to be entered into the data base, and members of the public should have direct access to the data base.

iii) 7.4 Application of the new CEPA Biotechnology Part

The current CEPA provisions require that ***all*** products of biotechnology be regulated either under CEPA or another Act of Parliament which provides for pre-manufacturing or import notification and an assessment of potential "toxicity." The government's proposal would weaken this standard in three ways.

First, the government's proposal states that the new CEPA part would not apply to products of biotechnology that *may* be regulated under other Acts of Parliament. This means that products would be exempted from the CEPA requirements on the basis of a *potential* to be regulated under another Act, and not the *actual* existence of notification and assessment regulations equivalent to those made under CEPA, as is presently the case. In practice, this provision would mean that it would be unlikely that the new CEPA biotechnology part would actually apply to any products of biotechnology, including those currently expected to be regulated under the proposed the CEPA *New Substances Notification Regulation Part III - Biotechnology Products*, such as microorganisms used in bioremediation, mining, waste-water treatment, and other applications.

Secondly, the government's proposal suggests that there may be "circumstances where (notification and assessment) regulations are not required" for biotechnology products. This means that there may be categories of products of biotechnology which are left unregulated from an environmental and human health perspective.

Third, under the government's proposal, CEPA would no longer provide a benchmark standard of assessment for products of biotechnology regulated under other Acts of Parliament. Different standards of notification and assessment would apply to different products of biotechnology depending upon under which other Act of Parliament they fall. Any consistency in notification and assessment processes for biotechnology products in Canada would be lost.

The government's proposal is clearly a major step backwards from the existing

provisions of CEPA. It is a distortion of the intent of the Standing Committee's recommendation, which has the potential to endanger the lives, health and environment of Canadians and to undermine any consistency in the regulation of products of biotechnology in Canada. It must be rejected for these reasons.

Furthermore, conflicts of interests inherent in the promotion and regulation of biotechnology by Agriculture and Agri-Food Canada in relation to agricultural biotechnology must be recognized. The past 30 years provide numerous examples of the consequences of giving the same government agency responsibility for simultaneously regulating and promoting an industry. The role of the Federal Department of Fisheries and Oceans in the destruction of the East Coast groundfish fishery in Atlantic Canada provides an obvious illustration these perils.[39]

It was these kinds of considerations that lead to government transfer responsibility for the regulation of agricultural pesticides from Agriculture Canada to Health Canada last year. Over the years, Agriculture Canada's active promotion of the use of pesticides in agriculture undermined its credibility as an evaluator and regulator of their health, safety and environmental impacts.[40]

The same logic must be applied to the situation regarding agricultural biotechnology products. Agriculture Canada cannot simultaneously play the role of promoter and regulator of genetically altered plants, microorganisms and animals. Regulatory responsibilities regarding biotechnology products must be transferred to non-promotional agencies of the government if the health, safety and environment of Canadians is to be protected.

Recommendation:

8) *The new biotechnology part for CEPA should apply to <u>all</u> products of biotechnology which may enter the environment, without exception, including those currently proposed to be regulated under other Acts of Parliament, such as the Seeds Act, Pest Control Products Act, Fertilizers Act, and Feeds Act. The new CEPA biotechnology, and regulations made under it, should be administered by Environment Canada and Health Canada.*

3) 7.5 Cost Recovery and the Issuing of Permits

The government's proposals on this issue address two distinct issues. The first is to establish authority for setting fees for services provided to Canadians in relation to CEPA regarding biotechnology products, such as the conduct of notification and assessment procedures, the issuing of permits, and the monitoring of the environmental and health effects of activities authorized under permits. These proposals deserve strong support. They are consistent with the polluter pays principle, and provide a means of ensuring that Environment Canada and Health Canada's capacity to assess and oversee the importation, manufacturing, testing, sale and use of biotechnology products in Canada is maintained.

Recommendation:

9) *The new CEPA biotechnology part should include authority for the imposition of a full-cost-recovery, user-pay system for the processing of notification and assessment information, the approval and monitoring of field trials of products on biotechnology, and monitoring related to conditions imposed on the import, manufacture, use, sale, or export or products of biotechnology.*

The government also proposes to establish clear authority for the issuing of permits relative to the importation, testing, manufacturing or use of biotechnology products that are regulated under CEPA. This proposal appears to be consistent with the Canadian Institute for Environmental Law and Policy's recommendation to the Standing Committee that the process for granting approvals for field trials, and the import, sale, manufacturing or use of products of biotechnology be clarified.[41] Implicit in this proposal is a separation of federal regulatory authority over biotechnology products from a finding of "toxicity" under CEPA.

