
CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW & POLICY

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A Preliminary Response to:

Enabling Biotechnology: A Strategic Plan for Ontario

CIELAP Brief 94/8

**Canadian Institute for Environmental Law and Policy
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I. Introduction and General Comments

The Canadian Institute for Environmental Law and Policy (CIELAP) is pleased to have been invited to comment on the report of the Biotechnology Council of Ontario (BCO) *Enabling Biotechnology: A Strategic Plan for Ontario*. The Institute has been involved in environmental law and policy research and education activities related to biotechnology for more than a decade, and has participated in consultations on the subject with the Ontario Ministry of the Environment, the federal departments of the Environment, Agriculture and Agri-Food, and Health, and the Canadian International Development Agency.

Unfortunately, the BCO report suffers from a number of major flaws. These issues must be addressed prior to any action being taken on the report's recommendations, particularly with respect to the expenditure of public funds, and the regulatory system for biotechnology products.

In general, the report completely fails to place the question of the role and development of the biotechnology industry in Ontario into a context of environmentally sustainable development, despite the government's repeated public commitments to this principle.¹ In addition, notwithstanding growing evidence of serious public concerns regarding the environmental, social, economic and ethical implications of many emerging biotechnology applications, the BCO did not undertake any meaningful public consultation on these issues in the development of its report.

Furthermore, the report reflects a very weak understanding of the environmental, social, economic and ethical issues raised by emerging biotechnology applications in the areas of environmental protection, agriculture and food, and health care. No action should be taken on the BCO report until a meaningful public discussion of these issues has occurred, and the Ontario government has developed a strategy designed to regulate and control biotechnology activities that are potentially hazardous, as recommended by the Premier's Council of Health, Social Justice and Well-Being 1993 report *Our Environment Our Health: Healthy Ecosystems; Healthy Communities; Healthy Workplaces*.²

II. Specific Concerns Regarding the BCO Report

1) Discussion of Applications in the Agriculture and Agri-Food Sector (pg. 29)

The BCO report provides a brief overview of emerging biotechnology applications in the agriculture and agri-food sector. Unfortunately, this discussion ignores the wide range of environmental, social and economic concerns which have been raised regarding these applications. In the case of herbicide resistant crops, for example, it has been argued that such crops entrench herbicide use by farmers at the expense of more environmentally sound alternatives, increase farmer's dependence on inputs provided by multi-national agricultural chemical firms, and ultimately lead to the development of more herbicide resistant pests, resulting in requirements for even more powerful herbicides.³

Similarly, the social, economic, and human and animal health issues related to rbST have been widely documented, most notably by the Standing Committee of the House of Commons on Agriculture and Agri-Food in its April 1994 report *rbST in Canada*. The moratorium imposed on the sale of this product by the federal government in August 1994 is reflective of the extent of the public concerns regarding the use of rbST in Canada.⁴

2) Environmental Applications (pp.29-30)

As is the case with the BCO's discussion of biotechnology applications related to agriculture and food, the report fails to recognize the environmental risks associated with the emerging uses of biotechnology in the environmental field, particularly with respect to bioremediation. One of the primary reasons for the slow pace of the development of federal regulations under the *Canadian Environmental Protection Act* in this area has been the level of uncertainty regarding the likely environmental effects of biotechnology products and the lack of adequate means of predicting these impacts.⁵

3) Ethics Consultation (pg.41)

The BCO report claims that a wide range of stakeholders were contacted in the course of the "social and ethical issues consultation" conducted under the auspices of the Council. Notwithstanding its extensive work on environmental and regulatory issues related to biotechnology applications, in some cases under contract to the Ontario government,⁶ CIELAP was not contacted as part of this process.

The BCO's references to public participation in its working group are also very surprising, as it is our understanding that this participation was extremely limited. Indeed, CIELAP withdrew from the Advisory Board process after attending one meeting, when it became apparent that environmental, social, and ethical issues were not going to be

addressed in any meaningful way.

With respect to the round table discussion on biotechnology hosted by the BCO in May 1994, it should be noted that an overwhelming majority of the participants, who came from a wide range of backgrounds and interests, refused to engage in a discussion of substantive issues prior to the establishment of a more meaningful process in which these issues could be addressed. Indeed, it was the inadequacy of these processes which promoted CIELAP to express its concerns regarding the BCO process to the Minister of Trade and Economic Development in May 1994.

