

**BIOTECHNOLOGY AND THE RESOURCE SECTOR:
THE NEED FOR POLICY DEVELOPMENT**

Canadian Environmental Law
Research Foundation

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Foundation
Biotechnology and the Resource Sector: The
need for Policy Development**

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1. INTRODUCTION

Biotechnology offers a wide variety of potential benefits to Canadian agriculture, pulp and paper, mining and fishing industries through such measures as increased crop yields, more effective pest control and improved treatment of toxic waste products. At the same time, the release of genetically altered organisms to the environment inevitably carries with it certain potential risks of environmental damage.

At present there is no legislation in Canada intended specifically to govern industrial application of recombinant DNA techniques. To ensure environmental protection and to provide industry with the stable and predictable regulatory environment needed for research and development, it is essential that biotechnology policy be developed and implemented as quickly as possible.

The proposal presented in the following pages is for a grant of \$8,975 which would be used by the Canadian Environmental Law Research Foundation to prepare background papers and to prepare and distribute proceedings for a workshop titled A Roundtable Discussion of Biotechnology Policy Development. The Roundtable is intended to bring together all those concerned with biotechnology for discussion and clarification of the next steps required for

timely and successful policy implementation.

The Roundtable has been designed in consultation with relevant federal officials in order that it will complement and assist the policy development process currently being undertaken by the Government of Canada. As such, it will provide distinct benefits to all those in Canada working toward commercially successful and environmentally sound application of biotechnology methods in the resource sector.

2. THE NEED FOR BIOTECHNOLOGY POLICY

Commercial applications of recombinant DNA techniques which alter the genetic structure of living organisms offer a variety of potential benefits to industrial development in Canada. Canada's international competitive position is dependent upon taking full advantage of these potential benefits.

The National Biotechnology Advisory Committee, an advisory body appointed by the Minister of State for Science and Technology, which includes representatives of industry, university and the federal government, has stated in its most recent annual report that:

Advances in biology and biochemistry have opened a window of opportunity and, at the same time, have provided a challenge for Canada's industrial base. Industries and governments throughout the world are moving swiftly to capitalize upon these opportunities. The reaction of Canadian industry must be accelerated substantially if Canada's traditional markets are to be preserved and new markets developed.

The Science Council of Canada has also stated that Canada's international competitive position is dependent upon biotechnology development and has suggested that Canada follow a strategy of focusing development upon the resource sector industries such as agriculture, forestry and mining.

Like every other new technology, biotechnology carries with it potential risks as well as benefits. The release of genetically altered organisms to the natural environment may upset checks and balances of the ecosystem which have developed over time through evolution, thus producing unforeseen and significantly damaging consequences. In the United States, such releases to the environment have been the subject of extensive controversy and litigation. In November, 1985 the Environmental Protection Agency gave final approval to field testing of genetically altered bacteria which will be sprayed on strawberry plants to protect them from frost damage. Other such test releases are expected to follow. To date, no approval has been given for comparable tests in Canada.

The Canadian Environmental Law Research Foundation believes that the federal and provincial governments in Canada must act now to ensure that legislation provides adequate protection from potential risk associated with biotechnology development. This belief is shared by others. Mr. John Evans, President of Allelix, at a workshop on biotechnology, held in Toronto on October 29, 1985, advanced the view that, from an industry perspective, immediate regulatory action is essential to provide the certainty and predictability in the regulatory system which industry requires for successful development. The National Biotechnology Advisory Committee has stated that priority must be given to "clarifying the regulatory framework to ensure safety and to allow effective

planning for industrial biotechnology developments." In a similar manner, the Science Council of Canada has called for immediate action to develop biotechnology policy and clarify the regulatory approach. In recognition of this need, the Ministry of State for Science and Technology has initiated a biotechnology policy development program.

Thus at the present time all sectors - industry, government and environmental - agree that steps must be taken to put in place an appropriate policy and regulatory framework before the first release of genetically altered organisms to the environment in Canada.

3. CURRENT STATUS OF BIOTECHNOLOGY POLICY

Although in the 1970's the Medical Research Council developed voluntary guidelines governing laboratory research funded by the Council, to date no legislation specifically intended to regulate biotechnology has been enacted in Canada.

In 1983 the government of Canada adopted the National Biotechnology Strategy, intended to ensure that Canadian industry fully benefited from biotechnology opportunities, and created the National Biotechnology Advisory Committee. Although the bulk of its attention has been centred on research and development, the Committee mandate includes regulatory issues. In 1984 the Canadian Environmental Law Research Foundation developed a paper on the regulation of biotechnology which was presented for comment at a one-day conference on October 9, 1984, hosted by the Foundation. In that same year, the Science Council published the paper titled Regulatory Policies on Biotechnology in Canada.

