CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW & POLICY

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THE REGULATION OF BIOTECHNOLOGY

A one-day conferernce presented by the Canadian Institute for Environmental Law and Policy

Toronto, October 9, 1984

FORMERLY THE CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION

THE REGULATION

OF

BIOTECHNOLOGY

A one-day conference presented
by the Canadian Environmental
Law Research Foundation

Toronto, October 9, 1984

October 9, 1984

Dear Delegate:

I am pleased to welcome you today to our one day symposium, "The Regulation of Biotechnology", presented by the Canadian Environmental Law Research Foundation.

The luncheon menu today is:

Freshly Made Soup of the Day

Ballottine of Chicken "Chasseur"

Filled with Mushrooms, Rice and

Pate, Laced with Green Peppercorn Sauce

Cauliflower Polonaise

Green Beans with Almond Butter

Rainbow Bombe

Basket of Rolls and Butter

Coffee - Tea

Should you have any dietary restrictions please see me or other staff members at the registration table during the mid-morning coffee break.

MESSAGE CENTRE

Please have telephone messages left at the hotel front desk. Ask the caller to specify that the message should be taken to the registration desk inside the Essex Room.

Should you have any questions please do not hesitate to see me during the course of the day.

Yours sincerely,

Doug Macdonald
Executive Director

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THE REGULATION OF BIOTECHNOLOGY

October 9, 1984

THE CURRENT STATE OF BIOTECHNOLOGY IN CANADA

Mr. Alain Albagli, Ph.D. M.B.A.
National Research Council

CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION

October 9, 1984

THE CURRENT STATE OF BIOTECHNOLOGY IN CANADA

Alain Albagli, Ph.D., M.B.A.

National Research Council

Industry Development Office

Program for Industry/Laboratory Projects

Mr. Chairman, Ladies and Gentlemen,

I was relieved and excited when Grant called me last February to discuss the subject of a conference centered upon the topic of Biotechnology. Relieved, because I felt then, as I feel now, that in a democracy like Canada, debate is the most effective means to educate the public, clarify the issues and develop policy options. I was also excited at the opportunity to participate in such a debate and in the process increase my own knowledge.

Last January, Linda Simms of the CBC Journal called me while she was researching the ice-minus issue in order to prepare the program which was aired January 18. I would like to congratulate her and the CBC for the quality of that program. At that time I not only provided her with factual information, and research leads; but also warned her that Biotechnology evolves so fast that it is difficult to remain on top of it. It is even more difficult to identify which specific research result may have an industrial application. If you allow me, I would like to compare the state of Biotechnology today to that of the information field a decade ago. Then mini computers had just entered the market and although we all saw the potential, I doubt if our collective crystal balls could have predicted that computers and information would merge into what is sometimes called Informatics.

For my part I will define biotechnology and describe the nature of the technologies involved. With your indulgence, I will make some attempt at delineating the parameters which will shape the future of Canadian bio-industries. I will conclude by describing the national biotechnology strategy and some of the Canadian initiatives.

DEFINITION OF BIOTECHNOLOGY

Any gathering on Biotechnology starts with the awesome task of defining what one is talking about. Indeed, as member of the Canadian delegation to the OECD group of experts, I witnessed a large number of experts spending quite a lot of time in defining what the term meant.

Everytime you open a book on biotechnology you find a new definition and they are all more or less equivalent. The one we use at the National Research Council is as follows:

> The application of science and engineering to the direct or indirect use of cells from plants or animals, of micro-organisms, in their natural or modified forms, for the production of goods or the provision of services.

Modern applied biology is sometime used instead of Biotechnology. This terminology may be more accurate, as what we are witnessing represeents the industrial application of a modern science namely: biology in much the same way as we have witnessed the application of other sciences such as chemistry or physics. Modern applied biology involves many technologies, such as genetic engineering, cell fusion, and process engineering. It includes research disciplines and topics such as genetics, physiology, biochemistry, enzymology, microbiology, etc.... These novel techniques allow a large amount of control over biological systems. To quote Ron Cape "we are now doing genetics with our eyes open". This industrial application also requires industrial interest, financial backing with a degree of experience, practical manufacturing expertise, marketing skills, and certainly a perspective on the future.

Recombinant DNA technology can be used in a wide range of industrial sectors to develop micro-organisms that produce new products, or existing products more efficiently, or large quantities of otherwise scarce products. This technique can also be used to develop organisms that themselves are useful, such as micro-organisms that degrade toxic wastes or new strains of agriculturally important plants.

Cell fusion, the artificial joining of cells, combines the desirable characteristics of different types of cells into one cell. Monoclonal antibodies are obtained through this technique and are used in the diagnosis and treatment of disease and the purification of proteins. Applications of this technology are limited for the most part to the bio-medical field and to the agricultural/forestry industry (fusions of plants cell protoplasts to generate hybrids).

Bio-engineering, though not a novel genetic technique, allows the adaptation of biological laboratory procedures to large-scale industrial use. Modern fermentation technologies will be applied in most industrial sectors, but the extent of their use will depend on the successful generation of new and useful micro-organisms that can be grown on a large scale. Likewise, immobilized bio-processes, such as on-stream bioreactors for waste stream detoxification, will be utilized only to the extent that other biotechnologies generate worthwhile organisms or enzymes for the purpose of attachment.

The development of a product via recombinant DNA begins by obtaining DNA either through organic synthesis or derived from biological sources such as tissues. The DNA obtained from one or both sources is tailored to form a basic gene which contains the genetic information to code for a desired product, such as human interferon. Control signals containing instructions are added to this gene. The circular DNA molecules, called plasmids, are isolated from micro-organisms such as E.coli, are cut open, sliced back together with genes and control signals to form recombinant DNA molecules.

These molecules are introduced into a host cell. Each plasmid is copied many times in a cell, each cell then translates the information contained in these plasmids into the desired product, a process called gene expression. Cells divide and pass on to their offspring the same genetic information contained in the parent cell. Subsequently, fermentation of large populations of genetically engineered micro-organisms is carried out first in flasks then in small fermenters and eventually into large fermentation tanks. Cellular extracts obtained from the fermentation process is then separated, purified and packaged.

The reason I have gone through this long winded explanation is to give you a sense of the complexity of the operation that is required to be performed first in the laboratory and then in industry.

FUTURE CANADIAN BIO-INDUSTRIES:

There appears to be agreement that biotechnology will affect trading relationships. Hence it is important for Canada to at least have the capability of making use of the technology if not of developing it.

The attractive feature of bio-industries are that they require a relatively lower level of energy input, are renewable resource based and are less polluting. Thus the future of bio-industries depends to a considerable extent upon the availability of renewable and other raw materials. It is also predicted that waste emissions from bio-industrial processes will be less polluting than those from present industrial processes.

It is clear that Canada is well endowed with, and dependent upon, renewable resources (such as biomass and water) and raw materials (such as minerals). I also do believe that bio-technology is of paramount importance for the economic well-being of the Canadian economy.

I will review some of the recent developments and assess their potential for commercial applications in a rather critical way as opposed to the usual upbeat reviews. My caution has more to do with the time frame in which commercial-applications will occur then with the inevitability of the advances. Despite the major advances made in the past 15 years, industrial application of biological processes is nowhere near the stage of broad adoption. Indeed I saw recent forecasts that indicate that wide adoption of this technology by the health sector will occur in 1990 and only in year 2011 for bio-electronics. In order to put this field in context I will invite you to visualize an increasing level of biotechnological sophistication as follows:

1. Extension of the concepts of selective breeding and animal husbandry;
2. forced evolution of organisms by placing them in a selective rigorous environment and selecting out the strains which resulted from the evolutionary pressure; and

3. application of true molecular biology and/or cell fusion techniques

The present industrial biotechnological processes are mainly based on organism selection (that is number one and two) as opposed to true molecular biology/cell fusion. I submit that industry will thoroughly investigate naturally occuring biological systems, for potential commercialization, prior to making significant investments in recombinant DNA technology.

Applications of Biotechnology in the health field are currently receiving the most attention. These applications probably account for 60-70% of all funds (on a worldwide basis) expended on R&D in Biotechnology. Several factors have increased the attractiveness of investment opportunities in the health field. Chief among these is the clarity of the path from laboratory to commercial exploitation. Our knowledge of the systems and mechanisms that affect health have markedly increased over the last fifteen years. This knowledge has led to an explosion of diagnostic products (MAB's and DNA probes). In Canada, aside from R&D directed to our national protein (insulin), the major part of industrial research is directed towards the production of vaccines and diagnostic products. The diagnostic market is expected to grow more rapidly than the market for pharmaceuticals in percentage term. It is expected that biotechnology will influence 85% of diagnostic products while only 40% of pharmaceuticals will be affected by biotechnology. If that is the case, then certainly our present industrial efforts are rightfully directed towards those commercial niches where Canada has already assembled active research teams.

Canada has traditionally been strong in agricultural research if only because you cannot just pick up a plant and grow it in a cold country without some strain development. Biotechnology could have a substantial impact on our agriculture and food production. Examples of the type of development which are envisaged are: plant-strains with built-in nitrogen fixing capabilities, and/or disease, drought and pest resistance, and/or salt and frost tolerance; production of biological pesticides to replace chemical pesticides, and production of protein for animal feed from biomass. Plant genetic engineering started only in the late 1960's and several scientific and technical barriers still remain on the way to the development of generalized effective genetic modifications techniques of plants at the cellular levels. The first obstacle is related to the fact that regeneration of whole plants from single cells is difficult. The second problem results from the fact that many agronomic traits are tissue-specific. The expression of these traits is found in only one or a few tissues within the plant and is often not found in cells cultured in vitro. The third scientific obstacle to surmount is the development of an effective method for inserting and expressing foreign genes in plant cells.

The mining sector is very important to the Canadian economy. Significant quantities of copper are being mined in the United States and Chile using microbial leaching processes. I was recently told that South African mining companies are using a rDNA strain of T. ferroxidans with cyanide resistance. The bacterial degradation of copper sulfides normally proceeds in two stages: separation of copper ions from the sulfur, followed by oxidation of the sulfur to sulfuric acid. Thus the roasting step is eliminated. This step is energy intensive and highly polluting. The B.C. Research Council claims that its leaching process blocks the second step and thus precipitate elemental sulfur. Research into leaching of uranium ore has also been undertaken and some attempts have been made with gold. Unfortunately, many of the biochemical intricacies of bacterial leaching are unknown. The multi-disciplinary nature of biotechnology is evident in mineral leaching more then in any other areas. Our limited knowledge has been ascribed to the fact that researchers are either microbiologists who know how to handle organisms but don't know mining or they are engineers who are not sensitive to biology, but know what blasting ore and carting it away means.

To conclude this overview of just a few sectors, let's pretend that I was called upon to prepare a critical evaluation of the state of the art of Biotechnology in oil production; and report for say to a Board of directors of a large oil company, who know nothing about science but have a perspective on the future. Some of the result might read like the following:

Microbial enhancement of oil recovery (MEOR) and other applications of microbial systems in the oil industry will no doubt capture an important niche in petroleum technology. As with for other applications it will not become the universal means of increasing oil recovery but will become an added tool. Present research in MEOR attempts to define/optimize either of the following

1) the production of various compounds which, when injected into a petroleum reservoir, will enhance oil production, for example, bio-polymers are used in drilling mud preparations and/or in waterflooding activities. Biosurfactants can be used as emulsifiers to decrease the oil viscosity.

2) Injection of micro-organisms into the reservoir for in situ production of products that will enhance oil recovery for example, production of carbon dioxide that could repressurize oil fields.

There are still many developments that require attention. Most notable would be the development of micro-organisms which can grow on petroleum feedstock and the resolution of the adsorption problem. Further study of indigenous petroleum reservoir flora is, of course, required since in most environmental applications the micro-organisms of choice are those indigenous species.

Such a report may induce a Board of directors to embark in a cautious manner upon an R&D program in MEOR. Of course my report will have to include a cost/benefit analyses and other economic facts which are understandable to accountants.

I hope I have given you an appreciation of the complexity of biotechnology in relation to some of the awesome objectives it has set for itself. I am sure you have an increased appreciation of all the R&D that is still required in order to reap the benefits of Biotechnology, and the necessity for Canada to press on with developing an indigenous capability in Biotechnology.

NATIONAL BIOTECHNOLOGY STRATEGY

In first year economics one learns that there are two ingredients which control production: Capital and Labour.

Capital can be from either private or public sources. In Canada, major funding for research originates within the federal government. This funding takes many forms: University research via NSERC and MRC; in-house research by NRC and various government departments; and assistance to industry through direct contributions and/or generous tax write-off schemes, namely the SRTC. Unfortunately, in Canada it would appear that many corporate bodies regard anything with less than a 90% chance of success as a risky venture. Although that perception is slowly changing, the requirement for government assistance remains.

Labour: Unless sufficiently trained people are available, the development of a Canadian biotechnological industry will not occur. Reliance on the importation of manpower is not practical because of the rapid expansion of biotechnological activity worldwide. Canadian institutions are in direct competition with every other institution involved in biotechnological research. Of particular need will be interdisciplinary skills which will provide graduates from both the universities and technical colleges with the flexibility to adapt and thus contribute to the broad range of opportunities presented by biotechnology. Thus the required disciplines includes not only molecular geneticists and cell biologists but also biochemists, protein chemists and other chemists as well as fermentation engineers and many others. Shortages in many of the skills required for biotechnological development are already apparent in Canada.
Training of students is only one component of the biotechnology manpower picture. Today's scientists and technologists must also be offered the opportunity to acquire new skills relevant to biotechnology and its developments.

The federal government identified biotechnology as a long-term economic development priority. The reasons for the government intervention were described as follows:

- Canada's economic growth is heavily dependent on its natural resource sector;
- this sector is characterized by stiff international competition;
- this sector will be drastically affected by biotechnological advances;

- even if Canada is able to buy technology from abroad, foreign development may not be adaptable to the Canadian milieu;
- our natural resource industry will become uncompetitive unless we develop our own indigenous bio-industries;
- if our natural resource industry becomes uncompetitive, Canada's economic growth will at best stagnate.

The strategy identified four area of application of particular interest to Canada, namely: plant strain development-nitrogen fixation, cellulose utilization and waste treatment, mineral leaching and human and animal health care products. Networks involving universities, provincial research organizations, industry, and federal and provincial research establishments have been created in order to strengthen the research base and promote on interdisciplinary approach. Furthermore the Cabinet directed that a thorough examination of the role of regulation be undertaken and that an interdepartmental Committee be instituted to ensure the effective implementation of the strategy.

In support of the National Biotechnology strategy, the Government has approved a major expansion of the National Research Council's Biotechnology research program. As an element of the NRC expansion, the Government established a Biotechnology Research Institute in Montreal and an extension to the Plant Biotechnology Institute (formerly the Prairie Regional Laboratory) in Saskatoon. The major capital cost of the building and equipment for the Biotechnology Research Institute is estimated at $61 million, and that for the extension of the Plant Biotechnology Institute is estimated at $6 million. Moreover, NRC has obtained approval for an addition to a building in the Montreal Road Campus to house the molecular genetics section of the Division of Biological Sciences.

The objectives of the NRC Biotechnology research program program are:

1) to conduct research in biologically-based techniques and technologies that could lead to new applications, improved efficiency, and new or improved products and processes in the Canadian agricultural, resource, and other industries;
2) to acquire and develop biotechnologies that will enable the Canadian agricultural, resource, and other industries to enhance their competitiveness;
3) to ensure the maintenance and growth of national competence in biotechnological research and development;
4) to contribute to and encourage the dissemination and adoption of new or improved biotechnologies in Canadian industry; and
5) to interact with and to encourage regional research and industrial capabilities.

The work of the Institutes in Montreal and Saskatoon will complement the existing NRC activities in Ottawa. Each of these three major research centres will be national in scope and relevance, but individual programs will reflect regional interests and specializations. The NRC Biotechnology programs will also provide, through secondments and exchanges of staff and students, assistance to universities in their development of manpower skilled in biotechnology.

The Division of Biological Sciences in Ottawa will continue to work on molecular genetics and genetic engineering; cellulose utilization; microbiology and immunochemistry; animal and cell physiology, and the biological production of fuels.

The Plant Biotechnology Institute will expand its work on plant cell systems and cultures, the development of new plant strains, new uses for crops, plant-related fermentation, and cellular fixation of nitrogen and carbon. The extension of the facility will include a Controlled Environment Facility for studies of plant and cell growth. Future activities of PBI will be geared to assisting the development of plant-related industrial forest and agricultural biotechnology specially in the business sector and with Canadian universities.

The Biotechnological Research Institute in Montreal will emphasize the industrial application of Biological Sciences and will focus on the development of new processes and products. The Institute facility will employ 220 people but could accommodate as many as 300 to allow industry and university researchers to use its resources.

The particular aims of the Montreal Institute will be:

1) to scale-up biotechnological and fermentation processes from the laboratory to the pilot plant stage as the basis for the development by industry of full-scale industrial processes;
2) to undertake, in collaboration with industry, research that is beyond the scope of an individual company;
3) to establish close ties with institutions of higher education and the industrial sector so that research projects can be carried out cooperatively; and,

4) to develop know-how and expertise to assure a sufficient supply of expertise to biotechnological industries.

Among the main research areas will be fermentation engineering, utilization of wastes, and microbial ecology. The major fermentation facility will allow large-scale experimentation with new methods of fermentation and will be large enough to permit economic evaluations.

The national biotechnology strategy also directed the creation of the program where I work, which is called the Biotechnology Development Program. This program is administered by the National Research Council through the PILP Office, and will serve to link the needs of the developing biotechnology industry in Canada with the skills of researchers in universities and provincial research organizations. The budget of this program is approximately $7 million per annum. Within the guidelines of this program, NRC will provide a financial contribution to a participating company toward the cost of R&D projects. A proportion of this contribution will be for payment by the company for work done by the university or provincial research organization teams. The program has a target of contributing 25% of its budget toward funding of such work by researchers in Canadian universities and provincial research organizations. Firms will be required to make a significant contribution to the total cost of a project. Cost-sharing of projects is considered essential to the success of the program by strengthening the corporate commitment to the ongoing course of the project. The contributions from companies to the project are expected to increase with time.

Information on individual projects which were eligible for PILP contribution, is considered proprietary in nature. Nevertheless one can already draw some lessons from our experience with the program. Since last year projects with a total value of approximately 21 million dollars have been launched with a federal contribution of 13 million dollars. The individual companies in turn issued research sub-contracts to universities for a value of 6 million dollars. You will agree with me that this is not a bad record for a one year old program and on which indicates that there was a need that has been filled. In other words, industry required government assistance to embark upon Biotechnology R&D, and the PILP program fulfilled the industry need for assistance. Indeed I am proud of being associated with the PILP program, particularly as the Wright report (the Task Force on Federal Policies and Programs for Technology Development) specifically singled out the IRAP and PILP programs as those two government programs that "really do work".

But let's look more closely into the kind of projects which were funded under this program. The objectives of these projects range from the development of such products/services as animal and human vaccines, diagnostic tests, hybrid seeds, fruit cultivars, mineral leaching, nitrogen fixation systems, alcohol production, pheromones and other biological control systems and waste treatment. Out of 40 odd projects, only half a dozen were undertaken by large companies (over 1000 employees); another half a dozen by medium companies (200-1000 employees), and the great majority by small companies. Since most of the companies with whom we interact have less than 200 employees, we are modifying our database to show some subdivisions within the 0-200 employee range. I should add that only 3 projects were with foreign-owned companies.

Other government departments such as Agriculture Canada have also developed strategies to address the application of biotechnology. Indeed, Agriculture Canada took an early lead in allocating resources to support these high-technologies for effective R&D in the agri-food sector. Back in 1972, this department set up a plant genetic engineering program at the central experimental farm. Today this department commits more than 125 person years and an operating budget of $10 million on biotechnology. Nevertheless Agriculture Canada believes that Biotechnology will complement conventional technologies, not replace them. Furthermore they expect that the new strains currently under development will not be commercialized until the next century. This is because after a new cross is made, an intensive selection process is carried out followed by extensive testing over several years. Licensing follows, and only then can commercialization begins.

If we look at federal granting agencies and review, for example, what the Natural Sciences and Engineering Research Council (NSERC) is doing; we note that Biotechnology is one of the areas identified under their Strategic grants program. In the 1983-84 competition for strategic grants in the Biotechnology field, 81 proposals from 23 universities were received and 29 awards were made, representing a 36% success rate. Instalment payments on 34 awards made in preceeding years were also funded, bringing the dollar amount in 1983-84 in the Biotechnology field to $3.341K.

Of the 23 application from universities, seventeen proposals came from those in the Western provinces; these universities received 9 awards.

Thirty four submissions came from Ontario universities, which received 11 awards. Québec universities submitted 28 proposals, which resulted in 9 awards.

This review in no way gives justice to what NSERC and Agriculture Canada are doing in Biotechnology. Similarly, other government departments and other granting agencies are also attempting to capitalize on this opportunity.

Unfortunately time does not permit me to elaborate any further.

CONCLUSION:

I hope I have fulfilled my objective of defining for you what is biotechnology, what it can do and how much more R&D is necessary in order to develop a Bio-society. I have also reviewed the National Research Council initiatives in Biotechnology both for in-house research and for assisting industry to undertake cooperative R&D with universities/PRO and government. I have also given you as an example what one government department (Agriculture) and one funding agency (NSERC) are doing for Biotechnology.