4) S.W.O.T. Analysis (p.43)

The Strengths, Weaknesses, Opportunities and Threats Analysis presented on pg. 43 of the BCO report identifies public fears, regulations and the patent process as significant threats to the biotechnology sector. However, no substantial analysis of the basis of public fears regarding biotechnology applications is provided. With respect to the issue of patents, many commentators have raised serious questions regarding the moral, economic and social implications of permitting the patenting of life.⁷

5) Regulatory Issues (pg. 53)

The BCO report expresses concerns regarding the development of "made in Canada" regulations for biotechnology products rather than simply adopting the standards and procedures adopted by Canada's trading partners. CIELAP rejects this position.

Canadians have a fundamental right to make their own choices regarding how biotechnology products will be regulated in Canada. The question of what constitutes "acceptable risk" arising from the application of biotechnology products is a fundamentally political question. Canadians may reach different decisions in this regard from the citizens of other jurisdictions.

The BCO's claims regarding the safety of biotechnology products and the focus of public concern on applications related to human genetic technologies and "gene therapy," are not supported by the extensive and growing scientific literature on the potential environmental and human health impacts of biotechnology products released into the environment. In addition, the recent controversies regarding the use of rbST in Canada, the United States and Europe provide ample evidence that public concerns regarding biotechnology application extend far beyond human genetic technologies and "gene therapy."

The rbST issue also provides strong evidence that public concerns regarding

biotechnology products extend beyond the immediate questions of safety and human health impacts. Serious questions are being raised regarding the value, purpose and long-term socio-economic effects of these products. These issues must be addressed as components of the evaluation and approval of biotechnology products for use in Canada.

The BCO report also makes reference to the need to develop regulations which balance the needs of the industry with the safety of consumers and workers and the protection of the environment.⁸ This appears to contradict the Council's earlier claims regarding the safety of biotechnology products, suggesting that there is a conflict between the needs of the industry and consumer, worker and environmental safety.

Furthermore, CIELAP finds the suggestion that the protection of workers, consumers and the environment should be compromised to further the development of the biotechnology industry completely unacceptable and morally reprehensible. Biotechnology products which pose the potential to harm human or animal health or the environment should not be approved for use in Canada. Human health and environmental integrity should not be sacrificed to serve the interests of a particular economic sector.

6) Recommendations

Recommendation 1 - Ontario Office of Biotechnology

The BCO proposes the establishment of an Ontario Office of Biotechnology to work with the proposed Biotechnology Sector Council, be responsible for providing the policy framework necessary to implement Ontario's strategic plan for biotechnology, and to coordinate the efforts of the relevant government departments.

This proposal raises a number of concerns. The Office appears to be intended to promote the interests of the biotechnology industry within the Ontario government. Given this orientation, granting such a body a central role in the development of the government's policy framework regarding biotechnology seems a potentially dangerous approach, particularly in light of the BCO's recommendations regarding the need for a "reasonable" regulatory environment and the "balancing" of the needs of the industry against such concerns as consumer and worker safety and environmental protection. It is far from clear how such a body would take into account (if at all) the wide range of concerns which have been expressed regarding the ethical, environmental, social and economic consequences of many emerging biotechnology applications.

If a body of this nature is to be established, its structure must ensure the meaningful representation of the full range of stakeholders, including the industry, who have taken an interest in this emerging technology. In addition, rather than focusing on the exclusive promotion of the interests of biotechnology industry, it should be charged

with developing a policy framework for biotechnology in Ontario which addresses the concerns of all stakeholders.

Recommendation 2 - \$30 Million Capital Fund

The BCO proposes that a \$30 million capital fund be established by the province to assist biotechnology firms with capital investments and commercialization costs. No criteria for the evaluation of requests for support from the fund are proposed other than to require at least 50% of project costs to be provided by private sources.

Given the government's current fiscal situation, requests for investments of this nature must be weighed carefully against other potential uses for such funds. The greater public good might be better served, for example, through the investments in community and preventative health care, the development of alternative/sustainable agricultural practices, or the prevention of pollution by toxic substances.

Recommendation 3 - Purification Plant

The BCO recommends the construction and operation of a purification plant for biopharmaceutical products. No estimate of the costs to the public purse of this project are provided, and there is no evidence presented to support its commercial viability.

Recommendation 4 - Expert Investment Corporation

This proposal apparently would not involve the significant expenditure of public funds and we have no comment on it.

Recommendation 5 - Research and Development Tax Credit

The BCO recommends the provision of refundable tax credits for research and development related salaries of private and public biotechnology firms. No estimate of the potential cost to the public purse of this measure is provided, although it seems likely to be substantial (i.e. several tens of millions of dollars). Again, the question must be asked if this would be the best possible use of scarce public resources. In addition, the federal government's experience with Scientific Research Tax Credits should be examined carefully in the design of any such program for Ontario.

