"Old Issues in New Life Forms"

A Submission on the

Government of Ontario Green Paper

Biotechnology in Ontario - Growing Safely

by

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1. INTRODUCTION

Biotechnology is a timely subject for policy-makers and the public owing to its potentially broad range of applications, its incredible growth as an industry, and for the lack of a better term, its mystique. It is essential that policy makers and the public think through the myriad of ethical, social, regulatory, policy and economic issues relating to biotechnology, now, before this new technology has come fully on stream.

The Canadian Institute for Environmental Law and Policy (CIELAP) congratulates the Government of Ontario for initiating this policy discussion on this very important subject and welcomes the opportunity to comment on the Green Paper - Biotechnology in Ontario - Growing Safely. [Hereinafter referred to as the "Green Paper".]

In this submission, the focus of discussion examines predominantly "process" issues - namely, what is the appropriate legal and policy framework to govern biotechnology in the province and what mechanisms should be in place to ensure that the public has a meaningful role in that framework. The submission, therefore, primarily relates to Section VII of the Green Paper - Possible Legal Frameworks for Ontario. Further, this submission focuses almost exclusively on regulatory and policy issues related to "open environment" releases of both products and wastes.

The thrust of this submission is that the Green Paper has

both failed to address a number of fundamental issues relating to biotechnology and has made a number of fundamental regulatory assumptions which are simplistic and inappropriate. The issues the Green Paper has failed to address include: a discussion of the ethical issues relating to the genetic engineering of all life forms; an examination of how biotechnology relates to the principle of sustainable development; an analysis of the long-term ecological consequences of biotechnology, especially those impacts pertaining to open environment releases; and an overview of an educational component to a biotechnology policy that will ensure that all the people of the province will have a basic understanding of the industry.

In addition, the Green Paper has made a number of questionable regulatory assumptions, and most important, that current controls for toxic chemicals are sufficient to regulate biotechnology. Inherent in this assumption is that controls for chemical risks are transferrable, appropriate, and sufficiently comprehensive to deal with biological risks arising from open environment releases of biotechnological products.

In our view, a biotechnology policy for Ontario must incorporate the fundamental principles entrenched in the concept of sustainable development - a concept which the province of Ontario has formally endorsed. When the concept is applied to the regulatory process, that process must ensure, at a minimum, that environmental factors are integrated with, and part of, other decisions affecting the industry, that a "prevent and

anticipate" approach is taken over a "react and cure" one, and that the public can effectively participate, both in terms of access and resources, in the environmental decision-making process. In essence, many of the themes discussed in this submission are not new or particular to biotechnology. Instead, they represent many existing regulatory problems in the context of a new area of regulatory endeavour, or simply, old issues in new life forms.

This submission is divided into three parts. The next part addresses a number of specific issues raised in the Green Paper. Part 3 then examines in detail a number of these issues by proposing the operative principles or elements of a regulatory regime for biotechnology in Canada. Part 4 then examines the need for an education component which supports the regulatory program. The last part reviews and summarizes the recommendations of the paper.

2. COMMENTS ON SECTION VII OF THE GREEN PAPER - "ISSUES OF CONCERN TO ONTARIO"

This section will briefly comment on the issues raised in section VII of the Green Paper, entitled "Issues of Concern to Ontario." The issues commented upon are restricted to those areas this paper has focused upon - namely, those issues concerned with the release of biotechnological products into the environment.

ISSUES THE GREEN PAPER DOES NOT ADDRESS

It is essential to first note that the Green Paper neglects to deal with a number of fundamental issues that must be included in any policy development document for this industry. These issues are as follows:

* Ethical Issues Arising from Biotechnology - The Green Paper assumes that biotechnology is inherently devoid of any ethical or philosophical issues pertaining to the genetic engineering and manipulation of life forms. However, the biotechnology industry does raise a number of ethical issues which should be publically discussed and debated. Some of these issues include: Are there any biotechnological techniques or products that are, from a societal standpoint, unacceptable? Are there any limits to this industry, whether in the laboratory or in the environment? Who should decide these limits and in what fashion?