Recommendation:

10) The CEPA biotechnology part should establish clear authority for the issuing of permits relative to the importation, testing, manufacturing or use of biotechnology products that are regulated under CEPA. This authority should include the capacity to:

- *approve the testing, manufacture, use, processing, release or discharge into the environment, sale, offering for sale, import or export the new biotechnology product and products containing the new biotechnology product without conditions;*
- *approve the testing, manufacture, use, processing, release or discharge into the environment, sale, offering for sale, import or export of the new biotechnology product and products containing the new biotechnology product subject to any conditions which the minister chooses to impose; or*
- *impose a total, partial, or conditional prohibition on the testing, manufacture, use, processing, release or discharge into the environment, sale, offering for sale, import or export of the biotechnology product or a product containing the new biotechnology product.*

4) 7.6 International Commitments

The government proposes to provide authority to make regulations necessary to implement agreements made under international protocols and conventions, where regulations do not exist under other federal Act. The limited focus of the discussion of this matter to "transboundary movements of live products of biotechnology" which "could have an adverse effect on biological diversity," is disappointing. The provisions of the *Convention on Biological Diversity* clearly give rise to a much wider range of issues related to biotechnology and biodiversity, and the precise scope of the proposed Protocol on Biosafety under the Convention is yet to be determined.

Notwithstanding these limitations, authority to implement international commitments in relation to products of biotechnology which may enter the environment should be provided through CEPA. As Environment Canada and Health Canada would be lead agencies responsible for the environmental and health regulation of biotechnology products, the CEPA biotechnology part should be the government's primary vehicle for the implementation of such commitments.

Recommendation:

11) *The CEPA biotechnology part should provide authority to make regulations to implement international agreements regarding biotechnology to which Canada is a Party.*

5) 7.7 Application to Pollution Prevention

The government proposes to provide authority in CEPA to set criteria for the effective and safe use of live products of biotechnology in pollution prevention where regulatory authority does not exist under other federal Acts. The rationale for this provision is unclear, as the necessary authority to deal with such products would be provided elsewhere in the proposed CEPA biotechnology part. As noted earlier, there are serious concerns regarding the portrayal of biotechnology as an "environmentally friendly" technology.

6) 7.8 Agreements to Develop, Gather, and Share Data on Biotechnology

The government proposes to provide authority in a renewed CEPA for the Ministers of the Environment and of Health to enter into bilateral, multilateral and international agreements to develop, gather and share data on biotechnology. This seems a useful and necessary provision.

Recommendation:

12) *CEPA should be amended to provide the Ministers of the Environment and of Health the authority to enter into bilateral, multilateral and international agreements to develop, gather and share data on biotechnology.*

VII. CONCLUSIONS

The government's proposal for a new biotechnology part for CEPA would significantly weaken the provisions of the existing Act as they apply to biotechnology. The minimum standards for notification and assessment of toxicity for ***all*** products of biotechnology currently provided for by CEPA would be eliminated. The application of the proposed CEPA biotechnology part would also be much narrower than is currently the case. In effect, the government is proposing a biotechnology part which would be unlikely to actually apply to any products of biotechnology, and would not set a standard of

assessment for environmental and human health evaluations of biotechnology products under other Acts.

This proposal is inconsistent with the intent of the Standing Committee's recommendations regarding the regulation of biotechnology under CEPA, and could potentially endanger the health, safety and environment of Canadians. Consequently, the government's proposal cannot be supported.