If Canadian biotechnology is to grow from its present small beginnings, the public, including politicians and industrialists, must understand that although tangible research results can be expected within a five year period, commercialization of most products is likely to take at least ten years, and that assumes that the research will proceed in a favorable manner. Of course, there will be breakthroughs and hopefully some of these will happen in Canada. This kind of long-term vision is essential to encourage high quality postgraduate and postdoctoral students to enter, learn and develop in what will hopefully be a growing industry. As it is, the educational community is unable to satisfy the demand for qualified professional staff by the developing biotechnology sector. Without public

commitment to biotechnology, the more talented forward looking scientists will gradually drift away, the young scientists will be less stimulated and Canadian biotechnology will wither on the vine. There is also no doubt in my mind that job opportunities will dwindle if Canadian industries resist technological change and allow more technologically tuned foreign industries to increase their competitive edge in our markets, both abroad and within Canada.

Thank you Mr. Chairman Ladies and Gentlemen for your attention.

Alain Albagli

Alain Albagli is Project Manager for Biotechnology in the Program for Industry/Laboratory Projects (PILP) of the National Research Council. He obtained a Ph.D. (Chemistry) from the University of British Columbia and a M.B.A. from the University of Ottawa. Previously, he served as Director, Policy Branch, Environmental Protection Service, Environment Canada, where he wrote a background paper identifying DOE's role in Biotechnology. He is a member of the Canadian Delegation to the OECD group of experts on Safety and Regulations in Biotechnology.

THE REGULATION OF BIOTECHNOLOGY

October 9, 1984

HARMFUL ENVIRONMENTAL EFFECTS OF BIOTECHNOLOGY

CONSEQUENCES OF DELIBERATE RELEASE

Ms. Judith Miller,
Scientist and biotechnology
consultant

HARMFUL ENVIRONMENTAL EFFECTS of BIOTECHNOLOGY:

CONSEQUENCES of DELIBERATE RELEASE

paper prepared by Judith Miller

for "Regulation of Biotechnology"
a conference sponsored by the
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Toronto, Ontario
October 9, 1984

Biotechnology, the use of advanced biological processes in the production of goods and services, is welcomed as the potential solution to many of the world's problems. Applications of scientific breakthroughs in recombinant DNA, cell fusion, enzyme technology and tissue culture offer prospects of more food for the hungry, more fuel for energy, use of renewable rather than fossil fuels as feedstocks for the chemical industry, plentiful supplies of pure hormones and safe artificial vaccines to improve human health and new successful environmental clean-up. I share these optimistic hopes that in time the application of biotechnology will reduce pollution, improve the economy and positively transform the agricultural, forest, energy, food and pharmaceutical industries. Today however, I shall address a far less popular issue, the possible negative environmental consequences of biotechology.

The application of biotechnologies carries with it risks that are difficult to define, much less to assess. Many uses of biotechnology will involve the release into the open environment of life forms not currently found in nature. The effects of such organisms on the surrounding environment cannot be predicted with certainty - it might be extremely serious. The environmental hazards of deliberate release of biotechnologically modified organisms is the subject of this paper.

Judge David Bazelon defined the role I shall play today. He said:

> When scientists participate in the public debate over biotechnology - as I hope that they will - they must keep in mind a specific role that they play. They are not, unless so designated, the policy makers. Their role is not to make conclusions concerning the appropriate trade-offs - in the trade-offs among risks, but rather to make clear what the estimated trade-offs are. What the public needs most from any expert, biologists included, is his wealth of intermediate observations and conceptual insights adequately explained. Decision on the ultimate questions must be left to the public decision-making process."(page 21)

This paper will discuss:

1) the nature of deliberate release of biotechnological products

2) anticipated risks

3) the scientific evidence for risk
   the information needs
   the record

4) the problem of uncertainty

toxins and fluctuations in environmental conditions. In fact in order for the release to be effective, the organism must have a selective advantage over naturally occurring members of the ecosystem.

Many of the promised boons rely on deliberate release of modified organisms in a wide diversity of applications. These include:

1) agriculture

-genetically superior plants and animals with increased abilities to resist disease or pests, to survive in extreme conditions or to produce new useful products such as oil from trees or increased protein in corn.

-new microorganisms as pesticides or agents to inhibit processes such as frost formation or enhance processes such as nitrogen fixation which will increase agricultural productivity.

-genetically engineered insect pathogens to improve physiological tolerance and expand host range to such factors as cold, moisture, drought and salinity, thereby reducing dependence on chemical pesticides

-food crops with herbicide resistance to allow more effective use of chemical herbicides such as atrazine.

2) Mining

-enhanced mineral leaching by bacteria, e.g. copper by Thiobacillus ferroxidans and Thiobacillus thiooxidans

-bacterial concentration of metals from dilute waste streams or settling ponds

3) Energy

-ethanol production from biomass

-ethane generation by anaerobic digestion of biomass

-enhanced oil recovery through:
-the injection of oil-degrading bacteria into an oil field to reduce the viscosity or convert oil to natural gas
-the injection of microbes to repressurize a spent well by synthesizing gases
-the injection of microbes that manufacture and secrete chemical surfactants that would mobilize tightly bound oil

4) Pollution control

5) conclusions

BACKGROUND

Safety within the context of a research lab has been extensively addressed. In Canada the Medical Research Council took responsibility for formulation and administration of guidelines for biohazards, including use of recombinant DNA. The guidelines are designed to guard against dangers to human health of laboratory research and of accidental escape from the laboratory. In principle the guidelines apply only to laboratory research funded by MRC. In practice many groups voluntarily comply and attempt to apply guidelines meant for small-scale use in a laboratory to other circumstances.

The gradual relaxation of guidelines reflects the abatement of fears on the part of the scientific and regulatory communities concerning the potential dangers to human health. This change rests on accumulated evidence, new knowledge of the organization of genetic information which makes accidental expression of newly acquired traits unlikely, and successful use of physical and biological containment. As Professor Ron Johnston concludes, the important lesson is not that the techniques were safe all along, but that if sufficient care and effort are taken, then procedures can be made safe. (Johnston p. 261-62)

Today's symposium is designed to begin to assess whether the social and economic benefits outweigh the potential costs and hazards to the environment from deliberate release of biotechnologically modified organisms and to plan what regulations and mechanisms might be necessary to protect the environment and minimize any negative consequences. MRC is currently reviewing its guidelines in its Committee on Ethics in Experimentation. However it is unlikely that MRC will or, given its mandate, should attempt to provide environmental safety guidelines in instances of deliberate release of biotechnologically modified organisms .

The NATURE of DELIBERATE RELEASE

Planned release of biotechnologically engineered organisms ranges from limited field tests to full scale commercial applications. In some ways purposeful release is diametrically opposed to laboratory containment. Instead of creating weakened strains which cannot survive without special support provided within the laboratory (and most lab strains are less viable than the wild counterparts), one is trying to develop strains that will persist, function and multiply despite the low concentration of food sources (substrates), the presence of

-use of organisms to digest herbicides such as Agent Orange or to degrade specific industrial organic compounds such as polychlorinated biphenyls

-bioreactors for waste stream detoxification and production of useful products

-bacteria to digest oil spills or other environmental pollutants

These illustrate some of the proposed uses. Obviously different applications employ different processes, different organisms and different environmental circumstances for release. "Biotechnologically modified" may describe fusion products, new enzyme capabilities, new fermentations or, as is most often meant, new recombinant gene products. The processes may be applied to microorganisms, plants or animals. Environmental hazards will differ from case to case.

ANTICIPATED RISKS

While most releases of biotechnologically modified organisms are likely to prove benign and some promise to be beneficial to the environment, a few may cause harm. Past experience indicates that many harms, especially those to the environment may take years to manifest and often cannot be traced to their source.1(Bazelon, p. 18) The problem of detrimental effects if they occur is magnified simply because organisms reproduce and migrate. Potential harm may spread and become more severe. Some believe the probability of undesirable ecological effects is zero. Others find the likelihood very high, with a strong possibility of irreversible damage.

New strains can affect the environment in a variety of ways. They can do so directly by replacing or competing with an organism currently in place, by acting exactly as hoped for by the researchers; by eliminating natural enemies of members of the ecosystem; by altering nutrient flows within the environment, for instance as a result of effects on soil micro-organisms. (Schrecker, "Living...," p. 25). The interaction may result from the organism itself, or from any of the substances which it produces or whose production is impeded by the presence of the organism.

Harm could result directly through toxicity, predation or pathogenicity. Thus anticipated risks include such events as the unintended infection of an animal by a biological insecticide.

In addition indirect effects are possible. Depletion of a nutrient, mobilization of metals, or a change in pH, for example, could adversely affect another member of the ecosystem.

Increased use of chemical pesticides with the attendent problems is a likely indirect effect of successful commercialization of current research to introduce pesticide resistance into food crops.

The literature abounds in conjectural risk scenarios of both a direct and an indirect nature. (See, for example, Zaugg, Krimsky, Segal) These include:

-Oil eating bacteria to clean up oil spills might continue to consume oil after the spill is cleaned up, perhaps destroying oil resources.

-Bacteria which prevent ice nucleation might migrate to northern crops that require a freezing period to grow and might adversely alter the climate.

-Lignin degraders used for single cell protein synthesis might attack living trees.

-Pollution control sites might generate biological aerosols with the capacity to transmit disease.

-The acid environment required by bacteria for mineral leaching could increase production of sulfuric acid and contribute to acidification of fresh water.

-Disease could be spread by the potentially serious pathogens which are the favoured organisms for enhanced oil recovery (Pseudomonas and Acinetobacter).

Overall risk depends not only on the nature of the organism released, but also on the nature of its interaction with the given environment. Mr. Don Clay of the EPA attributes risks from release of genetically engineered organisms to three sources: (1) ecological disruption from the lack of natural enemies in the environment, (2) infectivity, pathogenicity or toxicity to nontarget organisms and (3) exchange of genetic material with other organisms in the environment, infecting organisms or disrupting the ecosystem.(Clay in "Environmental Implications of Genetic Engineering," hereafter called Hearing, p. 250) Even organisms which might be harmless as released may exhibit or develop harmful characteristics after interaction with the residents of its host ecosystem, or after its numbers have increased." (McChesney p. 10367) A released organism may cause environmental changes that perturb the ecosystem. It may have negative effects if it establishes itself outside the specific environment for which it was intended. (Staff report)

Biotechnology takes advantage of genetic exchange among organisms and the ability to manipulate genes to expand the desired range and functions of a particular organism. These manipulations are often accomplished by means of vectors called plasmids which carry genetic information and are transferred between cells. Therefore in addition to the risk assessment

procedures for environmental use of inanimate chemical or naturally occurring organisms, one needs to consider the genetic stability, the potential for inadvertant introduction of new material and the capacity for genetic exchange with other members of the ecosystem.

Through genetic manipulation biotechnology may allow production of new useful biological pest controls. The genetic manipulation which would facilitate more widespread use of biological pest control would attempt to reduce sensitivity to environmental factors which limit field life and efficacy, to increase their virulence and to broaden host range. Such manipulation simultaneously removes natural safeguards such as target species specificity and apparent low risk to man and other nontarget species which have made biological pest control desirable from an environmental perspective. Thus biotechnological modification could contribute to deleterious environmental (or human) health effects. (Betz p. 135) Risk assessment must include examination of the effect of a modified organisms on a variety of members of the ecosystem under conditions likely to be encountered in the environment. Genetic manipulation could also introduce new safety features such as temperature sensitivity or substrate dependencies to limit viability.

The biggest controversy centers around unforseen harm from organisms believed safe. Lack of information about the probability of occurrence and the type and extent of damage characterize the discussion. Attempts are underweigh to determine the probability of occurrence and the likely extent of risk of at least the direct negative impacts of release of biotechnologically modified organisms. Alexander described the sequence of events which might lead to environmental damage. Each event has a particular chance of occurring as indicated in Figure 1.

Figure 1. Series of Events (and Likelihood of Occurrence) Leading to Harm Caused by the Deliberate Release of Genetically-Engineered Microorganisms [8,9].

Event	*Likelihood of Occurrence*
1 Incorporation of gene for hazardous trait into microorganisms	L_1
↓ (Deliberate release into environment)	
2. Survival in the environment	L_2
↓	
3 Multiplication in the environment	L_3
↓	
4 Contact with species or biological systems that the microorganisms can injure	L_4
↓	
5. Causing harm	L_5

source: Rissler p.22.

As the final probability of harm is the product of the individual probabilities, the probability of harm is low whenever the likelihood of occurrence of any of the events in the series is low. This is likely to be true in most cases; however the consequences may be severe. Steps 4 and 5 are the major concerns when deliberate release is employed. (Alexander, Hearing,p.6)

SCIENTIFIC EVIDENCE for RISK: the INFORMATION NEEDS

It is not difficult to define the information needed to assess the environmental effects of deliberate release although "It is...important to recognize that the data requirement for a risk assessment will vary from life form to life form and no simple, generic set of data will suffice." (Brink p. 1) Most of the data elements are the same as those required for release of a naturally occurring organism. One needs information about the conditions of release, about the environment into which the organism is to be released and about the organism (pathogenicity, toxicity, genetic stability, ecological niches, involvement in significant environmental processes and effects on population levels of other organisms in the ecosystem). With biotechnologically modified organisms one wants not only information about the source organism, but also about any donors contributing genetic material. In addition one wants to know methods to detect and monitor the released organism, to control the organism after release and information concerning environmental transport possibilities. (OECD, Rissler, Betz)

Accurate quantitative prediction of potential harm would require as a minimum all the information necessary for risk assessment with pesticides. As Ted Schrecker summarizes with regard to assessment of pesticides, "The information requirements for such an assessment are extensive. A highly simplified list of these begins with the human health effects of exposure to the pesticide, including not only acute toxicity but also the long term of effects of low-level exposures, such as cancer, reproductive defects, brain and nervous system damage, etc. Also essential, however, is information about the relationship between exposure and response (dose-response relationship), especially as it applies to long-term effects. Without this information, quantitative risk estimate is impossible; it is essential to know the probability that individuals exposed to certain concentrations of the pesticide will develop specific adverse health effects. Available test data may simply not be adequate to permit such assessments." (Shrecker, "Living...," p. 7). In considering long term environmental effects from substances with the potential to mutate, reproduce and interact with the environment, quantitative risk assessment becomes that much more complex.

The chart in Appendix A identifies some relevant research questions.

SCIENTIFIC EVIDENCE for RISK: the RECORD

The scientific data base to allow accurate predictions about the specific kind, severity or likelihood of environmental impact is inadequate. As the testimony before the Congressional Hearing on "Environmental Implications of Genetic Engineering" indicates, "This is principally the case because no historical and scientific data base exists concerning the behavioral characteristics of genetically engineered organisms in the environment, and no standard ecological methodology for predicting the outcome of an exotic introduction currently exists. In addition, as experiences with naturally occurring organisms have demonstrated, it is possible to make only an imprecise estimate, at best, of the effect that an organism may have on the environment." (Staff Report p. 20)

The questions are clear, the answers less so. Some evidence exists, however. Past experience (1) with release of exotic organisms into new environments, (2) with the changes of organisms in laboratories and in nature, and (3) with symbiosis and pathogenicity bear on the anticipated risks.

(1) Release of exotic organisms

The past record of introduction of new strains into the environment is admirable. Most of the agricultural crops in North America are nonnative. Fungal innoculae for legumes and bacterial strains for mineral leaching are widely used. Microbial pesticides have been used since the late 1940's. While both naturally occurring and biotechnologically modified organisms are capable of ecological disruption, any seed catalog attests the routine release of new strains. In some cases biotechnology would just streamline the process to arrive at a new plant or animal strain which could have been developed with classical genetic breeding and selection. Such an identical endproduct may pose no special risks.

Yet concern arises from a few disasterous attempts to introduce new organisms for beneficial purposes and from the way unpredictable environmental events can lead to significant fluctuations in an ecosystem. (Lawton and May,p. 744-45; Segal p. 14) The kudzu plant was imported from Japan to control erosion along the highway and railroad; it has become a serious pest. Major problems resulted from the introduction of the rabbit into Australia where it had no natural enemies. Introduced into a new environment, apparently harmless organisms such as gypsy moths and Japanese beetles can create real damage. (Brink p. 1-2)

A powerful illustrative example is that of the purposeful release of the mongoose from Calcutta to Jamaica in 1872 to control rats in sugar cane fields. The mongoose is an aggressive animal, with omnivorous feeding habits, generalized habitat requirements and a high reproductive rate. The imported mongoose ate not only rats, but also birds, snakes, land crabs and poultry. It has been called the greatest pest ever introduced onto the island. The introduction was a scientific error. Feeding habits are rarely so specific that the prey will be limited to the pest to be eliminated. Beyond that, the purposeful release failed to take into account that the mongoose is a diurnal animal, the rat a nocturnal one! (Sharples) Scientists are fallible, reaffirmed by the reported cloning of the wrong gene by a researcher in California.

Sharples testified at the Congressional Hearing on the Implications of Genetic Engineering that "ecologists usually do not understand enough about the complex interactions in an ecosystem to be able to predict the outcome with any degree of certainty. There are too many uncontrolled and unknown factors at this point to handle new situations on anything but a case-by-case basis." (Sharples, Hearing, p.21)

On occasion it has been argued that biotechnologically modified organisms which closely resemble a natural member of the ecosystem in question pose less of a problem, and that small changes result in small risks. A conference to assess strategies for more effectively and safely managing waste and toxic substances in the environment concluded that "Potential ecological hazards should be minimal so long as genes are transferred within bacteria or within fungi, as opposed to moving mammalian genes into plants or bacteria." (Omenn p. 31) Others hold that the scientific evidence does not support this position. In fact the new part of the genome may not establish the extent of impact, which is fundamentally an ecological question. The addition of a small selective advantage to an organism can modify the balances established in a given ecosystem. (Sharples p. 6, Alexander, Hearing p. 55)

The evidence to date requires respect for the complexity of the ecosystem and the unpredictability of the consequences of release of a particular organism in a particular environment. Unpredictable does not necessarily mean hazardous. <u>These extreme examples do not prove that most modifed organisms present unreasonable risk, but rather indicate that a small unidentifiable proportion of deliberate releases could, through a relatively minor modification, result in a severe problem.</u>

(2) <u>Adaptation of Organisms</u>

Experience with fermentation with microorganisms affirms the potential for change of organisms, engineered or otherwise. In a discussion of selection and preservation of improved strains, Dr. S.M. Martin stated: "The culture...chosen for use

in any process represents a complex dynamic system and is subject to loss of viability or loss of the ability to carry out desired functions." Changes can have serious consequences and careful procedures are utilized in the laboratory and in industry to maintain the desired strain. Growing cultures are "subject to degeneration or variation and the risk of contamination is high." Brewers maintain quality control sampling to assure maintenance of the correct uncontaminated organisms. The chemistry of a proved and licensed fermentation process can alter in response to physiologic and genetic change, and these changes can be very difficult to detect especially in a continuous culture. Care is required to maintain pure cultures in contained environments.

Microorganisms released in the environment are also likely to change. "In natural environments, microbial cells are freeliving and as such they are not able to control their environment although they may alter it profoundly as a consequence of their growth. Microbial cells must, therefore, be capable of adjusting their physiology to allow growth under wide variations in temperature, hydrogen ion concentration, nutrient supply, oxygen concentration, inhibitory concentrations of metabolic products, etc. Nutrient solutions in natural environments are frequently very dilute and may have low concentrations, or be depleted of one or more essential nutrient...Thus growth in natural environments is often nutrient-limited and microorganisms respond to the conditions that prevail by altering their structure and function."

Organisms grown in a chemostat which controls the concentration of substrates in the nutrient solution more closely approximate natural environments. "Choice of environmental conditions (in a chemostat) allow the investigator to control the activities of cells and this can lead to enhanced production of known metabolites or possibly to the production of some not considered as normal for a given organism." (McDonald)

Even the toxicity of an organism changes with its growing conditions. Thus "Cell walls of rapidly growing phosphate limited Klebsiella aerogenes NCTC 418 are only slightly toxic to mice; similar carbon limited walls are highly toxic." Cells of the vaccine strain Francisella turlarensis when grown in continuous culture are less toxic to mice. (Walgate p. 126-27). In addition the same trait may be harmful or beneficial depending on the organism and on the environment. Antibiotic resistance is an extremely useful marker in the lab; outside it leads to difficulty in curing infections. Extracellular polysaccharides are used as thickenening agents in foods; yet pathogens with this trait have an increased ability to resist responses of the mammalian immune system. (Segal p. 9-10).

In a release situation where the investigator frequently cannot control the conditions of growth, the organism may manifest new, perhaps undesirable, properties and undergo both

physiological adaption and genetic change in response to selection pressure. Dr. Lindow used a genetic deletion to reduce the potential for change and particularly for reversion to the original organism in development of the ice minus strain. (Lindow, Hearing,p. 70-71) (See also Anderson, p. 7-8).

As noted previously, biotechnology often uses vectors called plasmids to introduce foreign genes into a new host. In the laboratory, nutrient limitation can affect the retention or rejection of the plasmid, and hence genetic stability of the modified organism.(McDonald) With deliberate release, the investigator has limited ability to control the environment so as to promote the desired metabolic properties or to favour stabilization of the plasmid. Much research remains to be done to understand the relationship of the stability of plasmids to the physiology of microorganisms or to ascertain how to maximize stability.