Recommendation 6 - Capitalizing Small Firms

No comment.

Recommendation 7 - Technology Diffusion

Over the past few years growing concerns have been expressed regarding the impact of business/university "partnerships" on the direction and quality of research conducted within publicly funded universities in Ontario and elsewhere in the world.⁹ Universities are provided with public funding to support research activities for the creation of knowledge for public use and to serve the public interest. These funds should not be employed to research intended to serve private economic interests. The costs of such research should be fully funded by the sponsoring businesses. Significant issues continue to exist regarding the ownership of research results from research conducted in Ontario universities.¹⁰

Recommendation 8 - Human Resources Management

This recommendation includes a proposal for an outreach program aimed at elementary and secondary science teachers to upgrade education in biotechnology at an early level. CIELAP is strongly of the view that any programs introduced into Ontario schools regarding biotechnology must reflect the range of ethical, social, and environmental concerns about biotechnology which exist in Ontario society. Such programs should seek to enhance student's ability to think critically about the choices which technologies like biotechnology present to us, rather than simply promote the technology.

Recommendation 9 - Biotechnology Network

The idea of a clearinghouse function for information about biotechnology may have some merit. However, steps would be required to ensure that any information provided represented the range of views which exist in society regarding the technology, and not just those of the industry. The multi-stakeholder steering committee, in which the industry would be one of many interests represented, would be required to ensure such an outcome.

Recommendation 10 - QC/QA Research and Training Program

No comment.

Recommendation 11 - Public Interest Awareness Forums

The BCO recommends the establishment of a regular forum for dialogue on biotechnology among all stakeholders. We welcome this recommendation. However, the precise role of the forum must be laid out in much greater detail. Research support would have to be provided to public interest stakeholders in order to ensure their effective participation. In addition, there is no clear indication of how such a forum would affect the government's course of action with respect to the support and regulation of the biotechnology sector in Ontario.

Recommendation 12 - Product Regulation

Refer to comments under point 8. **Regulatory Issues**

Recommendation 13 - Review Government Programs

Any government program review should ensure that programs serve the public interest, defined to include ethical, social, environmental, and economic concerns, rather than the interests of a particular industrial sector.

Recommendation 14 - Biotechnology Sector Council

The BCO recommends the establishment of a Biotechnology Sector Council, representing biotechnology stakeholders, to oversee the implementation of the proposed sectoral plan. Government funding is requested to provide administrative support to the Council. "Biotechnology stakeholders" are never defined, but would appear to include only industry representatives. If such a body is established with public funding, it should be multi-stakeholder in nature, with industry represented as one of several groups with an interest in biotechnology. Non-governmental representatives should be compensated for their time made available to the Council and research funds should be provided. If such a body is established it should be provided with the following mandate:

- (1) to raise public awareness and deliver public education programs on biotechnology issues;
- (2) to solicit responses to the Biotechnology Industry Strategy;
- (3) to receive input on the proposed policy and regulatory framework from the public; and

- (4) to recommend a provincial policy and regulatory framework which protects the environment and human health, but which also allows beneficial applications of biotechnology to proceed.

While a consensus among parties in the consultation is desirable, consensus should not be required in the development of the final recommendations.

7. Ethics Consultation Process

The "ethic's consultation" undertaken under the auspices of the BCO is a major disappointment. There was a complete failure to place the role of biotechnology application into a context of environmentally sustainable development, despite the government's strong public commitments to this principle. In addition, the "ethics consultation" reflected a weak understanding of the environmental and scientific issue related to biotechnology applications in the environmental and agricultural fields. There was also a failure to address meaningfully the wide range of social and economic concerns which have been identified in relation to biotechnology applications in these fields.

As noted earlier, CIELAP was particularly surprised not to be contacted as part of this consultation, despite its extensive work on issues related to the environmental release of biotechnology products, including work done under contract for the government of Ontario.

CIELAP also rejects the report's argument that modern biotechnology applications do not differ substantially from previous human efforts at genetic manipulation through selective breeding and uses of life forms for industrial purposes, such as making cheese. Recombinant DNA and cell fusion technologies permit the species barrier to be overcome. This constitutes a fundamental change in the potential scope and nature of biotechnology applications comparable, if not greater, in scale to the chemical and nuclear revolutions of earlier decades of this century.

The scope environmental, human health, social and economic changes and problems which have resulted from previous technological revolutions of this nature have been enormous. This reminds us of the importance of learning from our past mistakes, and ensuring that we have a complete understanding of the environmental, health, social and economic implications of applications of this new technology before they proceed into commercial use.