In 1985 the National Biotechnology Advisory Committee created the Working Group on the Safety and Regulatory Aspects of Biotechnology, an inter-departmental committee co-chaired by representatives of Environment Canada and Health and Welfare Canada. The Working Group, as its first task, initiated a comprehensive review of all potentially applicable legislation in Canada.

In the fall of 1985, the Science Council published the report titled Seeds of Renewal: Biotechnology and Canada's Resource Industries which called for a number of steps intended to further develop and clarify biotechnology policy. At the same time, the Ministry of State for Science and Technology initiated a biotechnology policy development process. Consideration is also being given to biotechnology policy within the context of the review of the Environmental Contaminants Act currently being carried out by Environment Canada.

The research being done by the Working Group on the Safety and Regulatory Aspects of Biotechnology, intended to identify gaps in existing legislation, will be completed and made public by March, 1986. The Roundtable proposed here is intended to build upon that research by bringing together all those concerned for detailed discussion of the steps which must be taken to fill the gaps identified by the Working Group.

Such a discussion will stimulate and assist the policy development process currently underway in a number of federal departments.

4. THE PROPOSED ROUNDTABLE DISCUSSION OF BIOTECHNOLOGY
POLICY DEVELOPMENT

(a) Format

The Roundtable will be a one-day workshop discussion attended by twenty to thirty people, representative of all concerned sectors, who are knowledgeable and would benefit from discussion on a detailed level. Both a transcript and minutes of the discussion will be taken to be used in preparation of the Roundtable proceedings.

Three papers will be developed by CELRF staff and contract researchers and distributed to Roundtable participants before the event. The first two would be over-view papers, as follows:

- (a) a summary history of the development of biotechnology policy in Canada to date

- (b) an over-view of the present state of biotechnology policy in a limited number of other jurisdictions - those might be the United States, Australia and the United Kingdom

The third paper, which will be based on previous work done by the Research Foundation and the research currently being

completed by the Working Group on the Safety and Regulatory Aspects of Biotechnology, will set forth the issues which must be addressed in the next stages of policy development. Some examples include use of new versus amended legislation; implementation of policy by new or existing institutions; relative roles of the federal and provincial governments and methods of ensuring informed public participation in the policy development process. The identification of issues in this paper will provide the agenda for the bulk of the Roundtable discussion.

The agenda for the Roundtable, therefore, would be as follows:

Agenda:

1. Policy development in Canada to date
2. Lessons to be learned from other jurisdictions
3. Issues to be addressed
4. Next steps in the policy development process

To the extent possible, discussion will be structured so as to reach consensus on the next steps for policy development.

It is anticipated that the Roundtable will be held in May or June of 1986. Two hundred and fifty copies of the proceedings will be distributed to all interested parties in Canada.

(b) Participants

Representatives will be invited from the following agencies:

Federal government:

Agriculture Canada

Energy, Mines and Resources

Environment Canada

Health and Welfare

Ministry of State for Science and Technology

Department of Regional and Economic Expansion

Provincial governments:

agriculture, natural resources, environment and industrial
development ministries

Environmental organizations, such as:

Canadian Nature Federation

Federation of Ontario Naturalists

Pollution Probe Foundation

Canadian Environmental Law Association

Industry:

biotechnology industries such as Allelix
companies with an investment interest in biotechnology
development

Other agencies:

National Biotechnology Advisory Committee
Science Council of Canada
Medical Research Council
National Research Council
Law Reform Commission of Canada

(c) Budget

1. Background papers

Contract research: supervised and
finalized by CELRF staff

(a) over-view papers, \$1,000 each	\$2,000
(b) issues paper	<u>2,000</u>
	4,000

2. Roundtable

Room	400
Luncheon \$15 x 25	375
Copying and distribution of background papers	<u>200</u>
	975

3. Proceedings

Transcript	750
Draft proceedings (contract basis)	1,000
Print and distribute 250 copies	750

4. Administrative overhead 1,500

TOTAL \$8,975

(d) Benefits

By holding the Roundtable discussion in the spring of 1986 - after release of the Working Group report and before any of the current policy development initiatives are irrevocably committed to a particular course - a number of benefits will accrue. These include the following:

- . an opportunity for discussion among all sectors and co-ordination and information sharing among the different initiatives currently underway
- . a broadening of the policy dialogue by including non-government representatives
- . establishment of recommendations for next steps in the policy process
- . by distribution of the Roundtable proceedings, presentation of those recommendations to relevant officials

5. THE CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION
BIOTECHNOLOGY PROGRAM

The Canadian Environmental Law Research Foundation has undertaken work in the area of biotechnology law and policy since the early spring of 1984. The Foundation believes it is essential that government, industry and other sectors work together to design and implement adequate regulatory measures before the first release of genetically altered organisms to the environment. The focus of the program is environmental protection and other regulatory aspects, such as occupational health legislation, have not specifically been addressed.