Laboratory research and experience in the wild (Kralikova) demonstrates genetic exchange among species. However transfer depends on the concentration and the form of the organism to be released and on the life cycle phase and habits of the members of the ecosystem as well as the environmental conditions, so lab tests may not be conclusive. Nonetheless, "...the exchange of genetic material between different species and genera is so common that the species concept may no longer be meaningful." (Brink) This is especially true for microorganisms, but is probably not limited to them.

Because of this capacity for change and a limited ability to recall microorganisms once released, special care may be called for in deliberate release of microorganisms.

(3) Symbiosis and Pathogenesis

There is a very fine line between symbiosis and pathogenesis. Hence careful assessment is necessary to avoid potential environmental harm from biotechnology. Giles and Whitehead attempted to enhance the nitrogen fixing capability of pine trees by modifying fungus that inhabited tree roots. They fused two strains that are normally benign and found in one case a fungus that was pathogenic. The fused product invaded not only the intercellular spaces of the the cortex of seedling roots but also the cells. The fungus moved from a useful symbiont to a pathogen that killed the seedlings.(Giles and Whitehead) In fact the effect could have been overlooked. Some pathogens such as chestnut blight attack only mature trees and would not have been identified in the screening proceedures used.

Weeds have on occasion been defined as a plant growing where it is not wanted. The line between pathogenic and beneficial organisms is a fine one, as witnessed further by the genetic similarity of Agrobacterium (tumour-forming pathogen) and Rhizobium (nitrogen-fixing bacteria symbiotic with legumes

such as soy beans). Newly engineered symbionts could revert to a pathological form.(Hardy, Hearing p. 79-80)

Past experience then provides some clues to realistic appreciation of potential harms, but the scientific evidence is anecdotal and incomplete. The most certain fact now is the uncertainty. Many of the uncertainties are not unique to release of genetically modified organisms. Questions concerning survival, transport, competition for ecological niches, and genetic stability are also relevant for naturally existing organisms. "In fact many of the uncertainties that will be apparent even after some research is completed will relate not to the unique characteristics of these organisms but to the usual limitations of risk assessment methodologies and extrapolations."(Rissler p20) The state of the art is not at the point where the risks or their probabilities can be clearly defined. We have begun to define methodologies which will start to provide the information necessary to reduce the uncertainty for release of particular organisms in particular conditions.

The U.S. Environmental Protection Agency has sponsored a variety of research, both to define the adequacy of testing proceedures and to begin to fill in the many lacks of knowledge which are so evident from the inadequacy of the answers to quantitative assessment of environmental hazards. Projects include examination of the probability of exchange of genetic information between an altered E. coli and normal flora of a sewage treatment plant and survival, growth and genetic recombination of new genomes in soil and other natural ecosystems. (Rissler p24)

THE PROBLEM OF UNCERTAINTY

There is little concrete evidence of negative effects. However, care must be taken to distinguish between evidence for the lack of risk i.e. valid negative results and lack of evidence for risk. (Paraphrase of Dr. Upton, cited in Benbrook, p 237). The question becomes how far we have looked to establish such evidence and whether we act with the assumption of innocent until proven guilty or the converse.

In considering uncertain and limited scientific data bearing on the hazards associated with deliberate release, we have a choice. As Page puts it, the issues of standards of proof can be considered in terms of two contrasting principles: limiting false positives and limiting false negatives. A false positive is an indication that a stated hypothesis is true when it is not; a false negative is a finding that there is insufficient evidence for a hypothesis which is actually correct. Normally, greater weight has been given to limiting false positives. In scientific evidence tests of toxic effects are not considered sufficient to substantiate the hypothesis that a particular substance causes a particular effect unless

the results are statistically significant, usually corresponding to only a 5% chance of a false positive. (In keeping with the criminal justice system, hazards are innocent until proven guilty.)

As Page and Schrecker point out, environmental hazard policy has paid little attention to the probability of false negatives although the attainment of definitive proof can be quite difficult and thus it is extremely likely that there is a strong tendency to generate false negatives in the data base. Schrecker argues that "Minimizing the chance of a false positive by waiting for conclusive evidence of effect, in order to preserve a trivial benefit (more convenient spray containers), ignores the possibility of a potentially catastrophic and irreversible ecological effect." (Schrecker, Political, p. 27)

Environmental policy based on limiting false negatives would lean towards caution in avoiding uncertain, but potentially disasterous, adverse effects. Of course it is unreasonable and impossible to establish absolute safety (zero risk). The interpretation of the scientific evidence and the weighing of the uncertainty will depend on a value judgement of whether significant evidence is required to establish safety or harm.

CONCLUSIONS

It is impossible to be certain about the risks or the benefits of environmental release. Both are conjectural. It is clear that both may be significant and that we have a great deal to learn concerning impact on the environment and ways to assess such impact. Such learning must be done at least concurrently with the development and use of the technology. In the long run this is both environmentally and economically sounder.

In summary the following points are clear with respect to harmful environmental effects of deliberate release of biotechnologically modified organisms:

1) A wide variety of applications with different organisms in different circumstances is envisioned.

2) The risks vary with the particular case and depend on the nature of the organism and its interaction with the given environment.

3) Small changes which confer selective advantages could have severe consequences, but the probability of occurrence is likely to be low.

4) Much is currently unpredictable, which does not necessarily mean hazardous. Research and new assessment

methodologies can reduce the level of uncertainty with respect to a particular release.

5) The risks are similar to those of traditional release of exotic organisms and traditional use of pesticides, both of which have conferred real benefits and occasional problems

While the scientific evidence for harm is limited, there is a possibility of serious consequences with a low probability of occurrence and many recommend caution. (Alexander, in Hearing, p. 9-16; Robbins). Risks and benefits must be seen in the context of those of alternate choices and against a backdrop of widespread use and testing of biological and chemical pesticides, of routine introduction of new plant and animal strains and of already extensive use of biological organisms in sewage processing and in industries such as pulp and paper.

In the absence of clear and compelling evidence and in the presence of at least the possibility of risk with serious consequences, we must admit our uncertainty, conduct research to reduce it, and factor it into our value choices to proceed or not with a particular application of biotechnology. Even with clear evidence in hand, as David Bazelon states,

> ...at bottom, all the difficult decisions about biotechnology will rest on value-laden assumptions, priorities, and predispositions. Shall we release into the ocean a bacteria that cleans up oil spills? What effect will it have on fish? Who gives a damn about fish? I prefer white beaches - though I do have a tender spot for salmon. Uncertain risks coupled with unpleasant trade-offs - but decisions need to be made. (Bazelon p 16)

Notes

1. Talbot Page (1978) identified nine characteristics common to environmental risks:

1. ignorance of mechanism
2. modest benefits
3. catastrophic costs
4. low probability of catastrophe
5. internal benefits
6. external costs
7. collective risks
8. latency
9. irreversibility of effect

Page elucidated these characteristics on the basis of environmental risks such as toxic chemicals and the depletion of the ozone layer from fluorocarbon emissions by supersonic transports.

Deliberate release of biotechnologically modified organisms pose risks of the same nature. They also have the potential to mutiply, interact, mutate and migrate to another environment, hence expanding the opportunities for risk.

Appendix A

Source: Rissler, p 23.

TABLE 1
General Questions Proposed for Research on Biotic Environmental Effects of Deliberately-Released Genetically-Engineered Microorganisms (GEMs). Questions are Delineated According to Series of Events Leading to Harm

Event	*Questions*
1. Incorporation of gene for hazardous trait into microorganisms	a. Can the "new" part of the genome be thoroughly characterized to assure that genes for undesirable traits are not intentionally or unintentionally included? How?
	b. To what extent can the GEMs, their products, and their intended uses be characterized before release?
	c. Will any GEMs (other than those intended for use as pesticides) carry genes (either "new" or part of original remaining genome) for traits hazardous to natural plants, animals, microbes, or biological processes?
	d. Based on the knowledge and extent of genetic-engineering techniques used, is it possible to delineate different sets of GEMs which differ in likelihood of harm? How?
2. Survival in the environment	a. Can the GEMs be specifically identified and detected in nature? How?
	b. Can the population size be determined at sufficiently low levels? How?
	c. Do the organisms survive in the environment in which they are placed or to which they are transported?
	d. Are the means of transport significant in initiating new populations in similar or different environments?
	e. Can the organisms be engineered to survive only in particular environments? How?
	f. What are the natural levels of the non-engineered parent organisms?
	g. Do the GEMs have a selective survival advantage over the unaltered members of the species?
	h. Are the GEMs as stable genetically as the unaltered members of the species?
3. Multiplication in the environment	a. What is the quantitative population change over time in the environment in which the organisms are placed or to which they are transported?
	b. What environmental conditions affect multiplication and persistence? How?
	c. In these environments do the GEMs have a selective advantage over the unaltered members of the species?
	d. Can important environmental growth requirements be exploited to control or contain the microorganisms? How?
	e. Can the GEMs be engineered to multiply only in particular environments? How?
4. Contact with species or biological systems that the microorganisms can injure	a. What species or biological systems are exposed to the microorganisms?
	b. Is knowledge of the exposures associated with the unaltered parent organisms sufficient to predict the exposures of the engineered organisms?
	c. Do the intended pattern of use and knowledge of means of transport predict the species or systems to be exposed?
	d. What are the magnitude, frequency, duration, and routes of exposure?
	e. Are existing exposure assessment methodologies for microorganisms satisfactory for GEMs?
	f. Can engineered genes or other genes be transferred in nature to other organisms? Which ones?
	g. Can genes from other organisms be transferred to GEMs more readily than to naturally-occurring ones? Why?
5. Causing harm	a. Do hazards exist with GEMs which would not be revealed with existing methodologies for identification of hazards associated with naturally-occurring microorganisms?
	b. Can GEMs be subjected to a sufficient diversity of environments such that all "new" genes will be expressed?
	c. Is knowledge of the hazards associated with the unaltered parent organisms sufficient to predict the hazards associated with engineered organisms?
	d. Do GEMs have unique dose-response relationships or thresholds of activity that cannot be predicted from knowledge of unaltered parent organisms?
	e. What level of characterization of gene segments is sufficient to predict associated adverse effects? (i.e., is it possible to develop gene segment-activity relationships?)
	f. Can guidelines be developed for testing for adverse effects?

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THE REGULATION OF BIOTECHNOLOGY

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REGULATION OF BIOTECHNOLOGY

IN THE UNITED KINGDOM

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First, I would like to thank the Foundation for its invitation to speak to you today and to issue a small disclaimer.

Several years ago, I acted as a consultant to the Science Council of Canada in the work of its Science and Legal Process Committee. The report of that committee, prepared under the chairmanship of Dr. David Bates, was released as Science Council Report #35 : Regulating the Regulators. The topical area of science upon which the committee concentrated was the new biology - and in the course of the study I prepared for them a paper regarding the regulation of recombiment DNA research in Canada, the U.S. and the U.K.[4]

What little expertise i have regarding regulatory institutions in the United Kingdom was acquired in the course of that research, and I think it is better described as a sympathetic outsiders perception.

4. Eddy, Regulation of Recombinant DNA Research
Science Council of Canada, 1983

There is a very important difference between the institutions which I studied at that time and what will be developed to meet the challanges posed by biotechnology. Recombinant DNA regulation was a challenge posed by experimental science. Although it was a challenge very largely posed by academic science in all three countries, in the U.K. it became part of the agenda of a young, rapidly growing and somewhat unconventional trade union - ASTMS, the Association of Scientific, Technical and Managerial Staffs.

Organized labour plays a much different role in English social and political life than it does in North America, and ASTMS was inconventional in that its members were white collar (or perhaps more accurately white lab-coat) professionals. They nevertheless had available to them the experience, political clout and institutional devices produced over a long period of time by the activity of the Trade Union Congress and the Labour Party.

In the result, in August 1978, and at a very early stage compared to other countries, regulations requiring all recombinant DNA research to be reported to the Genetic Manipulation Advisory Group were promulgated under the Health and Safety at Work Act, 1974.[5] This Act, which represents

5. C19 74, c.37. See S1 1978:752

the reformed and consolidated factory legislation is designed to provide one comprehensive and integrated system of law dealing with the health, safety and welfare of workpeople and the health and safety of the public as affected by work activities. It is largely based upon principles developed by a committee chaired by Lord Robens.[6]

Several features of the English system are particularly relevant. It was developed on the paradigm of an organized industrial workplace. It relies very heavily upon notious of disclosure of risk to the employee and negotiation of safe practices between the employer and the employee. Obviously such a system places great reliance upon a well developed structure of labour-management relations.

Similarly the system relies on Codes of Practice. Such codes are approved by the Health and Safety Commission (the body exercising oversight functions which stands between the responsible Minister and the Health and Safety Executive) with the Ministers consent. A Code of Practice has no status

6. Report of the Committee on Safety and Health at Work (Cmnd. 5034) (1972)

in civil proceedings; in criminal proceedings evidence of breach of a relevant prohibition or provision of a code of practice raises a rebuttable presumption regarding that element of the alleged offence.[7]

In late August of this year, the Health and Safety Executive tabled for consultation and comment the draft Code of Practices fo the Control of Substances Hazardous to Health.

The document has been described as the most important legal event in English health and safety regulation since the Act itself, and now codifies the practices of risk assessment and cost/benefit analysis which the case law had imposed. It also deals with monitoring, health surveillance and employee rights in respect of health records and the management of individual health problems arising from exposure in the workplace.[8]

7. Health and Safety at Work Act, 1974 c.17(2)

8. New Scientist, 16 August, 1984 p.3

The major sanctioning mechanising of the Health and Safety at Work Act are the general duties created by ss. 2-7 and their supporting offence provisions. The crucial words in these sections are "reasonably practicable" - the duties arise from the workplace, they extend beyond the technical bounds of the employers-employee relation to persons analogous to worker/employees and to persons affected by the workplace. The duties extend under a different regime of organization and enforcement to Agriculture, which is likely to raise problems in the application of biotechnology to that area.

But the key to the duties is the reasonably practicable concept - to which the case law has attached concepts of cost-benefit analysis - and its evocation of expert technical knowledge.

This requirement is also implicit in any application of negligance law to biotechnology to predict liability outcomes in the event of accident or unpredicated occurence.

The significance of the Genetic Manipulation Advising Group to the Health and Safety Executive was that, in respect of recombiment DNA experimentation during the period of centralized control - that is prior to the delegation to local biosafety committees of the greater part of oversight - GMAG functioned as the body which confronted these expert technical issues with labour management representation. GMAG was a closed process. It had "public interest" members but it was not public and it was health and human safety rather than environmentally oriented.

As such, it may be a very poor model for environmentally oriented concerns - and it is certainly doubtful whether a closed process would satisfy North American ideas of legitimacy.

Another factor which rendered GMAG perhaps an unexportable sodel is for ASTMS - the major labour player - a successful recombinant DNA effort in English would be a very definite benefit. Therefore, no member group in GMAG had a negative - research never, Luddite - position on research. Whether GMAG could have functioned without a co-operative attitude is quetionable, and whether the public and labour members would have co-operated in what they perceived as win-win outcomes had not been present is highly questionable.

But do environmentalists perceive winning outcomes in biotechnology.

GMAG however, if one compares it to the quasi-legislative process in the United STates which dealt with the same issues, had some remarkable virtues. It was speedy; it was capable of reversing its field quickly; and its case-oriented approach allowed it to respond in a very situation - specific manner. These may well be vitues that would be useful in the management of conflicts over biotechnology and the environment.

One of the perennial questions in the design of closed processes is who shall be given seats at the table: proper answers dictate the success of the process. In GMAG labour and a general public interest had seats, as did management; the government played the role of interested observer. A different balance of interested parties argues for a different allocation of seats. There is no substitute of insight in to the underlying interest conflicts in deciding who shall have seats.

It may well be outside North American bounds of ligitimacy to close the process as well as allocate the seats. That is a question which is settled by the politics of the day - it may be useful to observe that the Canadian equivalent of

TALKING POINTS
CONFERENCE ON THE REGULATION OF BIOTECHNOLOGY
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EPA'S APPROACH TO BIOTECHNOLOGY

I. INTRODUCTION

- o Appreciate the opportunity to speak, etc.

- o Today, I will be describing US activities concerning biotechnology.

- o Before getting too far into the subject, some definitions:

  - Biotechnology: All of the technologies that use living organisms to make commercial products. Includes but is not limited to genetic engineering techniques.

  - Genetic engineering: Application of modern techniques to directly alter genetic material (DNA) and produc life forms with new or enhanced functions.

  - Recombinant DNA: A genetic engineering technique in which the genetic material from one organism is placed in the genetic material of a recipient organism.

- o These techniques are likely to lead in the near future to a wide array of commercial products that will provide great benefit to society, e.g, drugs, foods, pesticides and other agricultural products, products used in pollution control, etc.

- o At the same time, EPA is sensitive to the possible effects of inconsistent or excessive regulation on this new industry, and possibility that it could drive technological innovation and commercial applications overseas.

- o At this point, EPA is concentrating most of its activities within two major program offices -- the Office of Toxic Substances and the Office of Pesticide Programs, which have broad authority over a range of commercial products -- and its Office of Research and Development. Because I am directly responsible only for OTS activities, I will concentrate my remarks on that program. However, I will also touch briefly on the activities of the other offices.

II. OFFICE OF TOXIC SUBSTANCES/TOXIC SUBSTANCES CONTROL ACT

- o TSCA provides EPA broad authority to review and regulate "chemical substances" in a wide range of industrial and commercial applications. However, several important categories of products -- including drugs, foods, and pesticides -- are specifically excluded from coverage.

- o Specific applications of genetically engineered organisms that are likely to fall under TSCA jurisdiction include pollution control, production of industrial chemicals, nitrogen fixation.

- o In the case of biotechnology, the most important provision of TSCA is the section 5 requirement that companies notify EPA before producing a "new chemical substance." EPA has concluded that nucleic acids and other substances making up living organisms are "chemical substances," and that "new" nucleic acids developed through R-DNA and possibly other techniques of genetic engineering are "new chemical substances" subject to PMN requirements.

- o EPA is now working out the details of this general position, which will be addressed in a FEDERAL REGISTER notice, scheduled for publication some time this fall. Some of the major issues discussed for comment in the notice are:

  - Which organisms should be considered "new" under TSCA and therefore subject to notification?

- How should small-scale experimental releases be handled? For conventional chemicals, such releases would generally be considered to be R&D and would be exempt from PMN. Is a tighter standard necessary for microorganisms, which can replicate and spread in the environment?

- What level of information is necessary to adequately assess the potential risks of a new microorganism?

o After receiving comment on these and other issues, EPA will develop a final policy on PMN requirements for biotechnology-based products. We anticipate receiving the first PMNs for such products in 1985.

III. OFFICE OF PESTICIDE PROGRAMS/FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

o The FEDERAL REGISTER notice will discuss FIFRA as well as TSCA applicability.

o FIFRA provides EPA general authority to regulate pesticide products, including microbial pesticides. Therefore, new genetically engineered pesticide products will be subject to EPA review under FIFRA, just like any other pesticide product.

o To date, 14 non-engineered microbial pesticides have been registered. EPA anticipates receiving its first applications from companies developing genetically engineered microbial pesticides in 1985.

o Testing guidelines have been developed for microbial pesticides (Subdivision M), and final regulations are in place (Part 158). The need for additional data on genetically engineered or other novel microbial pesticides will be determined on a case-by-case basis, although EPA is likely to expect additional information on:

- genetic modification techniques

- identity of inserted gene

- description of new traits to be expressed

- tests of survivability, etc.

- o Lastly, a significant issue under FIFRA is how to handle small scale field tests, which under current regulations are generally exempt from experimental use permitting requirements. The Pesticides Program is planning to issue an interim field testing policy, which will require that EPA be notified of any field tests before they occur. This policy will also be discussed in the pending FEDERAL REGISTER notice and the ultimate policy may be modified, depending on comments. [As most of you undoubtedly know, this issue is the subject of a petition from the Foundation on Economic Trends, which is now being reviewed by EPA.]

IV. REVIEW STRATEGY/RESEARCH

- o In preparing to review novel microorganisms under FIFRA and TSCA, EPA is developing a research agenda and a general strategy for assessing risks associated with genetically engineering organisms -- particularly when released to the environment.

  Among the priority research items are:

  - Refinement of microcosm procedures to assess survivability and growth of test microorganisms.
  - Development of methods to assess the stability of novel genetic traits.
  - Use of genetic markers in engineered organisms to permit identification and monitoring.

- o Of course, general research on potential hazards of genetically engineered organisms and the development of risk assessment methods is a long project. In the shorter run, EPA believes that the state of our knowledge is at a point at which carefully controlled environmental releases are appropriate -- depending of course on the specifics of the case.

- Because of the need to examine these specifics, EPA believes that Federal oversight of each release, including case-by-case review, is important. We plan to address such questions as:

  - the properties of the parent organisms

  - the nature of the genetic manipulations

  - the specific properties of the engineered organism (such as pathogenicity, survivability, stability of the genetic material, and possible changes in the organism's host range)

  Federal regulatory agencies will be able to ensure against unreasonable risks to human health and the environment.