* Long-term Ecological Implications of Biotechnology - The Green Paper assumes, by and large, that the only notable risks of biotechnology are those associated with "something going wrong" - such as when a biotechnological product does not perform in an intended fashion. In addition to these risks, however, it is imperative to evaluate the long term risks associated with the release of genetically altered organisms into the environment - whether such organisms are new bacterial life forms or cross-breeds of crops. Certainly if such an analysis was undertaken at the onset of the "chemical revolution" following the Second World War, the optimism as to the benefits of the industry would have been severly dampened - especially if the costs of remediating toxic landfills, controlling contaminated sediments, and costs of evaluating and addressing the suspected human health impacts of persistent toxic chemicals are factored into the deliberations.

* Sustainable Development and Biotechnology - With the release of the report by the World Commission on Environment and Development, Our Common Future, (the Brundtland Report), governments have been urged to take alternative approaches as to how they do business. These approaches suggest that the environment should not be an "add-on" consideration to government policy, but an integrated part of the decision-making process; that a preventive approach is preferred over a "react and cure" approach, and that the public participate in all important environmental decisions. Unfortunately, the Green Paper neither explicitly nor implicitly recognizes these elements of

sustainable development. Hence, while the Government of Ontario on one hand boasts of its commitment to this concept, on the other it only gives "lipservice" to it when approaching an incredibly important new regulatory field - biotechnology.

ISSUE 2 OF THE GREEN PAPER - The Need for Mandatory Controls

The issue, as framed in the Green Paper, is whether mandatory controls for all types of biotechnology necessary to safeguard human health and the natural environment are necessary. Unfortunately, the context and intent of this issue is so vague that a coherent response is difficult. The essential point should be that mandatory controls should be required where there is actual or potential threat of harm to human health or the environment.

ISSUES 5 and 6 OF THE GREEN PAPER - Assessment of Safety of Biotechnological Processes

This issue is dealt with below, under section 2.2 (c). The basic thrust of this submission is that Ontario should develop an independent assessment process that is coordinated with the federal process and employs the available information and expertise from the federal process. Because there is a division over legislative authority to deal with biotechnology, this approach seem virtually inevitable. In other words, this approach is somewhat similar to Option 2 of the Green Paper. The primary difference is that, in our view, Ontario should employ a process that works towards making an independent assessment, even though the process may rely on federal information. However, the option

would still exist to collect and utilize further or other information).

ISSUE 8 - Needs of Investors and Innovators

As with Issue 2, the context and intent of this issue is too vague for a comprehensive response. Who are these innovators and investors? What is a "single standard of regulatory control"? In our view, a biotechnological policy for Ontario should be motivated by the desire to protect the long-term sustainability of the social and natural environment of Ontario. Other considerations such as the needs of innovators and regulations in other jurisdictions are secondary to these primary considerations and objectives.

ISSUE VII.2B OF THE GREEN PAPER - Environmental Releases, Discharges, Emissions and Waste Disposal

Subissue 1 - Should there be shared responsibility between federal and provincial governments governing biotechnology?

For all intents and purposes, there already is shared responsibility. The operative principle remains that the province has the prime onus to ensure that the industry develops in a manner which safeguards human and environmental health. In other words, Ontario decision-makers must decide whether the federal controls of biotechnology under the Canadian Environmental Protection Act are sufficient to deal with all the regulatory issues in this industry.

Subissue 2 - Should Existing Laws be Applied to Biotechnology?

See Section 3.1 below for a more comprehensive response. In our view, existing law is not sufficient to deal with open

environment releases of biotechnological products.

Subissue 3 - Pesticide Approval

In our view, separate protocols should be developed for biotechnological products in this field for reasons outlined in section 3.1.

ISSUE VII.2C OF THE GREEN PAPER - Communications, Public Education and Participation

See section 4 of this submission below.

3. TOWARD A LEGAL FRAMEWORK FOR BIOTECHNOLOGY IN ONTARIO

3.1 Introduction

Section VIII of the Green Paper, "Possible Legal Frameworks for Ontario", discusses alternative regulatory approaches to govern biotechnological activities in Ontario. Approach 1 involves the development of a new "Biotechnology Act" that would provide centralized receipt of notification of all biotechnological work and a "single window" referral mechanism to provincial control requirements. Apart from the notification and referral system, it would rely on existing environmental laws to control biotechnology. Approach 2 would also build on the existing legislation that provides for the control of chemical substances. It would require that some existing legislation be amended to control biotechnology.