Finally, the report on Social and Ethical issues states that there was a call for a moratorium on biotechnology research during the May 31 roundtable discussion. There was very limited discussion of any substantive issues during the roundtable, and CIELAP does not recall any calls for a moratorium on all biotechnology being made. However, it

was made clear that many stakeholders, including CIELAP were of the view that no Ontario government initiatives to support the biotechnology sector should be taken until a process to respond meaningfully to the ethical, social, environmental, economic and regulatory issues raised by non-industrial stakeholders regarding the biotechnology.

8) Regulatory Issues

The BCO's discussion of regulatory issues related to biotechnology raises a number of very serious concerns. Surprisingly, the report makes no reference to the Ontario government 1989 Green Paper *Biotechnology in Ontario: Growing Safely*, or the 1993 recommendation of the Premier's Council on Health, Social Justice and Well-Being, *Our Environment Our Health: Healthy Ecosystems; Healthy Communities; Healthy Workplaces*.

In its report BCO argues for a "reasonable" regulatory requirement, but provides no clear indication of what this might mean. The council also argues for the product-, as opposed to process-based regulation of biotechnology products. CIELAP strongly rejects this position, and is of the view that a full evaluation of a biotechnology product must include consideration of the process by which it was produced.

CIELAP is also surprised at the Council's suggestion that the "scientific" regulation of biotechnology products should be separated from the consideration of social and ethical issues. This raises the question of on what basis would the normative criteria for biotechnology products be established? Science, by its own epistemological claims as a system of knowledge insists that it can only provide answers to questions of fact, not value.

The evaluative criteria, by definition, must be based on some value framework, such as the protection of human health, or the maintenance of the integrity of species. These criteria can only be legitimately established through public discussion and debate. Unfortunately, such discussion and debate has been conspicuously absent for the development of Canadian public policy relation to biotechnology applications.

In this context, CIELAP has identified four criteria against which biotechnology products in the agricultural and environmental fields should be evaluated.¹¹ These are:

- 1) the purpose for which the product has been developed and whether the intended purpose will serve the public interest;
- 2) the potential immediate and long-term direct and indirect environmental, human and animal health effects of the product, including the cumulative effects of commercial scale use and impacts on biodiversity;

- 3) the effectiveness of the product for its intended purpose;
- 4) the availability of alternative means of achieving the product's purpose which may pose lower environmental and health risks.

Products whose assessment demonstrates:

- * the potential for harm to human or animal health or the environment
- * ineffectiveness for their intended purpose;
- * the availability of alternatives which pose a lower potential for harm to human health or the environment; or
- * whose intended purpose does not serve the public interest

should not receive public support for their development or be approved for use or manufacturing in Canada.

III. Conclusions

The BCO report suffers from a number of serious failings which must be addressed prior to any movement on the Council's recommendations. A process should be established by the Ontario government to effectively address the environmental, social, ethical and economic issues which arise from the emerging applications of biotechnology in Ontario. In addition the government should move forward on the development of an effective regulatory structure for biotechnology products which will be released into Ontario's environment.

CIELAP welcomed the opportunity to comment on the BCO report, and looks forward to being able to make further contributions to the Ontario government's development of policy in this important area.

Endnotes

1. See, for example, Restructuring for Sustainability (Toronto: Ontario Round Table on Environment and Economy, 1991).
2. Our Environment Our Health: Healthy Ecosystems, Healthy Communities, Healthy Workplaces (Toronto: Premier's Council of Health, Well-Being and Social Justice, 1993), pp.22-23.
3. For a general discussion of these issues see, for example, M.Mellon and J.Rissler, Perils Among the Promise: Herbicide Resistant Crops in A Global Market (Washington, D.C.: Union of Concerned Scientists, 1994).
4. See Government Response to the Report of the Standing Committee on Agriculture and Agri-Food "rbST in Canada (Ottawa: Government of Canada, August 1994).
5. See, for example, 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; 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; 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; 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; and Clement International Corporation Issue Paper: Development of Ecological Tier Testing Schemes for Microbial Biotechnology Applications (Washington D.C: United States Environmental Protection Agency, and Environment Canada December 1993)
6. The Regulation of Biotechnology (2 Volumes) (Toronto: Canadian Environmental Law Research Foundation, 1988).
7. See, for example, The Crucible Group, People, Plants, and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity and Rural Society (Ottawa: International Development Research Centre, 1994).
8. Biotechnology Council of Ontario, Enabling Biotechnology, p.54.
9. See, for example, J.C. Polanyi, "When to leave a scientist alone," The Globe and Mail, November 4, 1994.

10. See the Globe and Mail, Nov. 3, 1994.

11. See W. 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, 1994).