- In developing its review strategy and its overall program, EPA is relying on the expertise of specialists in universities and elsewhere as it develops its program. In addition, EPA is working with experts in other U.S. Federal agencies, such as NIH and USDA, to ensure that our approaches are consistent and that the agencies benefit from each others' expertise. We are also participating in an international effort, through the Organization for Economic Cooperation and Development, to look at these issues and coordinate our approaches to handling large-scale and environmental uses of microbes.

- Thank you for opportunity to speak, etc.

THE REGULATION OF BIOTECHNOLOGY

October 9, 1984

BIOTECHNOLOGY AND THE ENVIRONMENT

A REGULATORY PROPOSAL

A DISCUSSION PAPER PREPARED BY THE

CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION

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Biotechnology and the Environment: A Regulatory Proposal

1. INTRODUCTION

The application of biotechnology holds great promise for alleviating many contemporary environmental problems and improving our lives. For example, improving the growth potential and ability of plants to survive in hostile climates could increase world food and wood supplies, creation of organisms to clean up pollution could lessen the impact of many deadly chemicals and use of organisms to increase recoverable metals and energy could expand our resource base.

However, the promise of biotechnology should not lead us to ignore the risks associated with the development and use of new life forms. Until now concerns with and regulation of biotechnology have centred on research because this is where the most activity has taken place. Now that activity is moving toward industrial applications, questions are being asked about the impact of that activity and the ability of existing regulation to handle those impacts. Given the potential benefits and risks, and the existing regulatory vacuum, it is essential that all sectors in Canada - government, industry, environmentalists and others - immediately begin to actively debate the most appropriate means of regulating biotechnology.

The purpose of this paper is to open discussion of possible avenues for a Canadian regulatory response to the

environmental hazards of biotechnology. As with any discussion paper investigating a controversial area, it is not possible to explore the entire spectrum of issues or their immediate and long-term implications or to answer all questions in depth. Instead the paper is put forth to initiate dialogue on the questions that must be addressed and to articulate those areas in need of further research and discussion.

The paper is divided into three basic parts. The first part attempts to clarify the focus of discussion as well as provide a background on the regulatory process in Canada.

The second part of the paper then evaluates, in general terms, the potential for existing legislation to protect the environment from the hazards of biotechnology. Finally, the remainder of the paper sets out the principles which could form the basis of a new regulatory framework.

2. General Control Issues

To develop a regulatory response to the environmental hazards of biotechnology, it is important to have a clear understanding of the problem and what aspects of it are in need of regulation. In effect, the reach of the regulatory net must be determined. This fundamental determination is difficult now because of the considerable degree of uncertainty surrounding the future growth potential and trends in the industry, the

possible applications and their environmental impact and risks.

What is biotechnology and why are we concerned? The terms "biotechnology" itself has no generally-agreed definition and tends to be all-encompassing. For example, the Organization for Economic Co-Operation and Development (OECD) has defined the term as:

> the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services.

It has been noted that the OECD definition was designed to include a broad range of activities spanning from those simple applications such as fermentation which are employed to produce alcoholic beverages and bread to complex technologies of gene-splicing to create modified life forms and biochemicals.(1)

(a) The Subject Matter of Regulation - "New Life Forms"

Primary attention and concern have been devoted to the techniques of genetic engineering such as recombinant DNA which modify life forms and create genotypes(2) that do not occur in nature. Indeed, it is these applications of biotechnology that create new genotypes which pose the greatest potential risk but have the least certain impact. The degree of risk associated with new life forms involves a series of occurrences: release to the environment, survival and growth in that environment, transfer

to or contact with other species, harmful influence on that species, change so as to become harmful or acquisition of a competitive advantage.(3) Uses of biotechnology contained within a factory or laboratory involve the chance of all of these contingencies occurring. However, for uses involving direct release into environment, survival is expected, so the only contingencies are whether the life form is harmful to the life with which it comes in contact.

The consequences are today unknown and there is no reliable way of predicting what they will be. Exotic genotypes, when released into the environment, could cause harm or ecological disruption in several ways. They could establish a competitive advantage over naturally occurring species because of their resistance to particular diseases and lack of natural predators. Another fear is of transferrence of their characteristics to other species which would then be vulnerable to pests or disease. Disruption could also result if organisms expand beyond the expected niche or prove toxic to non-target organisms. Although such problems are considered to have a low likelihood of occurring, the potential consequences if they do are quite severe. The closest analogy is with the introduction of naturally occurring "exotics" into new ecosystems - e.g. chestnut blight, Dutch elm disease, gypsy moth, starlings and kudzu vine, all benign in their natural environments but disruptive where introduced. (4) In addition, experience with the radioactive substances and

petrochemicals, where severe health and environmental harm had to occur before controls over their use and disposal were implemented, has made the public wary of new technologies and claims for their safety. It seems reasonable to address this risk before, rather than after, the consequences are realized.

Because of the potential consequences, regulation must address environmental releases of "exotic" life forms and substances, however created. Thus, all present and potential biotechnological techniques, whether cell fusion, recombinant-DNA methods or any other applicable techniques, would be included within the regulatory net proposed below.

(b) "Contained" v. Open Enviroment (Direct) Releases

Although the regulatory response should be directed to all new or modified life forms, it is unrealistic to assume that a single regulatory regime could address each aspect in the research, development, distribution, manufacture, use and disposal of biotechnological products or processes particularly when the full range of activities is as yet unknown. Conceivably, a regulatory framework to deal with the environmental and health hazards of biotechnology would be comprised of a number of regimes. However, such regimes would not be according to traditional categorizations such as those dealing with "pesticides", "agriculture" and "food and drugs" laws. Instead, the regimes would be premised upon the manner in which

the products of biotechnology were applied. From a general perspective, there are two broad categories of biotechnological applications: (a) contained and (b) open environment (direct release) applications. Contained applications basically relate to those instances where biotechnological techniques are employed as an intermediate step in the production of inanimate end products. Use within a factory or laboratory would be contained, although there is some risk of accidental release to the environment. Examples of contained applications are pharmaceutical industries developing biotechnological methods to produce hormones in the manufacturing of commercial drugs such as human insulin and thus replacing other production methods (such as chemical synthesis and extraction from glands of dead humans and animals). Similarly, in the food processing industries, single cell protein, from such products as waste sawdust and methanol, may be produced more efficiently through various biotechnological methods.[5]

Open environment applications differ from contained applications in that the new life forms are directly released into an ecosystem. Open environment applications include

- the release of genetically superior plants and animals resistant to disease and pests or able to survive in extreme conditions;
- the use of new microorganisms as pesticides or as agents to prohibit frost formation or to promote nitrogen-fixation;

- application of organisms to chemical spills to render particular pollutants (such as oil) less toxic; and
- the use of organisms on ore and mine tailings to leach out valuable minerals.

From a regulatory perspective, the distinction between contained and open environment applications presents a plausable approach to address the health and ecological concerns of biotechnology. The regulatory regime pertaining to contained applications would be primarily directed to the issues of research, development and manufacture of new life forms and the problems of workers' health. Due to the infancy of the biotechnology industry, the only regulatory initiatives in this field have been directed to this realm. More particularly, the research guidelines of the Medical Research Council (MRC) and the work conducted by the Biohazards Committee of the MRC have made significant progress in ensuring the development of minimum standards for human safety and environmental protection in the context of recombinant-DNA and virus research. Further, it has been noted elsewhere that various provincial occupational health and safety laws, such as the Ontario Occupational Health and Safety Act,[6] are important and progressive initiatives within the context of contained applications.[7] Some thought may be given to further dividing this category at some time in the future as the industry evolves. For instance, it may be necessary to differentiate, for regulatory purposes, between

those activities involving the research of new life forms and those activities that apply biotechnological techniques to manufacture a given product. In essence, the difference reflects the unique concerns which must be taken into account in the laboratory and those within a factory setting.

Unlike contained applications, there has been no regulatory response in Canada to the potential release of new life forms into the open environment. The failure to explicitly address the issue of open environment releases may be due to the infancy of the industry in Canada. Ironically, however, it is in the area of open environment releases that the impact on the ecosystem would be the most immediate and the most difficult to control. It is for this reason that the remainder of the paper shall be limited to discussing the regulation of open environment releases and thus, reserve the regulatory response to contained applications for a later time. It should be mentioned however, that despite the conceptual distinction between contained and open environment applications, in reality there would be significant areas of regulatory overlap. For example, in both instances, provisions should be made applicable for accidental and inadvertent escape of new life forms, and their transport, storage and disposal.

At present, the only regulatory control over direct release of new life forms is through existing legislation. It is appropriate, therefore, to examine the extent and adequacy

of present regulatory controls to deal with direct open environment releases.

3. Evaluation of Existing Legislation to Control Open Environment Releases

The first question to be considered in developing a regulatory response is the extent to which existing regulation applies or can be adapted to apply to the problem at hand. Due to the sharing of constitutional powers between the federal and provincial levels of government over environmental protection, it is difficult to accurately evaluate the potential of existing legislation to deal effectively with bio-hazards. There is a considerable disparity in the nature, type and sophistication of legislation pertaining to environmental protection between each province. Hence, where federal legislation is not applicable, there may be a total regulatory vacuum in one province whereas, in another, existing controls may take into account, at least to some extent, the concerns under examination. Since it is unnecessary for present purposes to review the regulatory controls in all ten provinces, the Province of Ontario is used as the primary focus although recognizing that it may not be representative of other provincial jurisdictions.

Further, to simplify the discussion, present legislative controls shall be examined in light of a limited number of issues which are of particular concern to the regulation of open

environment releases. These issues are: (a) assessment of impact and risks, (b) regulatory powers, (c) accidental and inadvertent release, and (d) liability and compensation.

(a) Assessment of Impact and Risks

It is generally accepted that, prior to the introduction into the environment of potentially harmful substances, there is need for some degree of assessment of their impact. Because direct release of new genotypes has the potential to seriously harm the environment, assessment of the risk of harm is an important prerequisite to release. It is thus appropriate to examine the extent to which existing legislative controls provide for prior assessment of the release of the products of biotechnology in the open environment.

Both the federal and Ontario governments have in place formal mechanisms to assess the environmental impact of certain activities. However, it is highly unlikely that either mechanism will have any meaningful application to open environment release of new life forms.

At the federal level, the Environmental Assessment Review Process ("EARP") applies to the projects, programs and activities of federal departments, agencies and Crown corporations. Although there is some government involvement in the development of biotechnological applications, EARP is not likely to play an

effective control role because it is not mandatory.

At the provincial level, in Ontario, the Environmental Assessment Act[8] ("EAA") requires prior assessment of the environmental impacts of and consideration of alternatives to provincial and municipal government projects and "undertakings" (including policies and programs) unless exempted. The Act can be applied to private undertakings if designated, however, very few and only major private undertakings have been so designated.

With both impact assessment regimes, there are gaps with respect to those undertakings which are subject to assessment. For the most part, they only apply to a limited range of activities. Moreover, they do not in practice always apply to all activities within that range (due to the absence of mandatory application at the federal level and to the use of exemptions in Ontario). Thus, although the impact assessment regimes are important mechanisms, the fact that they are neglected in the seemingly most appropriate cases, particularly privately-sponsored releases, suggests they will have little relevance for the control of the environmental hazards of biotechnology.

Apart from the formal federal and provincial mechanisms, various other statutes provide more specialized but less formal procedures for the assessment of environmental impacts. Such statutes include the Environmental Contaminants Act, the Hazardous Products Act, and the Pest Control Products Act.

The Environmental Contaminants Act (ECA)[9]

The ECA is designed to control releases into the environment of those "substances" that may constitute a significant danger to human health or the environment. At present, the Act has no relevance for the regulation of biotechnology because of the narrow definition it attributes to "substances". Section 2(1) of the Act defines "substance" as any distinguishable kind of inanimate matter. Hence, all new or modified life forms are excluded from the procedure outlined in the Act. Nevertheless, if the definition section of "substance" was enlarged to include "animate" matter, the ECA could conceivably provide an avenue to regulate open environment releases as long as they are released "in the course of any commercial, manufacturing or processing activity."(S.18(a)). Under the Act, various substances undergo a review process by the Departments of Environment and National Health and Welfare. On the basis of their reports, the federal Cabinet has the authority to prohibit the release, import, manufacture, process or sale of the substance in question (s.8). Before the Cabinet may make such a determination, it must be "satisfied" that the substance will constitute a "significant danger" to human health or the environment (s. 7).

Despite the existence of this "review process", it is likely that the ECA control procedures will be employed sparingly and only in the most serious of circumstances. Before the

Cabinet can exercise its powers under the Act, it must be "satisfied" that a "significant danger" is present. This criteria creates onerous precedents considering the uncertainties with respect to the uses, effects and consequences of either the products or the applications of biotechnology. In addition, releases proceed until found to be a significant danger. There is no provision for preventing a release until its impact on the environment has been considered.

A further limitation is that the Act is residual in nature. When a substance is proposed to be regulated under the Act, the provincial governments must be consulted to determine whether the perceived danger will be eliminated by an action taken or proposed to be taken by these governments pursuant to any other law (s.5). Finally, an Environmental Contaminants Board of Review (ECBR) established under the Act (s.6) is empowered to hear objections (and thus provides a further review process) to any substance proposed to be controlled under the statute. However, the Act does not provide a mechanism to permit a person to object or require a hearing into why a substance is not subject to the Act. The Departments of Environment and Health and Welfare and the Cabinet retain the absolute discretion to initiate the review processes. Thus, effective prevention and control of the hazards with which we are concerned is unlikely using this procedure.

to have on hand and available such equipment and materials necessary to alleviate the effect of any contaminant on the natural environment (s.17).

The major tool under the EPA for controlling new pollution sources is the "certificate of approval".[21] A certificate is required before any person can

> (a) construct, alter, extend or replace any plant, structure, equipment, apparatus, mechanism or thing that may emit or discharge ... a contaminant into any part of the natural environment ... or
>
> (b) alter a process or rate of production with the result that a contaminant may be emitted ...

Specifications can be required before a certificate is issued and conditions of operation can be imposed. Unfortunately, while a certificate of approval might be necessary for some contained applications of biotechnology, it does not seem to be necessary prior to direct releases to the environment.

The applicability of all of these controls in the EPA is uncertain, in addition, because it is not clear whether a new genotype would fall within the definition of "contaminant" in the EPA. According to the Act, a contaminant is

> any solid, liquid, gas, odour, heat, sound, vibration, radiation or combination of them

> resulting directly or indirectly from the activities of man ...

which may adversely affect health or the environment.[22] This does not appear to apply to living organisms given the ordinary meaning of the words.[23]

Even if these uncertainties could be resolved and the Act made to apply, it could at most control known environmental hazards. Because of the uncertainty surrounding the hazards of new life forms, a mechanism for preventing release until more information is available is needed.

Aside from the direct control mechanisms, general environmental protection statutes creating offences for causing harm to the environment provide indirect regulatory control by allowing prosecution for the release of substances known to be harmful to the environment or human health. For instance, the federal Fisheries Act (24) makes it an offence to deposit a "deleterious substance" of any type into waters frequented by fish (s. 33). Under the Ontario EPA, it is unlawful to release a "contaminant" into the natural environment that causes or is likely to cause impairment to the environment, injury to property or to plant or animal life or that might adversely affect the health or safety of any persons (s.13). In addition to environmental protection legislation, other indirect controls include various provisions of the Criminal Code[25] such as common nuisance (s. 176), criminal negligence (ss. 202-204) and mischief (s. 387).

Such indirect controls provide a general deterrent by imposing the threat of criminal or financial liability for failing to follow certain acceptable courses of conduct. The basic problem with these types of controls, however, is that beyond the general deterrent effect, they are only triggered after the damage or harm has arisen. In those instances where the release is limited prior to the occurrence of damage, the controls can best be described as piecemeal or intermittent. Thus, the controls are marked with uncertainty as to their effect and success.

Traditionally, the present array of regulatory powers in the realm of environmental protection were designed to address the most obvious forms of pollution. They simply lack the sophistication and comprehensiveness required when dealing with new life forms which are associated with "low probability, high consequence" environmental and human risks.

c. Accidental Releases

In addition to the need to control hazards resulting from planned direct releases to the environment is the question of mechanisms to deal with accidental and inadvertent releases of new life forms. Such releases would include spills from otherwise "contained" applications of biotechnology and from direct environmental releases gone awry - release of the wrong organism, in the wrong amount or in the wrong place. The concern

here is that unknown or unexpected injury to the environment could occur before the organisms could be contained (assuming certain life forms can be contained and neutralized) and cleaned up.

Unfortunately, regulatory methods to deal with environmental emergencies are not well developed in Canada. Indeed, at present, there are only a few avenues available to provide authority for such measures.

First, the Environmental Contaminants Act (ECA) (s. 7(3) to (5)) vests the Cabinet with certain emergency powers when it is "satisfied" that "immediate action" is required to prevent a "significant danger" to human health or the environment from the release of the substance. If the Cabinet is so satisfied, it is empowered to prohibit the release of the substance without the necessity of provincial consultation or fulfilling other procedural formalities. As noted above, however, the present definition of "substances" in the ECA is limited to "inanimate matter", and thus excludes all new or modified life forms and substances.

Second, the Ontario Environmental Protection Act (EPA) authorizes the issuance of control and stop orders for the release of contaminants in contravention of the Act or which constitute an immediate danger to human health and property. However, the only authority provided under the Act to clean up the ensuing

release is a section 16 order to repair.[26]

Finally, it should be noted that there are various contingency plans in existence which provide co-ordinated responses to spills of hazardous material. (27) Further the Centre for Spill Technology is responsible for technological development of counter measures to deal with such spills. It should be noted however, that such mechanisms are primarily directed toward oil and chemical spills. The adaptability and suitability of these plans with respect to new life forms is a question in need of further research. Further, even if aspects of these measures could be made applicable, there would still be significant areas of concern where various open environment releases would not have the benefit of these emergency procedures.

(d) Liability and Compensation

Traditionally, the issues of liability and compensation for environmental harm have been dealt with under the various categories of tort actions including nuisance, negligence, trespass and strict liability.

It is beyond the scope of this paper to explore the adequacy and suitability of each of these tort categories to remedy environmental wrongs. Nevertheless, it is well-recognized that the traditional common law doctrines are ill-suited to deal with many of the issues inherent in an environmental lawsuit.[28]

The plaintiff must not only establish the particular legal elements under each of the categories but must also overcome the more general obstacles to recovery including standing, jurisdiction and costs.

When dealing with the release of new or modified life forms, the traditional problems associated with private environmental remedies are accentuated. Further and perhaps more serious practical and conceptual limits also present themselves. Perhaps the most difficult obstacle facing an aggrieved party would be that of causation - the task of establishing the causative link between the victim's injury and the defendant's conduct. Even in the simplest of cases, modern technological tracing devices are often unable to accurately correlate the release of a contaminant in one area and the adverse impact in another. It can be assumed that this difficulty would be aggravated when new life forms are released into the environment because it may be decades after the release before any impact on the ecosystem is detected or fully understood. Moreover, the release of genetically engineered organisms may cause a chain reaction of disturbances or consequences. It may therefore be impossible to delineate which consequences are the result of natural factors and which are caused by the releases.

In the event the plaintiff did succeed in his case, there still remains the problem of assessing damages. In some instances the award of permanent damages to aggrieved persons has been interpreted as a licence fee for the defendant to

continue operations.[29]

The recognition that traditional common law remedies have not kept pace with the current understanding of ecological realities has led some jurisdictions to enact legislation in their place, such as the U.S. Comprehensive Environmental Response, Compensation, and Liability Act.[30] The only Canadian legislative attempt which is relevant to the issue of compensation from the release of biotechnological products is the Pesticide Residue Compensation Act[31] (PRCA).The Act, administered by Agriculture Canada, provides a mechanism for a farmer to receive compensation for pesticide damage to crops that have been condemned under the Food and Drug Act.(32) Unfortunately, a number of onerous requirements must be met before the farmer is entitled to compensation. For instance, compensation can only be claimed if the pesticide is registered under the PCPA, used in accordance with appropriate recommended practices and all other legal avenues against the responsible party have been exhausted.

It should be noted that the Act has not been used to any significant extent since its introduction in 1969. In fact, only two requests for compensation have met the necessary requirements under the Act.[33]

4. Toward a New Regulatory Framework

(a) Overview

An evaluation of the current regulatory framework with

The Hazardous Products Act (HPA)[10]

The HPA provides a type of review process for the determination whether a product or substance is to be deemed a "hazardous product". A hazardous product is defined as:

> (a) Any product or substance that is or contains a poisonous,toxics, inflammable, explosive or corrosive product or substance or other product or substance of a similar nature that [the Governor-in-Council (the Cabinet)] is satisfied is or is likely to be a danger to the health or safety of the public, or
>
> (b) any product designed for household, garden or personal use, ... that he is satisfied is or is likely to be a danger to the health or safety of the public, because of the design, construction or contents.

The determination as to whether a product or substance meets this criteria rests with the Cabinet upon the recommendation of the Departments of Consumer and Corporate Affairs and National Health and Welfare.

It is thought that the ambit of application of the HPA to biotechnology is extremely small. The first limiting factor is the narrow definition attributed to "hazardous products". Under the first prong of the definition, it seems that a hazardous

product must not only be of a kind that is likely to be a danger to the health or safety of the public, but also be by its nature poisonous, toxic, inflammable, explosive or corrosive. Clearly, many open releases into the environment of new life forms would not contain one of these characteristics. Similarly, the second prong of the definition is limited since the product must be designed for household, garden or personal use.