Apart from the notification and referral issues, there are few differences between the two approaches. In our view, there are major weaknesses or gaps in both "Approach 1" and "Approach 2" because both rely on existing statutes and regulations to control biotechnology. These weaknesses and gaps include:

A. The existing legal framework was designed to evaluate toxic impacts from chemicals and to control chemical discharges and waste disposal. By relying on these controls to regulate biotechnology, there is an assumption that existing controls for chemicals can be transferred to deal with the wide range of issues pertaining to biotechnological issues verbatim,

or with slight modifications, and that such controls are appropriate for all biological risks, just because they are used to deal with chemical risks. Hence, there is no comprehensive review of what special regulatory provisions are needed, whether control regimes for chemicals are suited to control biolotechnological risks, and whether there are more efficient and effective regulatory controls available in light of the acceptance of contemporary policy concepts such as sustainable development.[1] In fact, the Green Paper conceded that the Ontario Environmental Protection Act[2] and the Ontario Water Resources Act[3] "do not currently regulate products for deliberate release into the environment."[4]

B. Second, by importing existing controls, the biotechnology regulatory framework would automatically import all weaknesses, deficiencies, and inequities from existing regulatory regimes. In particular, it would import weaknesses dealing with public participation in environmental decisions, exclude pollution prevention approaches in favour of the traditional pollution control approaches, and continue the deficiencies of the common law with respect to liability and compensation.

In our view, the question which must be addressed at this time is simply this - what kind of regulatory regime is needed to deal with biotechnology in Ontario? What would be the components of this regime? The decision as to whether existing laws are appropriate can only be responded to once these questions have been examined. In our view, the response will be that some of the

existing controls will be appropriate for biotechnology. However, there will also be many areas where new regulatory provisions will be needed to deal with this industry.

What is the nature of these needed regulatory provisions for biotechnology? It is not possible to give a full and comprehensive analysis of the weaknesses of all existing law and policies nor the need for reforms to remedy those weaknesses. What is possible, however, is to provide an overview of the necessary components of an appropriate legal framework for open environment releases for biotechnological products.

3.2 Components of a Legal Framework

In our view, a regulatory regime for biotechnology, and in particular, those aspects relating to open environment releases, must include the following elements or components:

(a) stated policy objectives;

(b) notification and referral provisions;

(c) an assessment and an approval process;

(d) effective public participation mechanisms;

(e) provisions to deal with accidental releases;

(f) a regime to deal with liability and compensation for damages or injury accruing from biotechnological releases;

(g) and some institutional reforms.

Each of these components are discussed below.

(a) Policy Objectives

The policy objectives set out in section 1.2 of the Green Paper provide an initial basis for discussion of a regulatory

biotechnology regime.

The primary comment with respect to these objectives is that they could be more specific to allow them to be more useful to decision makers and to clarify the policy intentions of the government. More particularly, in our view the first policy objective, namely, "to develop policy that assures protection of human health and the environment in a timely and sensitive manner", should specify the nature and context of this policy development process.

For instance, it should state that such policy will be undertaken with a "prevent and anticipate" approach to environmental regulation; that the concept of inter-generational equity is taken into consideration; that the public have fair opportunity for input into important decisions; and that those proposing risks have the onus of demonstrating that their activities are environmentally acceptable.

By making these policy objectives explicit, guidance will be given to those in charge of implementing the policy. Those subject to the policy, would also have a clear indication of the government's intentions.

The second objective, namely that the desire "to define an appropriate regulatory framework that sets out the requirements for all biotechnological work in Ontario", may be too ambitious. In other words, some biotechnological work, such as the making of beer, may be eventually excluded from a special regulatory regime for biotechnology. The issue in this context, then, is not that

all biotechnological work is part of a regulatory regime - but how biotechnological work is defined.