As an alternative, it is proposed that, consistent with the intent of the Standing Committee's recommendations on the regulation of biotechnology products under CEPA, the a new biotechnology part be established under the Act. The new CEPA biotechnology part would:

* apply to *all* products of biotechnology which may enter the environment, including those which the government currently proposes to regulate under other Acts, such as the *Seeds Act*, the *Pest Control Products Act*, and the *Fertilizers Act.*

* establish requirements for the assessment of biotechnology products in terms of their:
  * potential immediate or long-term, direct or indirect effects on human life and health, the environment, and biodiversity;
  * potential effectiveness of the products for their intended purposes; and
  * the availability of alternative means of achieving products purposes which may present lower potential for harm to the environment and human health;

* provide for public participation in decision-making regarding biotechnology products, including:
  * public notice of major decisions regarding biotechnology products;
  * public notice of proposed field tests of biotechnology products;
  * opportunities to appeal government decisions regarding biotechnology products, including the approval of field tests; and
  * enhanced access to information regarding products of biotechnology;

* provide authority to implement international environmental agreements regarding products of biotechnology;

* provide for the establishment of a database of environmental releases of products of biotechnology in Canada; and

* provide for establishment of a full-cost-recovery, user-pay system for the processing of notification and assessment information, the approval and monitoring of field trials of products on biotechnology, and monitoring related to conditions imposed on the import, manufacture, use, sale, or export of products of biotechnology.

This proposal for the establishment of a separate biotechnology part of CEPA is intended to provide the basis of a regulatory structure for biotechnology products which would ensure the protection of environmental integrity and human health, and strengthen public confidence in the government of Canada valuative and regulatory processes for these products.

SUMMARY OF RECOMMENDATIONS

1) *The protection of human health, safety and the environment should be the overriding priorities in the regulation of biotechnology by the government of Canada.*

2) *Where there is uncertainty regarding the likely environmental or health effects of a biotechnology product, field trials and other activities which may result in the product entering the environment should not be approved.*

3) *The onus of proof should be on proponents of biotechnology products to prove that their products are safe and will not harm the environment or human life or health, rather than on governments and the public to demonstrate the existence of potential hazards.*

4) *The current definition of biotechnology contained in CEPA should be retained.*

5) *The proposed CEPA biotechnology part should apply to <u>all</u> products of biotechnology which may enter the environment.*

6) *The evaluative criteria established by the CEPA biotechnology Part should include:*

   - *potential immediate or long-term, direct or indirect, harmful effects on human life or health, including cumulative impacts and the effects of occupational exposure;*
   - *potential immediate or long-term, direct or indirect, harmful effects on the environment, including cumulative impacts;*
   - *potential immediate or long-term, direct or indirect, harmful effects on biological diversity, including cumulative impacts;*
   - *the availability and likely effectiveness of monitoring control, waste treatment and emergency response plans with respect the product;*
   - *the potential effectiveness of the product for its intended purpose; and*
   - *the availability of alternative means of achieving the product's purpose which may present lower potential for harm to the environment and human health.*

7) *The new CEPA Biotechnology Part should make the following provisions for public participation in decision-making regarding products of biotechnology:*

   i) *Public Notice:*

   (a) *notification, in the Canada Gazette and/or on the proposed public registry, when applications for the approval of the manufacture, use, import or export of new biotechnology products, or products*

containing new biotechnology products are made, , followed by a public comment period of not less than ninety days;

(b) notification, in the Canada Gazette and/or on the proposed public registry, of the Ministers' decisions to approve, approve with conditions or prohibit, the import, manufacture, use, sale, export or discharge into the environment of biotechnology products, followed by a public comment period of not less than thirty days for decisions to approve or approve with conditions the import, manufacture, sale, export, or discharge into the environment of biotechnology products.

(c) notification, in the Canada Gazette and/or on the proposed public registry, of ministerial intentions to vary or rescind conditions or prohibitions imposed on the use, import, manufacturing, sale, export or discharge into the environment of biotechnology products, followed by a public comment period of not less than ninety days.

(d) notification, in newspapers of general circulation in vicinity of the test and on the proposed public registry, of proposals for field tests of products of biotechnology. Direct notification of the owners and occupiers of lands adjacent to the test site should also be required. A comment period of not less than sixty days should follow notice of a proposed field test.

ii) Notices of Objection

Members of the public should be permitted to file notices of objections under the following circumstances

(a) following public notice of the Ministers' decisions to approve, approve with conditions or prohibit, the import, manufacture, use, sale, export or discharge into the environment biotechnology products;

(b) following public notice of the Ministers' intention to vary or rescind conditions or prohibitions imposed on the use, import, manufacturing, sale, export or discharge into the environment of a biotechnology product;

(c) following public notice of proposals for field tests of products of biotechnology.