The major limitation on the usefulness of this legislation is that even if a product is deemed to be a hazardous product, section 3 of the HPA only regulates the advertising, selling or importation of that product. It makes no mention of research, manufacturing or the use of the product, the areas of primary concern.

Finally, the HPA is residual in nature. The Act does not apply to any product or substance that falls within the ambit of the Explosives Act, the Food and Drug Act, the Pest Control Products Act or the Atomic Energy Control Act.

Pest Control Products Act (PCPA) (11)

Under the federal PCPA, biological control agents formulated as pesticides are registered for sale and use in Canada. The Act, administered by the federal Department of Agriculture, applies to most biological pesticides including those consisting of microbial agents (bacteria, viruses, fungi

and protozoa) and those of a biochemical nature (such as pheromones, juvenile growth hormones and natural plant regulators which modify pest activities or growth processes) including those created using biotechnological methods.

Because pesticides must be registered before they can be sold or used in Canada, the Department of Agriculture can control the direct release of new genotypes as pesticides by failing to accept them for registration.

Under the pesticides registration process, a means to evaluate the environmental acceptability of biological pesticides is provided through review by an interdepartmental pesticides review group. Currently, the primary advisors to the Department of Agriculture in this review process include the Departments of Environment, Fisheries and Oceans and National Health and Welfare. Guidelines are being prepared to define the data required to support the registration of biological pesticides containing naturally-occurring microbial agents. Given adequate information, this review could be expanded to include new genotypes used as pesticides.

Although the PCPA does provide one of the few instances where a mechanism is provided for the prior assessment of impacts and risks of open environment releases, the Act's registration requirements are burdened with serious deficiences. A recent report studying the entire ambit of pesticide law in Canada

concluded that some of these deficiences included:

> ...inadequate testing requirements and practices; dubious assumptions with respect to acceptable risk of such products; and virtual lock-out of the public from participation in the decision-making process respecting registration or re-evaluation. The registration program also offers the possibility of some pesticides reaching the market and the environment despite lack of adequate health and safety data. These authorized departures from full registration requirements threaten the integrity of the federal government's program, yet adequate safeguards do not appear to be in place to prevent abuses.(12)

The controls of biological pesticides under PCPA are augmented by provincial legislation such as the Pesticides Act(13) (PA) in Ontario. Under the PA, Ontario controls the use of federally registered products through a system of permits and licences. Generally, those engaged in the extermination business must obtain licences whereas permits are issued for specific exterminations. This system acts as a control on the calibre of the persons using pesticides and the conditions of use.

The provincial Act also creates a Pesticides Advisory Committee. The Committee has the responsibility of reviewing the content and operation of the Act each year and making appropriate

recommendations for amendments. More specifically, it reviews and classifies all existing pesticides and undertakes research:

1. to find alternative pesticides for those which are deemed environmentally hazardous,
2. to determine potential environmental hazards of pesticides currently in use, and
3. to reduce pesticide input into the environment.

These research functions could be applied to new organisms to be used as pesticides, providing valuable information to be used in a review.

Like the federal Act, however, the PA has not been free from criticism. Most notably, farmers seem to be exempt from all or most permit and licensing requirements, despite the fact that agriculture is the predominant area of pesticide use in Canada. Further, enforcement measures and procedures have not always been applied consistently nor adequately responded to the problems of pesticide misuse.(14)

In summary, it is clear that, for the most part, existing legislative mechanisms tend to be either inadequate or incomplete with respect to the assessment of the impact and risks associated with open environment releases of new life forms. In short, existing legislation simply was not designed to take into account some of the basic concerns which are present with many open environment releases.

(b) Regulatory Powers

Aside from the issue of requiring an assessment of the environmental impact which could result from release of modified life forms, it is important to look at whether governments have the power to limit or prevent releases which entail the risk of harm or about which insufficient information exists to make that judgment.

At both the federal and provincial levels, there exist various legislative mechanisms which may provide direct or indirect controls on the release of new life forms into the environment.

Direct controls are found in some of the legislation discussed above. For example, under the Environmental Contaminants Act, once a substance or a product has been held to be a "contaminant", the control mechanisms are triggered to prohibit or limit its release, manufacture or sale of the substance or product. Similar direct controls can also result from the application of the HPA and the PCPA.

The Department of National Health and Welfare Act[15] and patent laws provide possible avenues for further indirect control.[16] Under the former Act, the federal Cabinet is empowered to make regulations for ..."all matters relating to the promotion or preservation of health, social security and

social welfare of the people of Canada over which the Parliament of Canada has jurisdiction..." To date however, no regulations specifically directed to the release of genetically engineered organisms, have been passed (although some have been considered).[17]

In light of recent court decisions in the United States and Canada indicating that new life forms are patentable,[18] it is conceivable that control could be exercised by making compliance with certain safety and release requirements a condition for obtaining patent protection. However, it is clear that the relevant governmental authorities in this area neither possess the resources nor the expertise to initiate standards or enforce the protections or criteria. Moreover, if the requirements were seen as too onerous, developers might simply avoid the patent process altogether, with trade secrets substituted for patent protection. Finally, there is some doubt as to the extent to which the federal government would be constitutionally justified in employing patent law in this fashion.[19]

Another form of direct control is found in the Ontario Environmental Protection Act (EPA).[20] The Ministry of the Environment (MOE) is empowered to issue "control orders" or "stop orders" to persons responsible for the release of "contaminants" into the environment in contravention of the Act or where the release constitutes an immediate danger to human life or health or to property (ss. 6-7,11). In addition, the MOE has the power to require the person releasing the contaminant

respect to open environment releases of new life forms strongly indicates that such applications of biotechnology, when they occur, will operate largely in a regulatory vacuum. In some instances, it may be possible to extend present legislative initiatives to control various aspects of open environment releases. Where regulatory gaps still persist, new legislation may be necessary. However, the inherent complexities and importance of the biotechnology industry suggest that this sort of piecemeal approach to regulation will provide neither acceptable and efficacious regulation which protects the interests of the public and the environment nor a setting conducive to efficient and productive industrial growth. Instead, what is needed is a streamlined framework whereby the public interest is sought to be protected while at the same time providing industry with an efficient and predictable regulatory process.

It must be emphasized that the balance between the protection of the public interest and the goal of economic and industrial prosperity is sometimes a tenuous one. On the one hand, the benefits of biotechnology will, in some way, have a positive impact in every sector of society. As the industry develops, it holds the potential to work toward addressing many of the world's most troublesome problems by increasing food productivity or making more efficient use of our already scarce resources, among many other examples which could be cited. On the other hand however, it is the responsibility of this generation to ensure

that future generations will have the benefit of a healthy and prosperous environment and a sustainable ecological balance. This goal may be achieved by providing a set of ground rules which are explicit and effective without being either unfair or too onerous. The development of the biotechnology industry will incur risks. The hard task that lies ahead will be attempting to find that middle ground where the risks are minimized without unduly or prematurely "chopping the knees off" industrial development.

It is submitted that this difficult task should commence in advance of full-scale Canadian industrial application of biotechnology. Indeed, the agreed upon rules should be laid out at the early stages of industrial growth in order to permit industry to take into account such requirements throughout its corporate planning processes. The creation of a workable regulatory framework in the very near future would seem to make both good environmental and good corporate sense.

Finally, it must be emphasized that the new regulatory framework proposed below is one of a number of schemes which could be devised. The following proposal is put forth as a starting point for discussion and should not be construed as a recommended concrete plan for regulatory action.

In a general light, it is suggested that the new

regulatory framework might result from a cooperative effort by the national and provincial governments. At the federal level, legislation would be enacted to provide for three avenues of protection for the release of new life forms in the open environment. First, an interdisciplinary commission would be established for the purpose of assessing the risks and impacts of all new life forms intended to be released into the open environment. This national commission, in effect, would develop and implement a certification process. Attributes of this certification process would include:

(a) a technical review of the product proposed to be released;

(b) a procedure to ensure for public input;

(c) regularized approval criteria and decision options; and

(d) various monitoring duties.

As a result of this certification process, all new or modified life forms intended for open environment applications would be certified by the national commission before they could be offered for use, sale or distribution.

In addition to its certification duties, the national commission would develop a nationwide information bank for the purpose of collecting and correlating studies and information on the use, effects, risks and impacts of new life forms.

The second avenue of protection under federal responsibility deals with accidental or inadvertent releases. At a national level, and drawing from the knowledge, experience and expertise of the national commission, formalized emergency response procedures and strategies would be developed in order to prepare for those situations when new forms are accidentally released, react in an unpredictable or unstable manner upon release, or are simply released in excessive quantities.

Finally, the federal government would have the responsibility for overseeing the establishment and administration of a compensation fund for persons suffering harm from the release of new life forms. The purpose of this compensation fund would be to supplement traditional tort law since, in many instances, it would be a very difficult task for the injured party to overcome some of the traditional obstacles in establishing liability against the culpable party.

The provincial role under the proposed regulatory framework would primarily involve implementation. It would be the responsibility of the provincial governments in the framework suggested here to devise a system for the safe use of those products certified by the national commission. This system might take the form of a permit or licence regime. Hence, provinces would be responsible for establishing:

(a) criteria as to the qualifications, training and experience of persons eligible for permits;

(b) conditions for use of the products released into the environment (in addition to those conditions

mandated through the certification process) including mandatory reporting requirements;

(c) the availability of equipment, apparatus or other means to ensure the effectiveness of the emergency response procedures and

(d) a system for enforcing the conditions of release.

With this general overview in mind, it is now appropriate to further examine the nature and content of the proposed regulatory framework. To simplify matters, the potential federal role is discussed first, followed by a review of suggested provincial responsibilities. Subsequently, there is a brief discussion of the constitutional implications of the framework under examination.

(b) The Federal Role

(i) Establishment of a National Biotechnology Commission

A. Nature and Purpose

Perhaps one of the most important features of the proposed framework is the establishment of an independent and interdisciplinary commission (hereinafter referred to as the National Biotechnology Commission or NBC). The primary purpose of the NBC would be to provide a means to study, assess and certify all new life forms intended to be released into the open environment. Other purposes of this commission include administering the nationwide information bank and the compensation fund described below.

The use of a permanent single body for all of Canada is important for several reasons. First, the highly complex technical issues involved in open environment releases requires a group with

specialized personnel and expertise which, because of its limited numbers, can be more easily pooled in one body rather than in each province. Second, uniformity of regulatory control throughout Canada is essential not only to prevent individual provinces from luring industries with disparate standards, but also to deal with problems interjurisdictional in nature. Third, uniformity of treatment of open release applications is most fair to proponents. Finally, the present uncertainty surrounding impacts requires a focal point for compiling data from studies and experience with open environment releases worldwide rather than having eleven jurisdictions repeat the task. The resources necessary to undertake such initiatives would be beyond the capability of most provincial governments acting on their own.

The NBC would be created and derive its mandate from enabling legislation. Such legislation would outline the Commission's purposes, powers, composition and organization. (34)

B. Composition and Organization

The Commission would consist of a small "hub" or administrative "core" and a far broader circle of experts. The members of the administrative core, the commissioners, can be considered the co-ordinating and the decision-making component of the NBC. (35) In Canada, it is most common for members of a commission to be appointed by the Governor General-in-Council (the Cabinet). As such, the Commission would be accountable to the Canadian public through the member of the cabinet whose portfolio included the responsibility for the NBC.

Some thought will have to be given to the question of what sort of representation should be included in the NBC. One possibility is that it would have representation from many disciplines due to the wide array of issues (including social, economic, ethical as well as technical) presented by open environment releases. Further, it may also be appropriate to ensure that the interests of the provinces are represented as well as some form of "public" representation.

Beyond the administrative core of the NBC, there would be a "roster" of experts who serve on the technical review (risk assessment) panels. This expert component would include both staff personnel and those who are asked to participate on various panels from government, industries and universities on an ad hoc basis.

Upon submission of a new life form to the NBC for certification, the commissioners of the NBC would select a number of experts from its roster who are specialized in the fields relevant to that life form and its proposed application. This group of experts would then make its investigation and make recommendations to the commissioners. The commissioners then make their decision as to certification.

It should be noted that the NBC would recognize the provincial role in the regulation of business and provide ongoing liaison in order to promote coordination with other aspects of biotechnology regulation under provincial control.

C. National Information Bank

An important feature of the NBC pertains to the development of a national information bank. The information bank would have the task of gathering and compiling as much information as possible on new life forms and their impact on the ecology and humans. With a national mandate, the information bank would, in effect, be a central registry for data concerning all facets of open environment releases. This data base could be collected from studies conducted around the world as well as the experience gained in the national context. As a consequence, the NBC would have at its disposal the most current and complete sources of information available. Such a source would be extremely valuable to ensure that its decisions are based upon the most recent data and scientific understanding. Further, the data base compiled under the information bank would become a valuable tool for the public in understanding the nature of new life forms together with the current understanding of their effects, impacts and characteristics upon release.

(ii) The Certification Process

It is suggested that all proposed releases of new life forms would first be assessed and certified by the NBC. Elements of this certification process should include: 1. the proposal must be supported by documentation of anticipated environmental impacts, 2. it must be subjected to a technical review; 3. the public should have an opportunity to comment on the proposal; 4. the approval decision should be based upon regularized criteria;

5. there should be a range of decision options (such as "approved with conditions", "require more information" or "reject"); and 6. the impacts of the releases must be monitored. Each of these elements are discussed presently.

A. Documentation

It should be the responsibility of the proponent (36) of each new release to provide sufficient documentation to enable risk assessment and a certification decision to be made. What is sufficient will vary with the nature of the particular release and as experience with environmental releases grows.

Generally, the documentation by the proponent would entail three categories of information. First, the proponent would have to reveal the nature and basic characteristics of the new life form or genotype under consideration relying on its own tests and other studies to document these characteristics. In most cases, this documentation would not pose a disclosure problem because it is clear that new life forms or genotypes are patentable. In those cases where trade secrecy (37) is an issue, special rules of confidentiality would have to be established. Such rules would need to balance the interests of the proponent in not revealing information about the development of its new product and the interests of the public in knowing the nature and impact of the proposed release.

In addition to informing the NBC about the nature of the new life form or genotype, the proponent must also specify the nature of the environment in which it proposes to release the new life form and provide information on the demonstrable

impacts of release to that environment. The basis of this requirement relates to the fact that the NBC certifies releases of the named organism only to the environment mentioned in the application. Releases to "different" (38) environments would require new certification.

The third category of information required by NBC from the proponent is precise details of the quantities, concentrations, densities, or otherwise demonstrable amounts of the proposed open environment release. With this information, the NBC would then have the ability to attach conditions of release on the certification.

B. Technical Review

After the documentation stage, it would be the task of the NBC to assess the risk associated with an open environment release. This task is essentially a technical activity to be done by experts. Involved in this step is evaluation of the lab research and field studies which address the nature and behaviour of the organism and the ecosystem at issue. One of the aspects of the technical review therefore would be to develop some sort of procedure whereby releases could be allowed for field tests although the new life form has yet to be certified.

Because this assessment will be used as the basis for the certification decision, it is imperative that it be done by as qualified and independent a group as possible. It is for this reason that ad hoc technical panels would be employed. From an array or roster of qualified experts, the NBC would select those experts most suitable for the assessment of risks and impacts

of the particular life form and release application under question. This technical panel would review, study and ultimately report to the NBC. In effect, it would be a fact-finding body striving toward the goals of neutrality and objectivity. Upon submission of its report, the NBC may accept the report, or send it back to the technical committee for further review and comment.

Since the technical panel is selected according to the needs and imperatives of each application before the NBC, a great deal of flexibility is achieved.

C. Public Comment

After the completion of the technical review by the risk assessment panel, the panel then submits its recommendations to the administrative core of the NBC.

Because members of the public are both the ultimate beneficiaries and the ultimate victims of environmental releases of new life forms, it is appropriate that they have an opportunity to comment on release proposals. Full-fledged public hearings on every proposal would likely lead to delay, hampering industrial activity. However, it does seem reasonable that, before the NBC makes any decision with respect to certification, a public comment period be permitted. Perhaps what could be included is a mechanism to allow or trigger a public hearing where the seriousness of the potential impact of the release is considerable.

A public comment period should be limited in time but must be of sufficient time to allow people to make a meaningful contribution. To be meaningful, features of a public comment

mechansim would include: notice of the proposed certification; the availability of technical information on the new life form (such as the report of the risk assessment panel); access to information on which the decision will be based, and funding if necessary to allow members of the public to hire experts to review the technical information.

Public participation is also provided for in the decision on whether to certify because of public representation on the commission.

D. Regularized Criteria

After the public comment period, the decision whether to certify a release should be made by the commissioners of the NBC relying on all available information. In order to facilitate uniform treatment of proposals (and thus fairness to proponents), a standard set of factors or criteria for making a decision should be considered. The factors can be spelled out in legislation or developed by the commission as guidelines. Legislatively specified criteria are rigid, in the sense that they are not easily changed if change becomes desirable, but they do give the commission clear guidance as to the government's preferred criteria and provide a basis for judicial review. Commission guidelines on the other hand, are more easily changed and would reflect the values of a broad range of individuals but would not have the approval of our elected representatives.

E. Decision Options

In order to have the flexibility to deal with a variety of situations and be an effective force in controlling the harmful effects of environmental releases, the NBC must have

more authority than simply the power to accept or reject a proposal for certification. Before certification is granted, the commission should be empowered to remit the proposal for further review by the risk assessment panel or simply defer the proposal until more is known about the new life form or genotype.

Further, authority should be given to the NBC to set conditions on the use and release on the new life form once the certification is granted. For example, the commission may make the certification conditional upon the requirement that the product only be released in certain defined environments, at certain times or for a certain period of time, or that the product can only be released in certain concentrations or quantities.

Two issues have yet to be discussed of some importance: re-assessment and appeals. Most would agree that a new life form should not be certified for release then forever forgotten. Instead, it is necessary to devise a mechanism whereby after a certain pre-determined period of time the product should be re-assessed. In essense, a re-assessment would be a review of the certified releases of the new life form and the data supporting those open environment releases. Further, it may be necessary to give the NBC power to re-assess the new life form and its release propensities before the expiry of the allotted time if conditions so warrant. As a result of the re-assessment, the NBC should be given the authority to revoke or modify the conditions of certification.

If a product is rejected for certification or its certification revoked or altered at the re-assessment stage, the proponent could suffer considerable financial hardship. Consequently, in order to snsure the fairness of the procedures, it would seem crucial that an appeal route be devised for all the interested persons involved. There are various ways appeals could be built into the system, such as judicial review or the creation of an administrative review board. Irrespective of the method chosen, care must be taken to ensure that the appeal route is efficient, fast and not too complicated.

F. Monitoring

After the NBC has made a certification, provisions should be made to permit the commission to monitor the release of the certified product. Monitoring in this context differs from the notion of enforcing the conditions of certification which would likely be left to the provinces. Instead, the monitoring function would assist the NBC to continue to build its information base on the types and nature of all open environment releases, the interim and long term impacts, and the problems that have been encountered with such releases. In addition, monitoring allows early detection of harmful consequences before damage is widespread and alerts authorities to possible dangers and complications.

G. Costs

Obviously, the certification process can have some substantial implications in terms of costs for the proponents. Although some costs would seem unavoidable, it is submitted that,by ensuring that each stage of the process is streamlined, efficient

and predictable, costs will be maintained at an acceptable level. Perhaps this is one area where open dialogue among industry, government and public interest groups may be fruitful in finding ways to avoid undue financial burdens on any of the parties concerned.

(iii) Accidental Releases

It can be expected that at some time there will be an accidental release of a new life form either during the research, manufacture or use of the product. In many cases, the accidental release will likely be easily contained and removed safely. However, considering the potential consequences involved in this sort of event, it seems logical that a more formalized method and procedure be created to provide for the reporting, containment, and clean-up of accidental releases. To accomplish this task, it is proposed that the NBC be given the authority to develop effective response strategies, procedures to ensure proper coordination of personnel and equipment and proper methods of removal and disposal of released products.

Except in certain specified realms, most of the present environmental emergency response procedures are developed and implemented at the provincial level. However, with respect to new life forms, the expertise and experience the NBC would have in this realm suggests that a central authority to develop and refine emergency response strategies as well as to study new and more efficient methods of clean up and containment is appropriate. The actual implementation of the procedures would be left to provincial agencies.

(iv) Liability and Compensation

The issues of liability and compensation for harm due to the manufacturing or use of bioengineered products represent two of the more difficult issues in this field. The limited usefulness of traditional legal doctrine was discussed earlier. Difficulties in proving causation - the link between cause and effect, in attributing harm to particular defendants and in assessing damages call for a non-traditional approach in order to ensure that victims will be compensated and promptly.

One suggested approach is to by-pass the issue of strict versus absolute liability by establishing a compensation fund to which victims could make claims as soon as damage becomes apparent without having to first establish fault on the part of particular defendants.

Contributions to such a fund would be made on a regular basis by those firms or groups which release new life forms into the environment, according to a predetermined formula. (This formula could be based on variables such as type of release, degree of risk involved in each, magnitude of harm associated with the type of release, etc.) If collected on a regular basis, this contribution would be analogous to an insurance premium. In any event, the amount of contribution should not be so high as to discourage commerical activity or send Canadian firms to other countries.