The third objective, the desire to seek "consistency with requirements in other jurisdictions" is difficult to comment on until there is a better understanding of the regulatory direction of those other jurisdictions. Certainly Ontario should regulate the industry in a way that it feels appropriate to protection human and environmental health. Consistency is important only when there has been agreement by the jurisdictions that the overall goals and objectives are similar and the regulatory controls of those other jurisdictions are not weaker than those adopted in Ontario.

(b) Notification and Referral

As noted above, the strengths of the possible legal frameworks for Ontario in Section VIII of the Green Paper were with respect to the notification and referral issues. In our view, the process outlined in Approach 1 is the most coherent, namely, that:

> All private and public sector parties engaged in biotechnological work would be required to notify the central agency, in accordance with the standardized information requirements.
>
> The central agency would assess the notifications to prevent federal-provincial jurisdictional overlap in responsibility and to provide the notification package to the appropriate ministry or ministries for specific regulatory action.
>
> Individual ministries would deal directly with the applicant, and the central agency would be kept informed of the applicable control requirements.

The nature of this "central agency" is discussed below, under "institutional considerations".

(c) Assessment and Approval Process

Having notified the appropriate agency, the next challenge is to assess the undertaking. According to both Approach 1 and 2, "Existing statutes and regulations would be used to control biotechnology." It is not clear what this statement means. Does it mean that all biotechnological controls will be tacked onto existing controls for chemicals? What about known and foreseen deficiencies and gaps?

In our view, what is needed is a process to assess, approve and monitor the release of biotechnological products in a way that is tailored to the industry. This process would encompass an agency approval for all biotechnological releases. Under certain circumstances, the approval decisions could be challenged before the Biotechnological Approval Board [described under subsection (g) below]. This Board would then determine a fair hearing process, including the right to intervene by interested parties and the right to adduce evidence by those intervenors.

A. Agency Approval

The agency approval process would incorporate the following components:

(i) Documentation

Once an agency is notified of a proposed release, it is imperative that enough information be forwarded by those proposing an environmental release to enable a full assessment of

the risks and an approval decision to be made. For example, the documentation would include information from the proponents; tests and studies as to the nature and basic characteristics of the new life forms, the nature of the environments in which the release will be made, and information on the demonstrable impacts of release to that environment.

This documentation may simply be the information submitted under the requirements of the Canadian Environmental Protection Act. At this time, the issue is whether existing law could require this information. Special provisions may have to be made for information pertaining to trade secrets.

(ii) Technical Review

Once the documentation is received, it is imperative that it be assessed by a qualified, independent body or group as to the risks associated with its release. This body or group would review, study, and report to the agency decision-maker, who then could either accept the report or send it back for further review.

In a sense, this task could be accomplished by an inter-agency review, together perhaps with a roster of qualified experts who are employed outside of the government.

(iii) Public Comment

When the documentation has been received and BEFORE it is officially approved by the agency, it is imperative that the public has the opportunity to comment and provide their views on the application. The issue of public comment is discussed more

fully below under public participation.

(iv) Regularized Criteria

Once the documentation has been assessed, it is necessary for regularized criteria or a standard set of factors to be developed and set out either in legislation or by way of guidelines. These factors or considerations are important to add certainty to the process, minimize the discretion of the decision-maker, and to ensure fairness to all applicants.

Some of the factors which may make up this criteria include: what policy objectives the decision should strive to accomplish, certainty of information, precautions and mitigation measures available, and other such criteria. The process should not be simply one of quantitative risk assessment - a methodology which is not appropriate for biotechnology.

(v) Decision Options

The agency decision maker should have the flexibility in approving the releases. For instance, numerous conditions could be attached to the approval, including when and in what matter released could take place, in what environments, or in what concentrations or quantities.

(vi) Onus of Proof

Finally, within the context of the assessment process, it must be made clear that the proponent of the proposed release has the onus to establish that the release is environmentally acceptable. Hence, unlike chemical regulation, the onus would not be on governmental agencies or the public to prove the risks of

the undertaking - the initiator of the risks has the onus of establishing those risks are acceptable.