Boards of should be required to be established unless the request is frivolous or vexatious, approvals should be suspended until any notice of objection is resolved, and intervenor funding should be provided for bona fide public interest intervenors.

iii) Access to Information

The public should be provided to the information submitted in response to the to the information requirements regarding new biotechnology products in a manner consistent with the following principles:

* *the definition of what can be kept confidential be narrowed to include only "trade secrets;"*

* *the claimant for confidentiality be required to provide supportive evidence of confidentiality when making a claim;*

* *requests for confidentiality on the identities of substances which will, or may, enter the environment, not be permitted;*

* *requests for confidentiality should not be permitted regarding information on toxicology, ecological effects, epidemiology or health and safety studies; and*

* *there be a public appeal process regarding determinations that information is confidential.*

iv) Biotechnology Release Database

The biotechnology part of CEPA should also provide for the establishment of a data-base on the environmental release of all biotechnology products in Canada. Such a data base would be of assistance to governments, researchers, and other members of the public in assessing the overall use and effects of biotechnology products released into the Canadian environment. All environmental releases should be required to be entered into the data base, and members of the public should have direct access to the data base.

8) The new biotechnology part for CEPA should apply to <u>all</u> products of biotechnology which may enter the environment, without exception, including those currently proposed to be regulated under other Acts of Parliament, such as the Seeds Act, Pest Control Products Act, Fertilizers Act, and Feeds Act. The new CEPA biotechnology, and regulations made under it, should be administered by Environment Canada and Health Canada.

9) The new CEPA biotechnology part should include authority for the imposition of a full-cost-recovery, user-pay system for the processing of notification and assessment information, the approval and monitoring of field trials of products on

biotechnology, and monitoring related to conditions imposed on the import, manufacture, use, sale, or export or products of biotechnology.

10) *The CEPA biotechnology part should establish clear authority for the issuing of permits relative to the importation, testing, manufacturing or use of biotechnology products that are regulated under CEPA. This authority should include the capacity to:*

- *approve the testing, manufacture, use, processing, release or discharge into the environment, sale, offering for sale, import or export the new biotechnology product and products containing the new biotechnology product without conditions:*
- *approve the testing, manufacture, use, processing, release or discharge into the environment, sale, offering for sale, import or export of the new biotechnology product and products containing the new biotechnology product subject to any conditions which the minister chooses to impose; or*
- *impose a total, partial, or conditional prohibition on the testing, manufacture, use, processing, release or discharge into the environment, sale, offering for sale, import or export of the biotechnology product or a product containing the new biotechnology product.*

11) *The CEPA biotechnology part should provide authority to make regulations to implement international agreements regarding biotechnology to which Canada is a Party.*

12) *CEPA should be amended to provide the Ministers of the Environment and of Health the authority to enter into bilateral, multilateral and international agreements to develop, gather and share data on biotechnology.*

ENDNOTES

1.House of Commons Standing Committee on Environment and Sustainable Development It's About Our Health! Towards Pollution Prevention (Ottawa: House of Commons, June 1995).

2.See M.Winfield and B.Mausberg, "CEPA, Chemical New Substances, and Biotechnology," in M.Winfield, ed., Reforming the Canadian Environmental Protection Act: A Submission to the Standing Committee on Environment and Sustainable Development (Toronto: Canadian Institute for Environmental Law and Policy, September 1994).

3.Environmental Protection Legislation Designed for the Future - A Renewed CEPA/A Proposal (Ottawa: Government of Canada, 1995).

4.Ibid, p.4.

5.Ibid., pg.5.

6.Ibid., p.51.

7.Ibid., p.53.

8.Ibid., p.7.

9.J.M. Tiedje, R.K. Colwell, Y.L. Grossman, R.E. Hodson, R.E.Lenki, R.N. Mack, and P.J. Regal, "The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations," Ecology 1989, Vol. 20, No. 2 p. 301. See also E.Smit, J.D. van Elsas, and J.A. van Veen, "Risks Associated with the Application of genetically modified microorganisms in terrestrial ecosystems," FEMS Microbiology Reviews 88 (1992), 263-278, and M.Mellon and J.Rissler, Perils Amid the Promise: The Ecological Risks of Transgenic Crops on a Global Market (Washington, D.C.: Union of Concerned Scientists, 1994).