Claims against the fund would be allowed in three circumstances. First, where funding is necessary in order to allow public participation in a certification procedure, money could be given by the fund.

Second, persons whose health or property is harmed as a direct or indirect result of an environmental release would seek compensation from the fund in lieu of starting a lawsuit.

Third, where harm to the environment (ecosystem disruption) is caused directly or indirectly by an environmental release, the cost of remedial action to control or clean up the damage could be recovered from the fund.

The NBC would be vested with the responsibility of administering the fund. Upon a claim being filed, the commission would undertake an investigation and then decide the appropriate award. After the payment of the award, the commission could then take action to recover damages and consequent costs from the party who released the product. In effect, the concept of the compensation fund would shift the onus from the injured party to the commission to establish liability. In this context, the commission would have available the traditional legal recourses to pursue its allegations.

(c) The Provincial Role

The federal role involves putting into place a procedure to ensure a minimum standard of review assessing the impact and risks of an open environment release of any new life form. Once this review has been completed and a release authorized, the provinces have an important responsibility to ensure the proper and safe use of certified life forms upon release. It is envisaged that this responsibility would be fulfilled through the development of a permit system and the establishment of mechanisms to provide for close federal-provincial liaison and enforcement.

In order to fulfill these goals, it would be necessary for each province to adopt legislation detailing the provisions of this scheme. No doubt in some instances, or for som aspects of its responsibilities, provinces may be able to amend some of their existing laws or expand some of their non-regulatory programs.

(i) Licensing

The primary provincial role in controlling direct releases to the environment is to establish a system to provide for licensing of the persons conducting releases. The licensing function would primarily be designed to ensure competence of the operator but may also include: reporting requirements to ensure compliance with federal and provincial conditions of release; requirements that certain equipment be available to ensure safe release and prompt response in case of emergency; and rules regarding conditions of release stricter than those allowed under federal certification, safe transportation (39) and disposal. It is possible that in many instances the licensing function may be administered by an existing provincial department.

A. The Competence of the Operator

Obviously, even a certified new life form may pose a significant danger if the product is released in a negligent or improper manner. Consequently, it is important for each province to ensure that the applicant is competent in dealing with the certified product. Hence, the province would have to develop a set of criteria outlining the minimum qualifications, training and

experience of persons allowed to conduct open environment releases. All releases would then have to be conducted by licensed operators.

B. Reporting Requirements

Safe conduct of an open environment release requires compliance with the conditions imposed by the commission or the province as well as a competent operator. In order to provide a check on compliance, the provinces would mandate that information on all releases be reported. This information is also necessary feedback to the NBC which needs this data to make more competent certification decisions.

C. Equipment Requirements

Operators granted licences to release would have to be required to have certain equipment (if and when appropriate) available for the safe conduct of releases. The requirement of proper equipment is also important as a first line of defence in case of emergency where immediate containment may be necessary to prevent widespread environmental harm.

D. Further Conditions

Although the NBC establishes conditions of release for particular genotypes, it should be open to the provinces to strengthen those conditions when local circumstances warrant. For example, when a particular area is ecologically more vulnerable to harm or the needs of a particular community demand it, the province should be able to take account of these circumstances and protect against them.

E. Enforcement

Although it is not our intention to deal with the issue of enforcement, it is expected it would be within provincial authority.

(ii) Federal-Provincial Liaison

It is clear that no regulatory framework over environmental releases can work effectively unless provision is made for close federal-provincial consultation and co-operation. At most every stage of the regulatory process, there would be need to co-ordinate scientific and technical information and other administrative resources. Consequently, there is need to develop networks and channels for open and efficient dialogue and communications. One way of achieving this is through provincial government participation on the NBC.

(d) The Constitutional Implications

With the proposal of any new legislation, the constitutional division of legislative authority between the governments of Canada and the provinces must be kept closely in mind. According to the Constitution, (40) and the judicial interpretations of its provisions, each level of government is assigned specific legislative areas with which it is exclusively competent to deal in its own right. Consequently, it is important to ensure that the proposed regulatory framework is feasible in approach in the sense that each level of government is constitutionally empowered to act in accordance with the design of the proposed scheme.

It is not the intent of this paper to discuss all of the constitutional implications of the proposed framework. Instead, it would seem appropriate to simply discuss how the role of each level of government under the proposed framework would be constitutionally justified and supportable.

Generally, it would seem that the provincial governments have primary constitutional authority over regulation of the biotechnology industry. This authority, for the most part, is derived from provincial powers over "property and civil rights" (s.92 (13)); local works and undertakings (s. 92 (10)); and "matters of a merely local or private nature (s. 92 (16)); Such powers provide ample support for the proposition that the regulation of business is a matter of provincial competence.(41) In addition to the above powers, it is generally accepted that the provincial rights of ownership of public lands and natural resources and the authority over the "exploitation, development, conservation and management of non-renewable natural resources, forestry resources, and electric energy production" (S. 92A) give the provinces the primary role for environmental management and protection.(42)

Although the provinces have primary legislative authority over the regulation of business and environmental management, their powers are subject to a number of constitutional constraints.

The first constraint is that if federal and provincial governments have enacted laws in areas of concurrent jurisdiction, the doctrine of paramountcy dictates that the provincial law is inoperative to the extent of the inconsistency. Second, the provinces have limited ability to enact laws with extra-territorial effect.(43)

The most important constraint however is that the provincial legislatures cannot enact laws on matters exclusively assigned to federal Parliament in section 91 of the Constitution Act, 1867. In other words, if the regulatory proposal defined above was contemplated to be implemented, it would be necessary to establish a basis upon which Parliament could justify its encroachment on provincial legislative competence. In this context, the justification for the proposed framework would have to be supportable either under one of the specific subjects given exclusively to the federal government or under the residual or general power of the Government of Canada to pass laws for the "peace, order and good government of Canada".

With respect to the specific subjects of federal competence under S.91, the federal government relies on its jurisdiction over regulation of inter-provincial trade and commerce (S.91 (2)), (44) sea coast and inland fisheries (45) (S.91 (12)) and the criminal law (46) (91 (27)) to enact legislation dealing with environmental protection. Indeed, it has been held that the "criminal law" embraces laws relating to "public peace, order, security, health and morality".(47) Hence, this jurisdiction over public health is the basis for federal environmental legislation and standards designed to protect human health.

More commonly however, Parliament has relied on its residual power found in section 91 of Constitution Act, 1867 as a constitutional basis for its federal environmental statutes. (48) This power has had an unwieldy history with judicial interpretation oscillating from extremely restrictive to extremely expansive. (49) However, it seems the Courts now accept reliance on this power

in three circumstances: (50) - where a national emergency exists; where a problem arises which did not exist in 1867 and which is not local or private in nature; and where a matter is by its nature of concern to the whole country and cannot be solved by co-operative provincial action. It is submitted that open environment releases of new life forms fall within both the second and third circumstances, so as to justify not only federal involvement, but also the establishment of the NBC, its certification process, the development of accidental release emergency responses and the compensation fund.

It is clear that, to support the level of involvement by Parliament under the proposed scheme, the use of the federal residual power would only modestly modify the existing division of legislative powers between the federal and provincial governments. Indeed, the proposed framework would not require the federal government to use the residual power to occupy the total field as it did in the areas of broadcasting, air transport, atomic energy and the national capital area. (51) Instead, the extent of involvement would be much more analagous to that jurisdiction exercised by the federal government, under the Environmental Contaminants Act, the Pest Control Products Act (52) and the Pesticide Residue Compensation Act.(53)

5. Conclusions

The issue of regulating biotechnology is a complex one. Regardless of which regulatory framework is put forth, there will always be various advantages to it over another, and of course, certain disadvantages. The essential task at this time is to actively commence and continue the dialogue on the nature, extent and type of regulation required. Through such dialogue, it may be possible to arrive at an acceptable and workable framework that satisfies all of the interests concerned.

There is little doubt biotechnology will bring with it tremendous economic, social and industrial benefits. It is our responsibility to ensure that all will be able to enjoy these benefits without having to risk unduly human health or the quality of the environment.

NOTES

1. Statement of Don R. Clay, Acting Assistant Administrator, Office of Pesticide and Toxic Substances, Before the Subcommittee on Science, Research and Technology and Subcommittee on Investigations and Oversight, Committee on Science and Technology, House of Representatives, June 22, 1984, p. 2

2. A "genotype" may be generally defined as an organism or group of organisms sharing a specific genetic constitution or characteristics.

3. Staff Report, "The Environmental Implications of Genetic Engineering" Prepared by the Subcommittee on Investigations and Oversight Transmitted to the Committee on Science and Technology, U.S. House of Representatives, Ninety-Eighth Congress, Second Session, February, 1984, pp. 20-24.

4. Frances L. McChesney and Reid G. Adler "Biotechnology Released From the Lab: The Environmental Regulatory Framework", (1983) 13 Env't L. Rptr. 10366, at pp. 10368 - 9.

5. See: Chemical Control Division, Office of Toxic Substances, Environmental Protection Agency, "Regulation of Genetically Engineered Substances Under TSCA" Preliminary Draft, March, 1983, pp. 6-7.

6. R.S.O. 1980, c. 321

7. Paul Davidson, "New Genetic Life Forms," A Study prepared for the Law Reform Commission of Canada, April, 1983, pp. 108-12.

8. R.S.O. 1980, c. 321.

9. S.C. 1974-75-76, c. 72, as amended.

10. R.S.C. 1970, c. H-3, as amended.

11. R.S.C. 1970, c. P-10, as amended.

12. J. F. Castrilli and Toby Vigod, Pesticides: An Examination of Canadian Law and Policy (Draft Paper, Prepared for the Law Reform Commission of Canada, Protection of Life, Health and the Environment Project, 1983), pp. 207-8.

13. R.S.O. 1980, c. 376, as amended.

14. Castrilli and Vigod, supra note 12, p. 209.

15. Department of National Health and Welfare Act, R.S.C. 1970, c. N-9, as amended.

16. Also see; The Transportation of Dangerous Goods Act, S.C. 1980, c. 36.

17. See Davidson, supra, note 7, p. 116.

18. In the U.S. see Diamond v. Chakrabarty, 447 U.S. 303; 65 L. Ed. 2d 144, 100 S. Ct. 2204. In Canada, see: Decision of the Commissioner of Patents in Patent Application 257177, March 18, 1982.

19. See Davidson, supra, note 7, pp. 55-58.

20. R.S.O. 1980, c. 141.

21. Ibid., s.8

22. Ibid., s. 1(c).

23. In the U.S., the emerging view seems to be that a new life form would be included under the definition of "chemical substance" pursuant to s. 13 (2) of the Toxic Substances Control Act, 15 U.S.C. ss. 2601-2629.

24. R.S.C. 1970, c. C-14, as amended.

25. R.S.C. 1970, c. C-34, as amended.

26. Whether Part IX of the EPA, the as yet unproclaimed "Spills Bill", is applicable to biotechnology, is a matter of speculation.

27. E.g., see: the Joint U.S.-Canadian Oil and Hazardous Materials Pollution Contingency Plan for the Great Lakes Region, Great Lakes Water Quality Agreement, 1972, Annex 8; Federal Department of the Environment (Ontario Region), Contingency Plan for Oil spills and other Hazardous Materials. For a discussion of the various contingency plans see; International Joint Commission, International Reference Group on Great Lakes Pollution from Land Use Activities, An Evaluation of Canadian Legislative, Regulatory and Administrative Programs (1977), pp. 240-1

28. E.g., see: P.S. Elder " Environmental Protection Through The Common Law" (1973), 12 West. Ont. L. Rev. 107.

29. E.g., see: Boomer v. Atlantic Cement Co., 26 N.Y. 2d 219, 257 N.E. 2d 870; 309 N.Y.S. 2d 312 (N.Y. App. 1970).

30. 42 U.S.C. ss. 9601 - 9657.

31. Pesticide Residue Compensation Act, R.S.C. 1970, c. P-11.

32. R.S.C. 1970, c. F-27, as amended.

33. Castrilli and Vigod, supra, note 12, p. 137.

34. It is also suggested that other aspects of federal responsibility be specifically detailed in legislation, including the certification process, provisions concerning accidental releases and the compensation fund.

35. Some thought should be given to how many commissioners should sit on the NBC. The agreed figure would probably range from three to seven members.

36. A "proponent" in this context is really the importer, manufacturer, distributor or any other person who intends to certify a product for open environment release. Once certified, the product may be sold or distributed in accordance with the conditions attached thereto.

37. E.g., problems may arise if certification is applied before the new life form is patented or the developer of the new life form wishes to keep the product a secret in order to ensue that the product remains out of the hands of the competitors.

38. "Different" in this context connotes release into a different medium (water, air, soil) or under different conditions (climate, season).

39. It should be noted that there is overlap in the transportation of new life forms. Intra-provincial transporation would be a provincial responsibility and inter-provincial and international transportation would be regulated by the federal government. (See: Transportation of Dangerous Goods Act, S.C. 1980, c.-36).

40. Constitution Act, 1867 (formerly the British North America Act, 1867)

41. Peter W. Hogg, Constitutional Law of Canada (Toronto: Carswell, 1977), pp. 502-3.

42. R.T. Franson and A.R. Lucas Canadian Environmental Law vol. 1 (Toronto: Butterworths, 1976) pp. 253 - 255.

43. See Interprovincial Co-operatives Ltd. and Dryden Chemicals Ltd. v. The Queen [1976] S.C.R. 477

44. E.g., see the Motor Vehicle Safety Act, R.S.C. 1970 (1st Supp.), c. 26, as amended.

45. E.g., see the Fisheries Act, R.S.C. 1970, c. C-14, as amended.

46. E.g., see the Criminal Code, R.S.C. 1970, c. C-34, as amended See: Standard Sausage Co. v. Lee [1933] 4 D.L.R. 501 (B.C.C.A.)

47. Ref. Re Validity of Section 5(a) of the Dairy Industry Act (The Margarine Case) / 1949 / S.C.R. 1.

48. E.g., The Clean Air Act, S.C. 1970-71-72, c. 47, as amended. The Clean Water Act, R.S.C. 1970 (1st Supp) c.5
Also see: R. v. Canada Metal Co. Ltd. (1982), 11 C.E.L.R. 130 (Man. Prov. Ct.), aff'd (1982), 12 C.E.L.R. 1 (Man. Q.B.), where the Clean Air Act was upheld under the federal general power.

49. Hogg, supra note 1, at 241-65

50. Labatt's Breweries v. Attorney General of Canada, et al, (1979), 110 DLR (3d) 594, p. 627 (S.C.C.)

51 Re Regulation and Control of Radio Communication, / 1932 / A.C. 304; Johanneson v. West St. Paul / 1952 / 1 S.C.R. 292; Pronto Uranium Mines Ltd. v. Ontario Labour Relations Bd., / 1956 / O.R. 862; 5 D.L.R. (2d) 342; Monroe v. Nat. Capital Com., / 1966 / S.C.R. 663.

52. R.S.C. 1970, c. P-10, as amended.

53. R.S.C. 1970, c. P-11.

Appendix I

Federal Legislation Reviewed or Considered

Animal Contagious Diseases Act, R.S.C. 1970, c.A-13, as amended.

Clean Air Act, S.C. 1970-71-72, c.47, as amended.

Clean Water Act, R.S.C. 1970 (1st Supp.), c.5, as amended.

Criminal Code R.S.C. 1970, c. C-34, as amended.

Department of National Health and Welfare Act, R.S.C. 1970, c. N-9, as amended.

Environmental Contaminants Act, S.C. 1974-75-76, c.72

Fertilizers Act,R.S.C. 1970, c. F-9

Fisheries Act,R.S.C. 1970, c. C-14, as amended.

Food and Drugs Act, R.S.C. 1970, c. F-27, as amended.

Hazardous Products Act, R.S.C. 1970, c. H-3

Northern Inland Waters Act, R.S.C. 1970, c. H-3

Ocean Dumping Control Act, S.C. 1974-75-76, c.55

Pest Control Products Act,R.S.C. 1970, c. P-10, as amended

Pesticide Residue Compensation Act, R.S.C. 1970, c.P-11

Plant Quarantine Act, R.S.C. 1970, c. P-13

Seeds Act, R.S.C. 1970, c. S-7

Transportation of Dangerous Goods Act, S.C. 1980, c.-36

Appendix II

Province of Ontario Legislation Reviewed or Considered

Environmental Assessment Act, R.S.O. 1980, c. 140, as amended

Environmental Protection Act, R.S.O. 1980, c. 141, as amended

Occupational Health and Safety Act, R.S.O. 1980, c. 321 as amended

Pesticides Act, R.S.O. 1980, c.376, as amended

Seed Potatoes Act, R.S.O. 1980, c. 467

Trees Act, R.SO. 1980, c. 510.

Weed Control Act, R.S.O. 1980, c. 530

Wild Rice Harvesting Act, R.S.O. 1980, c. 532.

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THE REGULATION OF BIOTECHNOLOGY

October 9, 1984

COMMENTS ON "BIOTECHNOLOGY AND THE ENVIRONMENT A REGULATORY PROPOSAL"

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Comments On "Biotechnology And The Environment A Regulatory Proposal

1. As the current biotechnological revolution gains speed and scope, contemporary concern for its possible consequences and implications is natural and justified. It is appropriate that existing controls in Canada be examined and the need, if any, for additional controls be assessed while development in the field in this country is at an early stage. Regulations in countries where the greatest advances have been made and the greatest activities are under way and the most extensive plans for further development are being made may provide valuable comparisons with canadian legislation and regulations. Indeed, a federal statute of the United States has already served as an example to canadian legislators and administrators in environmental assessment procedure, and others have provided patterns for legislation in this country.

2. It is no doubt trite but should be remembered that biotechnology is not new. It has been in use at least since men learned how to produce alcoholic drinks and leavened bread, and even longer, since they began to develop strains of plants and breeds of animals to serve their needs. It should also be remembered that the current surge in biotechnological operations is not confined to employment of new life forms. Existing organisms, plants, animals and insects are being used in new ways, in larger volumes and in new environments. Each such use creates new problems and new risks, as well, of course, as the new problems and new

risks created by introduction of new or altered forms of life.

3. A convenient starting point and base for a study of existing canadian controls is found in "Canadian Environmental Law", a Butterworths looseleaf publication in 7 volumes. The first volume contains a brief survey of federal and provincial legislation and regulations as well as of the federal environmental assessment procedure. The others contain statutes and regulations of Canada and the provinces and territories. It does not contain the Hazardous Products Act, R.S.C. 1970, c. H-3, or federal and provincial occupational health and safety legislation. I am at present attempting to verify whether it is otherwise complete and up-to-date.

4. The immediate impression gained from a rapid survey of the contents of this work is that of a statutory maze. Legislation has been enacted with diverse purposes and employing a variety of controls and procedures. There seems to be little consistency.

Not all of this legislation is directed to regulation of biotechnological operations. It appears on first examination that not all biotechnological operations are subject to its controls throughout Canada. Subject to confirmation, it appears that a careful and co-operative review by each legislative and administrative authority whose area of concern may be affected by such operations

should be undertaken to attempt to attain uniformity of standards, consistency of controls, elimination as far as possible of duplication of procedures, and reduction of formal requirements to the minimum consistent with protection of the public and the environment. Federal and provincial co-operation will be necessary for these purposes.

At the same time, consideration must be given to the growing demand for publicity of procedures and participation by members of the public and public interest organizations. It will not be easy to reconcile this consideration with the need for a procedure that is reasonably expeditious and not unduly expensive and takes into account the desire of entrepreneurs to preserve trade secrets.

5. A preliminary question, as always in Canada, is where legislative jurisdiction to enact such controls is situated. This question is addressed at pages 47 to 50 of the discussion paper. A few comments are added here.

It is agreed by all that the subject matter falls partly into the federal legislative area and partly into that of the provinces. Property and civil rights within each province, local works and undertakings and matters of a merely local and private nature are heads of provincial jurisdiction that would authorize regulation of nearly all biotchnological operations that were confined and whose products and wastes were confined within the individual province. Federal

jurisdiction is restricted to matters within specific heads of jurisdiction assigned to the Parliament of Canada or within the residuary power.

The specific heads of federal jurisdiction usually considered for our purpose are:

Criminal law,

Seacoast and inland fisheries,

Navigation and shipping,

Patents,

Trade and commerce,

Treaties,

Taxation,

Spending power

The last three will not be discussed here.

Criminal law includes power to create offences such as pollution of the environment, endangering public health generally or by specific means, and can extend to measures designed to prevent crime. Its provisions can be designed to protect health, safety or morals, but cannot be directed simply to protection or regulation of industry or commerce. Whether processes can include civil remedies has been questioned. Criminal legislation is found not only in the Criminal Code, R.S.C. 1970, C. C-34, but in other statutes of which parts of the Food and Drugs Act, R.S.C. 1970, c. F-27, the Hazardous Products Act, R.S.C. 1970, c. H-3, and the Pest Control Products Act, R.S.C. 1970, c. P-10, are examples.

The limits of the criminal law power are uncertain. Efforts to use criminal law for the purpose of regulating insurance and production of margarine have been struck down. It is not clear whether an appropriate preamble would lend support to a statute whose validity was otherwise in doubt.