B. REVIEW OF DECISION BY AN ADMINSTRATIVE TRIBUNAL

Once an agency has made a decision with respect to an environmental release, there should be circumstances where this decision could be challenged before an administrative tribunal. A tribunal, perhaps called the Biotechnological Approval Board, discussed below, would hear applications for review. The practice and procedure of this tribunal would incorporate the same principles that were described with respect to agency approval, including those principles dealing with documentation, regularized criteria, decision options, and onus of proof. Interested parties would be allowed to intervene with the benefit of intervenor funding. Once the Board had heard the evidence and submissions of the parties, it can make a decision to confirm, amend, or reject the initial agency decision.

(d) Public Participation

It is inevitable that the release of genetically engineered life forms into the natural environment will create some risks. Ultimately, it is the Ontario public that will have to bear the burden of those risks, and hence, should have a say as to which risks are acceptable. Public participation is an essential and needed part of any regulatory regime pertaining to environmental protection - a component which has yet to become integral to Ontario law. Public participation should be guaranteed at the agency and board levels, as described above. For example, under

the Environmental Protection Act,[5] there is no requirement that notice be given of an application for a certificate of approval, no right to comment on the adequacy or completeness of the certificate, no right to challenge the data it is based upon, and no right to appeal a decision to grant the certificate. Often, it remains a closed process between the regulators and the regulated, to the exclusion of those that must bear the ultimate risks of the activity - the public.

To overcome these weaknesses, there has been a decade long struggle to have the Ontario government enact an "Environmental Bill of Rights" - a law which would ensure that Ontarians have the right to a healthy environment, the right to enforce environmental laws, and the right to participate in environmental decisions.[6]

In light of these deficiencies in Ontario law pertaining to public participation, there is grave concern that past mistakes to exclude the public under present law will be repeated when designing a regime for a relatively new industry, especially in light of such statements in the Green Paper that "Existing statutes and regulations would be used to control biotechnology..."

In order to remedy these problems, it is proposed that the following avenues for public involvement be included in a biotechnology regulatory regime -

a. access to the documentation submitted in support of the application;

b. opportunity to comment on the adequacy of the documentation;

c. in certain circumstances, the ability to challenge the adequacy of the documentation in a hearing format, including the opportunity to adduce additional evidence;

d. the availability of intervenor funding by the proponent to ensure all parties have adequate resources in the approval process;

e. the right to have submissions considered and responded to in the final decision;

f. in certain circumstances, the right to appeal an adverse decision or have it reviewed, with minimum standing requirements.

(e) Accidental Releases

Ecological consequences from accidental releases can be greatly reduced, sometimes even avoided, with the appropriate emergency response strategies. In Ontario, are strategies in place for biotechnological emergencies? Formalized methods and procedures to provide for the reporting, containment and clean up of accidental releases are likely inadequate. For open environmental releases, the emergency response strategies, it is submitted, may have to be more stringent than those for chemical emergencies. Any regulatory regime, therefore, must include procedures to ensure proper coordination of personnel and equipment, and proper methods of removal and disposal of released

products.

(f) Liability and Compensation

One of the areas ignored by the Green Paper is the issue of liability and compensation for damages occurring as a result of the release of the biotechnological product. As a general rule, it is fair to say that traditional common law doctrines have been ill-suited to deal with many of the issues inherent in an environmental lawsuit. These weaknesses have been noted elsewhere:

> To generalize, in order to be compensated for harm, a plaintiff must establish that the particular requirements of the tort are fulfilled. The plaintiff also has the onus of establishing the causal nexus between the activities of the defendant and the harm for which compensation is being sought. There also exist more general obstacles to recovery including the lack of standing to enforce "public" rights, limitation periods which do not account for latent effects, limitations on the kinds of harm which can be compensated and the high cost and delay involved in litigation.[7]

Liability and compensation issues pertaining to biotechnological releases would only exacerbate these problems. In terms of causation, for example, it may be decades after the release of new life forms into the environment before any impact on the ecosystem and humans is detected or fully understood. Similarly, if the release causes a chain reaction of events, it is difficult to assess liability owing to the impossibility of delineating the consequences of natural factors and those occurring from the release of new life forms.

If there is a more generic harm, such as ecological disruption with resultant species loss, it is unlikely that individuals could seek remedy for such consequences. The law essentially is designed to protect individual rights, and not the right to protect the environment for its own sake.