In the spring and summer of 1984 the Foundation undertook a review of all potentially applicable Canadian legislation. A model for one potential regulatory approach, combining a newly-created federal regulatory agency with provincial licensing powers, was then developed and presented for public discussion at a one-day conference held on October 9, 1984.

The objectives of the CELRF biotechnology program are to broaden participation in the biotechnology policy dialogue and to inform the Canadian public of the need for government action in this area. The Foundation believes that by these means it can

best assist the development and implementation of regulatory policy which will both ensure environmental protection and allow for successful industrial development.

News media coverage of the 1984 conference succeeded in raising the profile of the issue. Since then, the Foundation has undertaken further research in the area and participated in the policy dialogue. The Roundtable proposed here is another component of the Research Foundation program.

The Foundation is also working with two volunteers, Ms. Tiina Kurvits and Ms. Yvonne Scof, who combine legal and genetic engineering experience, to develop the next stage of the Foundation research program.

6. THE CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION

The Canadian Environmental Law Research Foundation is a registered charitable organization, founded in 1970. The Foundation shares office space and works in close partnership with its sister organization, the Canadian Environmental Law Association.

The primary substantive focus of the Foundation's research activities is toxic chemical contamination of the environment. With respect to procedural matters, attention is centred upon such things as the interface between science and environmental law, the problem posed by political and administrative jurisdictional diversity for integrated, holistic environmental protection and the environmental assessment process. The Foundation carries out research in environmental law and policy areas related to these and other issues and disseminates the products of that research by means of its publishing and conference programs.

The Foundation's best known publication is Environment on Trial (C.E.L.R.F., 1978) a comprehensive guide to Ontario environmental law. Others include Poisons in Public (Lorimer, 1980), Acid Rain: The North American Forecast (Anansi, 1980), Environmental Rights in Canada (Butterworths, 1981), and,

most recently, Canadian Occupational Health and Safety Law Handbook (CCH, 1983). The Foundation is also publisher of the Canadian Environmental Law Reports, the only environmental law reporter in Canada.

In April, 1984, the Foundation published jointly with the Pollution Probe Foundation Breaking the Barriers which is a study of select action which might be taken by governments at all levels to facilitate increased recycling and reduction of industrial waste.

In June of that year, the Foundation, working under contract for Environment Canada, completed an analysis of potential elements which might be included in an environmental bill of rights to be introduced at the federal level.

Since April of 1984, the Foundation has carried out a study of legal reforms required to facilitate citizen intervention across the U.S. - Canada border in transboundary pollution cases. The study, carried out with financial assistance from the Joyce Foundation of Chicago, will be completed and published by Carswell Legal Publications in March, 1986. The Foundation intends to do further work in the transboundary area by initiating in 1986 a study of potential application of the concept of uniformity of law in the Great Lakes basin.

In October of 1983, working with the Environmental Law Institute of Washington, D.C., with financial assistance provided by the Donner Canadian Foundation and American sources, the Research Foundation initiated a study of legal reforms required to better regulate local and long-range transport of toxic and oxidant air pollutants. That study will be published in February, 1986 by CCH Canadian Ltd. and distributed in both Canada and the United States.

Other current research includes:

- . an examination of the environmental assessment process in Ontario
- . a study of news media reporting of toxic contamination cases
- . a study of waste management legislation in Ontario, done under contract to the Ontario Waste Management Corporation

Recent conferences and seminars hosted by the Foundation include:

- . October 9, 1984: a one-day conference on the regulation of biotechnology
- . October 31, 1984: a one-day workshop on toxic and oxidant air pollution
- . February 27, 1985: a roundtable discussion of pesticides law and policy, hosted jointly with the Law Reform Commission of Canada
- . February 28, 1985: a one-day workshop on the Ontario Environmental Assessment Act
- . May 6, 1985: a one-day workshop on jurisdictional barriers to environmental protection in the Great Lakes basin
- . November 1, 1985: with staff of Dartmouth College, New Hampshire, discussion of a proposed bilateral network for transboundary pollution issues

Curriculum vitae for Mr. Doug Macdonald, Executive Director and Ms. Marcia Valiante, Director of Research, follow.