10. D. Pimentel, M.S. Hunter, J.A. LaGro, R.A. Efroymson, J.C. Landers, F.T. Mervis, C.A. McCarthy, and A.E. Boyd. "Benefits and Risks of Genetic Engineering in Agriculture", Bioscience (1989), Vol.39, No.9, pp.606-614, at 609.

11.Ernst and Young and Bio-Industry Council, A Brief Examination of the Bioremediation Industry Final Report (Ottawa: Environment Canada, June 1994), p.38.

12.New Scientist, October 21, 1995.

13.New Scientist, November 11, 1995.

14.New Scientist, November 4, 1995.

15.Environmental Protection Legislation Designed for the Future, p.15.

16.On this issue, see, for example, C.G. Brunk, L.Haworth, B.Lee, Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy (Waterloo: Wilfred Laurier University Press, 1991). See, also M.Winfield, "Risk Assessment in Environmental Policy-Making," paper presented at the Queen's University School of Policy Studies Symposium on Regulatory Efficiency/Risk Assessment, October 1995.

17.Environmental Protection Legislation Designed for the Future, pg. 15.

18.Environmental Protection Legislation Designed for the Future, p.15.

19.Ibid., pg.44.

20.In his history of modern biotechnology, Robert Bud comments that, "Regulatory Conflicts have been exacerbated by conflicts between agencies. Just as departments within national governments have squabbled for the right to promote biotechnology, so the question of whose regulations should apply has been contested to the point of absurdity...To civil servants, the definition of biotechnology has become a matter of money and power," Robert Bud, The Uses of Life (Cambridge: Cambridge University Press, 1993), pg.212.

21.See, for example, The Ecological Society of America, "The Release of Genetically Engineered Organisms into the Environment."

22.See Optima Consultants Understanding the Consumer Interest in the New Biotechnology (Ottawa: Industry Canada, November 1994), Table 14.

23.According to s.11 of CEPA a substance is considered "toxic" for the purposes of the Act if "it is entering or may enter the environment in a quantity or concentration or under conditions

a) having or that may have an immediate or long-term harmful effect on the environment;
b) constituting or may constitute a danger to the environment on which human life depends; or
c) constituting or may constitute a danger in Canada to human life or health."

24.CEPA, s.29.

25.Ibid., s.29(3)(a).

26.Ecological Society of America, "The Release of Genetically Engineered Organisms into the Environment: A Perspective from the Ecological Society of America," Ecology Vol. 20, No.2, April 1989.

27.See Standing Committee on Environment and Sustainable Development, It's About Our Health!, Chapter 5.

28.The *Constitution Act*, 1982, s.95.

29.Ibid., s.91(12).

30.Ibid., s.91(2).

31.Ibid., s.91(27). See *Re Canada Metal Co. Ltd., and the Queen*, (1982) D.L.R.(3d) 124 (Man Q.B.).

32.For a detailed discussion of this issue see Winfield and Mausberg, "CEPA, Chemical New Substances and Biotechnology," pp.20-21.

33.See the Hon. D. Harkness, Minister of Agriculture, House of Commons Debates June 29, 1959 on the occasion of the second reading debate of the current version of the *Seeds Act*.

34.see, for example, Standing Joint Committee of the Senate and House of Commons on Regulations and Other Statutory Instruments, Fourth Report (1980) para 81 and Appendix II).

35.See, for example, D.P. Jones and A.S. de Villars, Principles of Administrative Law (Toronto: Carswell, 1985)).

36.Standing Committee on Environment and Sustainable Development, Its About Our Health!, Recommendation 68.

37.Ibid., Recommendation 69.

38.CEPA s.20(1)(f) only allows releases of summaries of this type of information.

39.K.Cox, "A calamity of biblical proportions," The Globe and Mail, December 21, 1993.

40.See: Pesticide Registration Review Task Force, Recommendations for a Revised Federal Pest Management Regulatory System: Final Report (Ottawa: Supply and Services Canada, December 1990); and Pest Management Secretariat, Government Proposal for the Pest Management Regulatory System (Ottawa: Government of Canada, October 1994)

41.Winfield, ed., Reforming CEPA, Recommendations 33 and 39.