Seacoast and inland fisheries have been interpreted to support provisions of the Fisheries Act, R.S.C. 1970, c. F-14, prohibiting contamination of fishing waters.

Under navigation and shipping regulation of discharge of waste from ships has been enacted in the Canada Shipping Act, R.S.C. 1970, C. S-9 and the Navigable Waters Protection Act, R.S.O. 1970, c. N-19.

The availability of patents for new life forms or the processes for producing them is debated, although the Patent Office is said to have granted such a patent. Researchers have complained about the inhibiting effect of foreign patents under excessively broad claims. Plant breeders rights legislation has been enacted in other countries but not in Canada. A bill for the purpose has been before Parliament and may be introduced.

The trade and commerce power almost seemed to have disappeared, but has recently been revived to a limited extent. It seems to be confined to:-

(a) a mysterious field described as general regulation of trade throughout the whole

country, specific applications of which are hard to locate,

(b) international trade and commerce,

(c) interprovincial trade and commerce, subject to uncertain limitations,

(d) trade and commerce under other heads of jurisdiction assigned to Parliament by specific provisions of section 91 of the Constitution Acts.

(e) ancillary matters and matters of control essential for the purpose of achieving the primary regulatory purposes.

Trade and commerce can also be regulated under the residual federal power in two situations,

(i) in a vague area of operations in which the national interest predominates and provincial legislation cannot meet the requirements of the problems addressed, as in such matters as food and drugs (otherwise than under crminal law), air traffic (also supported under the treaty power) radio and television, nuclear fission and some environmental concerns, extending also into other areas of operation such as some but not all biotechnological operations.

(ii) emergency situations, as when the Anti-Inflation Act was upheld, and possibly including emergencies of biological origin.

(iii) again, ancillary matters, as above.

6. An operation may be subject to a federal statute in one aspect and under a provincial statute in another. In Interprovincial Co-operatives v. The Queen (1975) 53 D.L.R. (3d) 321, (S.C.C.), certain provisions of a Manitoba statute relating to contamination in Ontario and Saskatchewan of rivers flowing into Manitoba were held to be ultra vires, because they purported to deprive persons who had discharged contaminants in the rivers in the upstream provinces of the defence of statutory authority under statutes of the upstream provincial legislatures. Only Parliament could enact such a statute. Conversely, the upstream provincial legislation could not give immunity from action brought in the downstream province. However Manitoba could otherwise legislate for effects of pollution of the rivers within the province.

Similarly, although the Clean Air Act, S.C. 1970-1-2 c.47, and the Canada Water Act, R.S.C. 1970 1970 (1st Sup.) C.5, have been enacted under the general power, since air and water cannot be confined within provincial boundaries, nevertheless The Environmental Protection Act, S.O. 1971, vol. 2 C. 86 was held to be intra vires in application to local air pollution. Similarly, the Pollution Control Act, R.S.B.C. 1967, c. 34 was held valid as applicable to a national harbour, because federal legislation had not "occupied" the field. However, a

municipal noise by-law and an air pollution by-law, otherwise valid, were held ultra vires as applicable to navigation and shipping.

The parallel operation of valid federal and valid provincial legislation governing the same activity may cause confusion. It is only when compliance with one necessitates contraventure of the other that the provincial legislation may be imperative to the extent of the inconsistency.

In enacting parallel legislation, two jurisdictions may set different standards. One may be more stringent than the other. Different procedures may be required for ensuring compliance with each. Such duplication is undesirable.

At the same time, the boundary between federal and provincial jurisdictions is uncertain and it may seem necessary to enact overlapping legislation in order to ensure that no gaps are left.

7. T.F. Schrecker, in a study paper, "Political Economy of Environmental Hazards", written this year for the Law Reform Commission of Canada, criticizes existing canadian legislation and administration among other defects, its secrecy and inadequate provision for public participation. The recent growth of public interest organizations and community groups concerned with environmental protection, will make provision for public hearings and public

participation a major issue in the movement for regulation of biotechnological operations. Judicialization of procedures will add to delay and expense in regulatory proceedings. Efforts to avoid this development may be unsuccessful for both political and constitutional reasons.

8. Both federal and provincial legislation may now be inoperative to the extent that it contravenes the Canadian Charter of Rights and Freedoms. Whether for this reason or another, all regulatory legislation and administration must satisfy at least the minimum requirement of natural justice described as fairness, and must to that extent at least be subject to judicial review. Expensive and time-consuming procedures may be inevitable.

9. The study paper distinguishes between harm that may result from accidental escape of biological organisms or substances into the environment from harm that may be caused by their purposeful use. Escape may occur in the work place, either accidentally or where a dangerous practice is deliberately followed in the belief that the work cannot otherwise be carried on a will otherwise be too costly. This possibility is contemplated in the Canada Labour Code where c. 997 forbids an employer to use in its operations a substance that is dangerous to safety or health of workers if it is reasonably practicable to use a substance that is not dangerous. If it is necessary to use a dangerous substance, and two or more such substances are available, the least dangerous one is to be used to the extent that is reasonably practicable. This is a rather

cold-blooded imposition of risk on workers.

Even when no such risk is deliberately run and standards of containment are prescribed in order to prevent escape of hazardous organisms or substances, as we found in preparing the Medical Research Council's Guidelines for Research into Recombinant DNA Molecules, Certain Animal Viruses and Cells, and as I have learned as a member of a university biohazards committee, it is practically impossible to ensure that absolutely no escape can occur, short of making the research or other operation impracticable. A balance must be struck, having regard to the perceived seriousness of the harm perceived as possibly resulting from escape. Such a balancing is extremely difficult where any life form and particularly a new life form may escape, since the direct effects may be conjectural or hypothetical in foresight but real in experience and indirect effects are even more difficult to anticipate.

It may be a cynical observation but my experience and my studies suggest that safety precautions usually have two characteristics. The first is that hindsight shows that they were inadequate. The second is that they are not observed. Continued compliance without incident tends to encourage skimping of performance and finally to omission of routine procedures.

10. Escape in the workplace can lead to escape into the outer environment. In either case, the quantity involved can affect the degree of risk. The MRC Guidelines were designed for quantities not exceeding 10 litres. Some industrial fermenters hold 100,000 litres. There may be an economic disincentive to using disabled strains in host-vector systems in recombinant DNA work. The chemistry of a proved and licensed fermentation process can alter in espouse to naturally occuring genotypic and phenotypic changes in the culture. Viruses can similarly change. Enhancement of virulence by phage traduction is a possibility. Fermenters can become contaminated by foreign substances. Enzyme based products may be contaminated by the enzyme. Various processes can release airborne particles. Long range airborne or water borne transmission of organisms may introduce exotic populations that upset the balance of nature. Continuous low-level discharge of antibiotics may promote selection by survival of resistant organisms. All these and other hazards are more dangerous on an industrial scale than on a laboratory scale.

The Canada Labour Code contemplates these possibilities and requires that a dangerous substance that may be carried by air be kept as close as is reasonably practicable to its source. Escape is simply accepted.

11. In addition, the Guidelines do not deal with plant viruses, some animal viruses, bacteria, fungi and many other organisms and organic substances. Much biotechnological research and many biotechnological operations are carried on with organic substances not covered by the Guidelines. Their existence thus creates a false sense of security. Except to the extent that they must be complied with by recipients of grants from funding agencies or have been adopted by government organizations, compliance is voluntary. Although it is understood that existing biotechnological entrepreneurs and voluntarily comply with them, they are, as we have seen, not necessarily adequate for work on the scale employed.

12. The study paper comments on certain statutes of Canada and Ontario that provide existing controls.

Although the Environmental Contaminants Act is now expressly confined to inanimate matter, Environment Canada is about to undertake a review of issues arising out of expansion of biotechnological operations and will probably propose amendments seen as appropriate.

While the federal Envirnmental Assessment and Review Procedure lacks direct statutory authority, in the sense that it is authorized by order-in-council, the Government Organization Act gives the Minister of Environment power to establish and operate environmental assessment processes that impinge on the authority and activities of

other government departments. Federal departments and agencies are bound by the process, except proprietary Crown corporations and federal regulatory agencies, which are invited to participate. Eldorado has done so on two occasions. Lessees and licensees of federal crown lands or coastal waters, as well as grantees of federal funds are subject to appraisal. One weakness may lie in the self-assessment approach. Although screening guidelines have been developed, it is possible that the initiator of a project may decide in error, without consultation, that appraisal is not necessary. There is at present no review of such a decision. However, once the process commences, it seems to be thorough. Public participation is encouraged. Although some lawyers object to the absence of some judicial features, the essential elements of adversarial procedure seem to be provided for hearings.

The Federal Environmental Review Office publishes guidelines and or guide to its process. It has also published several very detailed reports.

It appears that this process could furnish the basis for a general environmental impact appraisal procedure under a federal statute. Criticisms in detail would, of course, be considered.

13. I have begun a survey of provincial legislation and have asked provincial departments for information. Several have reviewed their legislation and are satisfied that it is adequate for problems they foresee as arising from biotechnological operations. Others are undertaking

such review and will introduce new provisions if any are found necessary. Several have indicated that advice would be appreciated. I am still receiving replies. It is too early for me to say much about this legislation.

The Ontario Environmental Protection Act has been criticized for both its provisions and its administration. Many undertakings of the provincial government and other public agencies and many private enterprises are exempt from assessment. The Minister may also grant exemption from assessment in his discretion. Complaints are heard that too many exemptions are granted. If exemption is not granted, he has discretion to determine what notice is given to the public and what individuals and organizations are to receive notice. In considering an assessment he decides in his discretion whether a hearing shall be held, unless a person or organization that has learned of the proposal demands a hearing. Unless he considers the request to be frivolous, he must order a hearing but the Board may hold it in public or in camera in its discretion. All these discretions arouse the frustration of public interest organizations and neighbourhood groups and T.F. Schrecker.

14. The difficulties encountered in Ontario in reaching satisfactory means of disposal of chemical and radioactive waste illustrate some of the problems to be faced by regulatory agencies in this context. Pressures are brought

from all sides through political influence, and neighbourhood and public opinion, while procedural problems, legal issues and court hearings throw up obstacles to decision. Meanwhile, entrepreneurs complain about delay and expense.

These pressures lead to an apparent lack of political will and firm hand in the administration of the Act that has furnished one of the grounds of T.F. Schrecker's criticism of canadian environmental protection regimes. Legislation in the field is only as good as its enforcement.

15. British Columbia has adopted an Environment Management Act in 1981 and a Waste Management Act in 1982. The former Act authorizes the Minister of Environment to order environmental impact studies, issue environmental protection orders and order envirnmental emergency measures. The latter Act provides an apparently comprehensive regime for management of all kinds of waste. It remains to be seen how these statutes work out in practice. Both could apply to biological hazards. However, the Environment Management Act does not operate until the Minister makes an order and then only to the extent of the order.

16. All controls in Britain of all work involving recombinant DNA and pathogens or potential pathogens are under a common statutory scheme with respect to safety in both the work place and the outer environment. The controls are

administered on a case-by-case method. Worthy of note is the association of representatives of industrial employees, employers and the universities, along with members representing the public interest, in the groups responsible for classification and approval of individual projects and determining conditions of containment. This structure appears to offer potential advantages and might furnish an example for Canadian agencies of control. The committees that work on the MRC Guidelines considered the British method of appraisal and preferred the setting of standads for different categories of research. However, the case-by-case approach might be appropriate as at least introducing an element of flexibility in an environmental impact appraisal process.

17. Controls of industrial operations in the United States, as in Canada, are found in a number of federal and state statutes. Two important federal statutes are National Environmental Policy Act, U.S. Code Title 42 chap. 55 and Toxic Substances Control Act, U.S. Code Title 15 chap. 53. Guidelines for research with recombinant DNA are promulgated by a government agency, the National Institutes of Health, but, as in Canada, have mandatory effect only on work by federal governments institutions and recipients of federal government grants. Unlike the Canadian Guidelines,

the NIH Guidelines deal only with recombinant-DNA research in much greater detail than their canadian counterpart. Also unlike the canadian Guidelines, the NIH Guidelines contain Part VI related to voluntary compliance by industrialists with their requirements for containment. It is said that such compliance is general, and until recently it may have been complete. Canadian researchers with recombinant-DNA who receive United States federal grants are required to comply with NIH Guidelines. The two schemes do not exactly correspond but there is a rough approximation between them in most respects.

18. A remarkable feature of United States legislation is the eloquent declaration of national environmental policy in section 4331 of the National Environmental Policy Act. Under section 4332 of that Act, the policy is to govern interpretation and administration of all federal legislation and action that may affect the environment. It would be helpful if the Parliament of Canada and each canadian provincial legislature made a similar declaration.

That section also requires a detailed environmental impact statement to be part of every recommendation or report on proposals and other major federal actions significantly affecting the quality of the human environment. Before making the statement the responsible federal official is required to consult widely. Copies of the statement and all relevant material must be made available to the public as well as the President and other officials. Public participation and effective interventions are anticipated

and provided for.

Title II of this Act creates a Council on Environmental Quality with extensively defined powers, and duties, including research, and funds. This is a very active body.

19. United States legislation in this area is highly structured and embodies an adversarially judicialized procedure, with important public contribution. This pattern is illustrated in part by sections 2614 to 2623 of the Toxic Substance Control Act. Each statute has generated a flood of ligation.

The requirement of an environmental impact statement has teeth, as illustrated by the decision of Judge Sirica of the Federal District Court for the District of Columbia, delivered on May 16, 1984, in an action brought by a public interest agency named Foundation of Economic Trends, and others, against the Directors of Federal Health and Human Services and the NIH, and others, all responsible for supervision of scientific research conducted or funded by NIH. The Regents of the University of California were added as defendants. NIH had made a grant to the university for research with a genetically altered strain of bacteria which, it was hoped, could be applied to potato plants and improve their tolerance of frost. Having created the bacteria in the lab, the university asked NIH for approval of applying them to a row of potatoes in northern California. The application was approved without the environmental impact statement or assessment required by NEPA. The

plaintiffs sought an injunction forbidding the giving of approval or acting on it, until such a statement was produced and dealt with as required by section 4332 (1)(C). In a long, closely reasoned decision, Judge Sirica granted an interim injunction until trial or compliance with section 4332 (1)(C), accepting the plaintiffs' contention that the granting of approval was "major federal action" authorizing a significant impact on the environment in the release of a substance creating a low but real risk of substantial harm to the environment. This decision was upheld by the U.S. District Court of Appeal, D.C., on May 25, 1984. Ironically, it appears from a report in Nature on October 13, 1983 that field trials with a similarly altered strain of bacteria had been conducted during three previous years and it was believe that no environmental hazard had appeared.

20. Much may be said for and against this case as an example for canadian practice. Something seems to have gone out of balance when an experiment on a row of potatoes goes to an federal appellate court. On the other hand, perhaps the principle of application of an objective standard of appraisal of significant environmental impact justifies the proceedings.

21. The scheme of control outlined in the study paper has considerable merit. Establishment of national standards is clearly desirable. Uniformity of application of standards seems to require that they be applied by one agency. Moreover, it will probably be easier for the necessary body of experts to be brought together in one place than in ten places. Federal jurisdiction for these functions is not absolutely certain but seems probable.

Against these favourable factors may be the imposition of delay if the number of applications exceeds the capacity of the central agency for processing them.

In addition, there seems to be a duplication of controls and controlling agencies. Requirement of provincial licensing and permits following federal appraisal seems to add to bureaucratic power to impose delay and frustration. Adding conditions on release to those already imposed seems like gilding the lily.

Provincial supervision of qualification would be feasible but national standards should be established.

In general if it is possible to impose controls effectively by regulation, inspection and enforcement, it is not desirable to add a system of licenses or permits.

H.R.S. Ryan

THE REGULATION OF BIOTECHNOLOGY

October 9, 1984

REGULATION OF BIOTECHNOLOGY

DEPARTMENT OF ENVIRONMENT RESPONSE

Mr. R.J. Herring
Assistant Deputy Minister
Canadian Forestry Service

REGULATION OF BIOTECHNOLOGY

DEPARTMENT OF ENVIRONMENT RESPONSE

The paper presented by the Research foundation is a timely and helpful stimulus to a debate of the issues involved in regulation of Biotechnology. The writers of the study point out that the scheme suggested is but one of a number which could be devised, and the elements proposed may be expected to elicit discussion, which is the purpose of this conference.

The Department of the Environment approaches biotechnology from three different perspectives. This tripartite approach includes a legislative dimension, a technological dimension, and a socio economic dimension. The department supports and carries out research on microbial methods of waste treatment which are means of dealing with intractable pollutants. The use of biotechnological approaches, including recombinant DNA technology could greatly enhance and accelerate this research. The Canadian Forestry Service, until lately part of Environment, also has a very active research program in the development of biological pesticides, nitrogen fixation and plant strain development, to which biotechnology can contribute much.

The Ministry of the Environment also administers laws which are or could be relevant to the regulation of biotechnology in Canada. These laws include The Environmental Contaminants Act, The Canada Water Act, The Clean Air Act, Section 33 of The Fisheries Act, and The Ocean Dumping Control Act. The Department is also involved in the administration of The Pest Control Products Act, The Transportation of Dangerous Goods Act and The Canada Labour Act, among others.

The department is represented on the Interdepartmental Committee on Biotechnology, and participates in the networks of researchers and industrial interests which were established to encourage the development of priority areas of biotechnological research in Canada (These include mineral leaching, cellulose utilization and waste treatment, Plant strain development and nitrogen fixation and health care and pharmaceutical products).

The Department is also involved in assessing regulatory approaches a the international level, with the OECD Committee on Safety and Regulation in Biotechnology. The committee is currently seeking information about the regulatory regimes in member countries, and, under the overall direction of the Ministry of State for Science and Technology, the Department of the Environment will be coordinating the responses of the Federal agencies.

The department has been developing its interest and concern in this area over several years, and a discussion paper on the environmental implications of biotechnology is being prepared within the Environmental Protection Service. This paper examines the development forecast for biotechnology, the potential for environmental disruption accruing from this development by sector, the legislative dimension, technical dimension, and socio/economic dimension of biotechnology in Canada. It will also suggest a series of recommendations to address Departmental concerns in this triad.

The areas of environmental concern within those sectors where commercial application of biotechnology is likely to occur appear to include Agri/food, Forestry, Pharmaceuticals, Chemicals, Pollution Control, Mining and Energy.

Concerns include both the areas in which development of biotechnological approaches are likely and the potential environmental hazards which can be associated with the developments. It is the intention of the Department of the Environment to anticipate the scope and nature of the impacts so that environmental protection can be maximized. Advocacy routes to environmental protection must be included in Environment Canada's approach, such as lobbying and liaison with other agencies to influence relevant decisions made by them, and to build awareness among the public and decision-makers at all levels. It is clear that regulatory routes must also be used, so that potential products can be safely released to the environment. Although we have not assessed our legislation in terms of its effectiveness in dealing with developments in biotechnology, preliminary indications from analogous work undertaken elsewhere suggests that in responding effectively to environmental risks of biotechnology a regulatory scheme must have several basic attributes.

i) it must apply to the creation, use, and release of living organisms, microorganisms, plants and animals.

ii) it must require a prior assessment of the risk of use and releases by a group with the expertise to understand these uses

iii) it must provide the authority to block or regulate the use of products of bioengineering where necessary to protect public health and the environment.

iv) biotechnology control laws should include authority to clean up released materials that pose health a environmental risks, and perhaps, since the threats are hard to predict, and may not be realized for decades, should include a mechanism to compensate for damages that cannot be abated (McChesney, F., and Adler, R.G., "Biotechnology Released From the Lab: The Environmental Regulatory Framework", Environmental Law Reporter, 13 ELR, 10366-10380. Nov. 1983.

Genetically engineered products may include not only those produced by recombinant DNA, but the products of cell fusion, transformation and organisms treated with mutagens, and all should be covered by legislation.

The issue of environmental risk from genetically-engineered organisms has only begun to be assessed. The concern is that they will become established in the environment, and thereby cause ecological damage by competing with organisms already present. In order to legislate for control of biotechnology, it is necessary to develop techniques for assessment of ecological risk. The comparison made in the Research Foundation paper between the release of 'novel' life-forms created by biotechnological means, and the introduction of exotic organisms into a new environment is a valid one. The ecological literature provides few examples of the documentation of how many organisms fail to establish themselves in a new biological assemblage. Only successes are noted, but it is probable that they represent a low proportion of arriving species. It is not yet possible to quantify the probability of an introduced organism, from whatever source, establishing itself and causing ecological disturbance, on historical grounds.

The data that we have on the development and spread of genotypes which confer resistance to an antibiotic or a pesticide are also relevant to this issue. The introduction of an antibiotic or pesticide to a population is analogous to genetic engineering in that a human activity causes a rapid change in the frequency of a particular genotype in the population, often over large areas. Resistance to the newly applied selective factor does not usually exhibit itself in a change in the

behaviour or appearance of an individual capable of surviving. The commonest mechanisms of resistance involve a difference in one gene only, which may affect the structure of an enzyme, or the permeability of a membrane. Thus it may be inferred that a biotechnologically modified organism would not have to differ greatly from members of the wild population in order to have a competitive advantage. A small change may have an impact which could not be anticipated. In natural populations, several resistance mechanisms allowing survival under pressure from one pesticide may be found. Breeding among survivors which have different mechanisms of resistance can increase resistance in the population multiplicatively not just additively. It may be assumed that biotechnologically altered organisms might interact in the same way.

In bacteria, the genes controlling resistance to antibiotics are often found on extra-chromosomal genetic elements called plasmids. Bacteria seem to be able to transmit plasmid-borne genes between species and genera. It may thus be very difficult to keep inserted genes isolated in single bacterial strains.

The authors of the study point out that the proposed regulatory scheme is but one of a number which could be devised. With this caveat I am in full agreement. The application of biotechnology from an environmental impact perspective remains to be precisely identified. The potential complexity of the impacts will require considerable cooperative assessment. CELA has identified the major elements which would be required for the application of biotechnology to minimize environmental impacts, and the proposed regulatory scheme presents the opportunity to address these concerns within a federal-provincial co-operative framework. This is essential since the application of biotechnology cannot be regulated except interjurisdictionally.

The most cost-effective, efficient, and safest approach to satisfy the requirements of government, industry and the public requires that discussion and consultation be as full as possible, to achieve the best cooperation and joint administration possible.

The Department of the Environment, addressing as it does the environmental concerns of the public in relation to all environmental hazards, has a formalized policy for public consultation and information availability. The policy provides a systematic framework for consultative activities, in the form of an annual meeting. It is designed to encourage an exchange of ideas, and aims at generating an ongoing dialogue which, it is hoped, is characterized by a spirit of openness among departmental officials, industry and members of the general public. This serves the department in providing it with the best possible overview on the environmental issues and concerns and promotes by this means the formulation of better policies, programs and regulations. The annual meetings are well-publicized in advance by mailing lists and media.

Regulatory initiatives are also publicized in a departmental publication called "Environmental Update" which provides an opportunity to gauge whether or not the public views the regulatory initiative to be of a significance to warrant formal consultation procedures. Informal dialogue is also used to assist in this determination. In both cases the rationale of the department in selecting a particular regulatory option is fully explained, together with the reasons why other options were deemed less suitable.

The public is not always well-served by the educational system in its need to become familiar with the nature of the hazards which may be developing. It is necessary that the scientific community, perhaps especially that part of the scientific community within the Federal Government, should take a leadership role in explaining the new technologies to the concerned public. Unless it undertakes this responsibility the scientific community cannot expect to allay groundless fears and place hazards in perspective.

The consultation policy in general, while assuring broad public commentary on any proposed regulatory initiative recognizes the need for full consultation with affected industries. This priority is especially applicable in the field of Biotechnology. The state of biotechnological development in Canada at the present time is that of a cottage industry, in comparison with developments in other countries. In formulation of appropriate legislation, it must be recognized that the federal government needs to address, from the most preliminary stage onwards, the relationship between Canadian biotechnological industries and potential international trade. Technology and products will both be transferred internationally and interprovincially. The legislation adopted must reflect both national and international concerns and obligations. In addition the legislative schemes of Canada's trading partners must be reviewed and analysed carefully, since they will affect potential Canadian importation and exportation activities. The potential of biotechnology demands a wide approach.

The legislation administered by Environment Canada, as already noted, includes control of the movement of products interprovincially and internationally, and the disposal of residual and waste products. These are also aspects of biotechnological industries which will have to be addressed in future legislation.

In summary, therefore, it must be emphasized that the regulation of biotechnology in Canada will involve long and extensive discussions between levels of government, industry and members of the public and many avenues will have to be explored in order to design the most effective regime.

The department of the environment has always had, and will continue to have, a complete willingness to meet with any regulatory body or any non-governmental organization to discuss issues of environmental concern in the area of biotechnology, as indeed is the case with all environmental pollution problems.

THE REGULATION OF BIOTECHNOLOGY

October 9, 1984

COMMENTS ON CELRF DISCUSSION PAPER:

"BIOTECHNOLOGY AND THE ENVIRONMENT:

A REGULATORY PROPOSAL"

Mr. Alan G. Bates,
President,
Allelix Inc.

COMMENTS ON CELRF DISCUSSION PAPER: "BIOTECHNOLOGY AND THE ENVIRONMENT: A REGULATORY PROPOSAL"

by Alan G. Bates, President, Allelix Inc.

GENERAL

Allelix, as a significant industrial participant in the field of biotechnology, strongly believes that biological organisms intended for use in the environment should be regulated at both research and commercial application stages. We further believe that the regulatory process should:

- entail a sound scientific evaluation of potential hazards based on guidelines established at the federal level;
- be flexible enough to reflect varying degrees of risk for different types of new life forms, so the time and cost required to develop data will not place impossible burdens on the applicant;
- involve a regulatory mechanism that will be immune to outside environmentalist or political pressures unless those pressures are supported by scientific evidence and not speculative fears;
- require a simultaneous assessment of benefits which will derive from proposed outside trials or commercial introduction of new life forms in the environment (more about this next).

BENEFITS

The CELRF review paper presents a useful overview of the inadequacy of current legislation to regulate new life forms in the environment. The bulk of the text sets forth a regulatory approach which I'll comment on later. As a proponent of biotechnology, I feel the greatest deficiency in the paper is the lack of any significant recognition of the benefits to be derived from the use of new life forms in areas such as agriculture, pollution control, minerals recovery, etc. In any area of new product development, there is bound to be some element of potential risk. The development of the video screen for TV and computer applications brought the risk of a certain degree of radiation exposure. Nearly all new drugs have side effects so some patients are at risk from adverse reactions. One could go on and develop a risk scenario for essentially every technological advancement. Yet the risks are always explicitly or implicitly weighed against the benefits in reaching a decision on whether society would be better or worse off if the product were introduced.

In the regulatory approach proposed in this paper, the total emphasis is on evaluating the potential hazards. Since a case can almost always be made for a certain degree of risk being associated with any new product, no matter how small the risk or its consequences, the totally safe course would be to reject most if not all applications. I believe the only objective and rational way to assess the environmental use of new life forms is to weigh the benefits against the risks. This aspect should be incorporated in any regulatory process.

REGULATORY BODY

The discussion paper recommends that a completely new regulatory commission be established at the Federal level. I question whether another layer or agency of government is needed or justified. I recognize that special considerations are involved with living organisms and that it would not be practical to develop all the necessary expertise required to evaluate potential risk within every department which might be concerned. Therefore, an alternative to the proposed commission would be to establish a scientific risk assessment unit within an existing department.

Since the great majority of new life forms used in the outside environment will be for the benefit of agriculture, the government department most heavily involved will be Agriculture Canada. Perhaps, therefore, the scientific risk assessment unit should be contained within that department. Other government departments having regulatory authority for different types of uses, such as pollution control or mining, would have full access to the risk assessment unit, even though it was administered within another department.

My argument here is to place the risk assessment unit in an existing government department where it would fit logically and avoid setting up an entirely new commission.

The final decision on whether to grant permission for tests or commercial introduction of new life forms would lie with the department having such responsibility under existing legislation. The scientific risk assessment unit would submit their risk analysis to the department involved which, in turn, would weigh benefits against risks and either grant or deny registration or request additional data.

A key responsibility of the risk assessment unit would be to develop guidelines for data required to evaluate potential environmental hazards. These guidelines should be flexible and be tailored to the nature of the new life form involved, the extent of its genetic alteration and the proposed use.

TECHNICAL REVIEW

The discussion paper recommends that technical reviews of proposed environmental tests or applications of new life forms be carried out by "ad hoc technical panels" made up of outside experts. I feel that this system could slow down the review process and delay the introduction of worthwhile new products. A preferred approach would be to staff the risk assessment unit with a core group of scientists and technical experts who could deal with the majority of issues related to risk. In cases where especially difficult questions are apparent, one or more experts could be called in on a consulting basis.

This would allow each application to be dealt with in a timely way rather than waiting for an ad hoc panel to convene - which would not be very often if composed of outside specialists who have other responsibilities.

CONCLUSION

In conclusion, I believe that new life forms proposed for testing or commercial use in the environment should be regulated at the Federal level. The review process should be objective and weigh benefits against risks. The risk assessment should be conducted by a team of full-time technical experts within an existing department of government. They would call in specialist consultants as required. The risk assessment unit would develop guidelines for data requirements and tailor information needs to the nature of the new life form and its proposed use. Final decisions on testing or commercial use would be made by the department having approval authority under existing legislation after considering both benefits and inputs from the scientific risk assessment unit.

September 27, 1984

AGB/CELRF

INTRODUCTION TO

THE CANADIAN ENVIRONMENTAL

LAW RESEARCH FOUNDATION

BACKGROUND INFORMATION

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 focus of the Foundation's research activities is the threat posed by toxic chemicals in our society. The Foundation carries out research in the environmental law and policy areas related to this 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., 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.

The Foundation is currently working jointly with the Environmental Law Institute of Washington D.C., on a study of legal reforms required in Canada and

the United States to better control the long range transport of toxics and oxidants. The Foundation is also engaged in a study of legal mechanisms for controlling toxic chemical contamination in Ontario and is presently in the opening stages of a major study of cross-border intervention, both with respect to court actions and participation in administrative hearings, in transboundary pollution cases.

The Foundation has recently initiated a short study of the implications for environmental protection of entrenchment of property rights in the Canadian Charter. Work has now commenced on a study of the environmental assessment process in Ontario. The Foundation is also engaged in a major study of legal reforms required to facilitate citizen intervention across the Canada - U.S. border in transboundary pollution cases.

Other projects still in the planning stages include production of a regular radio series on environmental issues, to be done jointly with the Federation of Ontario Naturalists, and the publication of a revised and updated version of Environment on Trial.

Each year the Foundation plays host to a major conference on a particular aspect of environmental regulation in Canada. The subject of the 1983 conference was "Hazardous Substances and the Right to Know". This was a one-day discussion of the tension between growing pressures between access to information with respect to the chemical composition of hazardous substances and the desire on the part of industry to maintain the confidentiality of proprietary information. Two such conferences will be held in 1984. In September the Foundation will present a discussion of the regulation of biotechnology and in November will host a conference on the environmental implications of Canadian aid to overseas development projects.

In March, 1984, the Foundation held a one-day seminar titled Uncertain Science in Law and Regulation. This provided an opportunity for discussion amongst scientists lawyers and policy-makers of the problems inherent in using complex and uncertain scientific information respecting toxic substances in the regulatory and legal processes.

CURRENT ACTIVITIES

CURRENT ACTIVITIES REPORT

FALL 1984

RESEARCH PROGRAM

RECENTLY COMPLETED:

Breaking the Barriers

Done jointly with the Pollution Probe Foundation, a study of select actions which can be taken by governments at all levels in Canada to facilitate increased reduction and recycling of industrial waste.

An Environmental Bill of Rights

Done under contract for Environment Canada, this report provides analysis of all the potential elements of an environmental bill of rights at the federal level and sets forth steps to be followed in working toward the adoption of such a bill.

IN PROGRESS:

Toxic and oxidant transboundary air pollution

This study, done jointly with the Environmental Law Institute of Washington, D.C., will be completed by December 31, 1984 and published in early 1985. A workshop to discuss the draft conclusions and recommendations of the study will be held in Toronto on October 31, 1984.

Cross-border litigation

Work on this study is being carried out both by Foundation staff and American researchers working on contract with the Foundation. An article based on research done to date will appear in the fall issue of Alternatives magazine.

Legal mechanisms for control of toxic contamination

This study is now in its final stages, which consist of detailed examination of judgements, pleadings and court transcripts of toxics law cases.

Environmental assessment in Ontario

Student researchers have now completed a detailed examination of a select number of environmental assessments carried out over the past decade. The two project directors, Dr. Robert Gibson of the University of Waterloo and Dr. Beth Savan of the University of Toronto have commenced work on initial drafts and expect to present their findings at a series of workshops to be held in January and February of 1985.

Future trends in legislation governing industrial waste

This study, done under contract for the Ontario Waste Management Corporation, is intended to assist in determining the quantities of special waste which will require processing by OWMC.

IN PLANNING:

The Ontario Municipal Board and environmental protection

An examination of the role played by the OMB and the relationship between land-use planning and environmental protection in Ontario.

An environmental radio series

With the Federation of Ontario Naturalists, the Foundation is considering the feasibility of production of a regular weekly radio series on environmental isses.

Uncertain science and the media

To be done under contract for the Department of Supply and Services, this project will consist of an examination of the way in which the media has presented complex and uncertain scientific information respecting toxic substances and will look for ways to improve communications between scientists and media professionals.

CONFERENCE/SEMINAR PROGRAM

RECENTLY COMPLETED:

- June 27, 1984 - seminar on environmental law for corporate supporters of the Foundation
- July 12, 1984 - seminar for waste management professionals to discuss the findings of Breaking the Barriers
- August 1, 1984 - jointly with the Canadian Environmental Law Association, a seminar on environmental mediation

- October 9, 1984 - a one-day conference on the regulation of biotechnology: papers presented covered topics such as the benefits and environmental hazards associated with biotechnology and regulatory approaches adopted in Great Britain and the United States; a discussion paper prepared by the Research Foundation, was presented, followed by comment from representatives of industry, government and academe; guest speaker was Mr. Jeremy Rifkin, proceedings are available at a cost of $85.00

IN PLANNING:

- October 31, 1984 - jointly with the Environmental Law Institute, a workshop to present the draft findings of the transboundary air pollution study
- 1985 - jointly with the Law Reform Commision and Canadian Environmental Law Association, a Roundtable Discussion of Pesticides Law and Policy
- 1985 - a one or two-day conference on the environmental implications of development projects, carried out with Canadian financial assistance, in the third world

PUBLISHING PROGRAM

Canadian Environmental Law Reports

Canada's only environmental law reporter, published six times a year, available at an annual cost of $55.00.

Canadian Environmental Law Reports Cumulative Index

an index to all cases reported since publication commenced in 1972; available for $35

IN PLANNING

Environment on Trial

third, revised and updated edition

For more information on any of the activities listed here please contact Mr. Doug Macdonald, Executive Director, or Ms. Marcia Valiante, Director of Research, at (416) 977-2410.

October 22, 1984

CURRICULA VITAE

Executive Director	-	Doug Macdonald
Director of Research	-	Marcia Valiante
Research Associate	-	Paul Muldoon

DOUGLAS CHARLES MACDONALD

Born: June 23, 1947

Office: 366-9717
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Toronto, Ontario

WORK EXPERIENCE

Oct. 1982 - present:	Executive Director Canadian Environmental Law Research Foundation
Sept. 1980 - Oct. 1982:	Special Assistant to Mayor Lastman Mayor of the City of North York
Oct. 1978 - Oct. 1980:	Secretary The Agora Foundation
July 1976 - July 1977:	Executive Assistant to Mayor Lastman
May 1974 - June 1976:	Research Assistant to Mayor Lastman

EDUCATION

M.A., Canadian History, University of Toronto

Completed first year of Phd. program, Canadian History, U. of T.

VOLUNTEER EXPERIENCE

- three terms a member of the Board of Directors of the Bain Apartments Co-operative, a 260 unit housing co-operative
- member of the Bain Co-op Refinancing Committee
- member Board of Directors and Board of Governors, Canadian Coalition on Acid Rain
- Secretary, Board of Directors, Canadian Environmental Law Association

PUBLICATIONS

- AGORA, the newsletter of the Agora Foundation: No. 1, Vols. I - IV

- "Shutdowns"; Perception Magazine, periodical of the Canadian Council on Social Development, Jan./Feb., 1981

  (discussion of the impact of plant closures in Ontario)

- "Where Does the Buck Stop?" Policy Options, periodical of the Institute for Research on Public Policy, Nov./Dec., 1981

  (examination of hazardous waste disposal in Ontario)

- "Out from Under"; Quest Magazine, November, 1982

  (proposal for reforming local government in Metropolitan Toronto)

- Radio program on quality of Toronto drinking water; to be broadcast by CJRT-FM, fall, 1984

- Managing Editor, Canadian Environmental Law Reports

Curriculum Vitae

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Status: Canadian Landed Immigrant
United States Citizen

EXPERIENCE

October 1983 to date — CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION, Toronto. Director of Research

Primary responsibilities include scientific and legal research and writing for the project entitled "Transboundary Toxic and Oxidant Air Pollution", done jointly with the Environmental Law Institute, Washington, D.C.; supervision of a number of other research initiatives of the Foundation.

August 1982 to August 1983 — CANADIAN ENVIRONMENTAL LAW ASSOCIATION, Toronto. Articling Student. Duties included legal research, preparation of legal memoranda, preparation for and attendance at administrative hearings.

EDUCATION

September 1979 to June 1982 — OSGOODE HALL LAW SCHOOL, Toronto, Ontario

Degree: LL.B.

Honours: Kenneth Gibson Morden Memorial Prize

February 1973 to December 1977 — UNIVERSITY OF NEW HAMPSHIRE, Durham, New Hampshire.

Degrees: B.S.C. (Environmental Conservation)
B.A. (Political Science)

Honours: Magna Cum Laude
Member, National Social Science Honour Society; Member, National Political Science Honour Society; Dean's List (every semester)

PUBLICATIONS

- Editor, Canadian Environmental Law Reports

- "Energy in Canadian-American Relations" and

- "Of Oil and Gas: A Primer on the Role of Oil and Gas in Canadian-American Relations"

  both in Journal of Natural Resource Management and Interdisciplinary Studies (University of Manitoba) Vol. III, No. 1 (March, 1978).

- Brief submitted on behalf of the Canadian Environmental Law Research Foundation and Canadian Environmental Law Association to the Royal Commission on the Economic Union and Development Prospects for Canada

- Brief, entitled "Nitrogen Oxides Emissions from Motor Vehicles as a contributor of Oxidant Air Pollution", submitted to the Sub-committee on Acid Rain of the House of Commons Standing Committee on Fisheries and Forestry on behalf of the Canadian Environmental Law Research Foundation.

CURRICULUM VITAE

NAME: Paul Robert M. Muldoon, Hons. B.A., LL.B., M.A. LL.M.

DATE OF BIRTH: May, 1956

MARITAL STATUS: Single

EMPLOYMENT:

April 1984 to Present: Research Associate
Canadian Environmental Law Research Foundation

1983
(Fall Term) Lecturer for course in Environmental Law at McGill University, Montreal, Quebec.

1981-1982 Articling Student with law firm of Agro, Zaffiro, Parente, Orzel, Hubar & Baker in Hamilton, Ontario

Duties included:

- research and drafting memos of law and pleadings
- preparation of cases for trial and assisting senior members of the firm during the trial
- handling own files in summary conviction offences, family law matters, administrative tribunals and small claims court

1981 Research Assistant - Parliament Hill

Employed on a contractual basis to do research for Members of Parliament in Ottawa. The research was directed to study the social, economic and legal implications of proposed legislation. The committees which I was involved with were:

- Special Committee on the Disabled and Handicapped
- Sub-Committee on the International Year of the Child
- Standing Committee on National Resources and Public Works
- Standing Committee National Health and Welfare

Summer Positions

1980 Employed by the Judicial District of Hamilton-Wentworth, Provincial Court (Criminal Division) in the capacity of relief clerk as well as other various administative duties.

1979 Employed by the Public Relations Department of the Hamilton Harbour Commission

1978 Project Manager, "Hamilton Awareness Project"
Hamilton Harbour Commission

1977 Project Manager, "Arts '77" Hamilton and Region Arts Council

EDUCATION:

Bar Admission Course
Law Society of Upper Canada (Ottawa) 1983 - 1984
Called to the Bar of Ontario on April 10, 1984

McGill University (Institute of Comparative Law) 1984
LL.M. (Masters of Law)
Specializations: Environmental and International Law

McMaster University Degree awarded in 1983
M.A. (Political Science)
Thesis: "The International Joint Commission and Point Roberts: A Venture into a New Area of Concern"

University of Ottawa 1978 - 1981
LL.B., Faculty of Law

1979- 1981:
. Member of the University of Ottawa Student Legal Aid Society
. Co-Editor of the Law School newspaper, Caveat

February, 1979:
. Selected to represent the University of Ottawa Faculty of Law in the Jessup Cup Moot Court Competition in Fredericton, New Brunswick

Wilfrid Laurier University 1974 - 1978
Honours B.A. (Political Science)

Awards:
. Wilfrid Laurier University "Gold Medal" for Academic Achievement
. Wilfrid Laurier University Proficiency Scholarship 1974 - 1977

ACADEMIC ACTIVITIES

1977 - 1978 Employed as Research Assistant to aid in the preparation of a number of articles published by or for the Department of Political Science.

Co-founder of Wilfrid Laurier University Political Science Association. This Association had an active membership of 170 students and was responsible for academic and social activities.

1976 - 1978 Appointed as Teaching Assistant for a second-year course.

Member of Senate Executive Committee
Chairman of the Student Caucus

1975 - 1977 Member of Wilfrid Laurier University Senate - Student Representative

1974 - 1978 Member of Political Science Council - Student Representative

STUDENT GOVERNMENT

1976 - 1977

Vice-President of Wilfrid Laurier University Students' Union Incorporated. This is an elected position with responsibilities for management of all office staff and business matters concerning the Corporation as well as all related legal matters.

The Vice-President was the Chairperson of:

- The Bylaw and Regulations Committee
- The Board of Directors
- Various Ad Hoc committees

The Corporation was responsible for all student-sponsored activities and appointments to all university administrative committees.