Even if standing was granted and causation proved, the assessment of damages would be a very troublesome task. Common law has not been well-suited for this task leading some jurisdictions to create compensation funds for the clean-up and compensation of environmental disasters. While there are a few compensation funds in Canada, it is very doubtful if they would pertain to the release of biotechnological products.

In our view, therefore, it is imperative that, before there is an ecological disaster, a compensation fund should be established that would provide a pool of monies for clean-up, compensation, and remediation. In terms of a liability regime, there are a number of schemes this fund could be modelled after, including Part IX under the Environmental Protection Act [Spills Bill].[8]

(g) Institutional Considerations

The Green Paper, under Approach 1, proposed "a 'single window' referral mechanism to provincial control requirements. This agency would develop and administer the provincial notification system and would facilitate referral to the appropriate ministry or ministries for detailed assessment."[9] Another function of this body would be to liaise with federal

responsible for the Canadian Environmental Protection Act, Pest Control Products Act, among other relevant agencies. The body, then, would serve a coordinating role to ensure there is the minimum of duplication and the maximum of efficiency.

In our view, this "single window" referral mechanism is appropriate and the preferred option. It will avoid duplication of efforts and efficiency of processes for all sector of society. The additional time and resources required to introduce and implement a new agency should not deter the long-term benefits from this endeavour.

As noted above, our view is that there should be an approval board to review, in certain circumstances, agency decisions pertaining to environmental releases. This body, we called the Biotechnology Approval Board, could merge its functions with the notification and referral functions. Some consideration would still be necessary to determine how best to integrate these functions, although a single coordinating body would at this time seem preferable.

4. BIOTECHNOLOGY - EDUCATING THE PUBLIC

4.1 The Need for An Educational Component

Under section VII.2C, "Communication and Education", the Green Paper advocates raising awareness and increasing the understanding of the parties in relation to the techniques, the potential hazards and the issues associated with biotechnology. In our view, sufficient resources and efforts by both government and industry are not being devoted to education of the public about these issues. What justifies the need for a strong education component? There are at least three arguments to support this component.

(a) To Fulfill the Stated Policy Goals

The objective of the Green Paper is "to give Ontarians an opportunity to participate in the development of regulatory policies relating to the exciting new advances in biotechnology." However, despite this objective, there has been little work undertaken by either government or industry to make the public aware of the issues in the field of biotechnology. The Green Paper is virtually devoid of an education plan to equip Ontarians with the necessary tools to effectively participate in the policy development process.

An education component to the biotechnology process is also necessary in order that an informed public can assist the government in achieving its primary policy goal of "protection of human health and the environment in a timely and sensitive

manner", as outlined in section 1.2 of the Green Paper. The role that the public can play in the process is only as effective as the plans that are in place to ensure that the public is aware and informed of the issues at hand. The public will need to be informed about biotechnology, its risks and benefits, before it can effectively contribute to any government process.

(b) To Ensure a "Prevent and Anticipate" Approach

When there is a basic understanding of the issues by all affected interests, the decision-maker can then evaluate the impacts, both short term and long term, on all constituencies. By using this approach, then, there is the potential to anticipate the consequences of important decisions.

(c) To Effectively Participate in the Decision- Making Processes

Industrial, governmental, and private interests are all influenced by different values and needs which causes them each to adopt varying mandates on societal issues. The evaluation of the limits and values of biotechnology are ethical questions based on scientific data and opinions. The needs of society and the risks that the population is willing to take are value judgments that only an educated public can make due to the complex nature of the issue. If the different sectors of society are to understand the range of views involved, including the uncertainty associated with risks that are poorly defined or unknown, and be able to communicate their priorities in a literate and contributing manner, then an education component to

the biotechnology process is essential.

During the decision-making processes pertaining to health and environment, the only way that decision makers will be able to account for the varied perspectives and priorities that the public holds will be to encourage the involvement of an educated group of people. Due to the potentially far-reaching positive and negative effects of biotechnology, all segments of society should have the opportunity to participate in important decisions with regard to biotechnology. To effectively participate in this process, those sectors must be informed and aware of the issues and trade-offs.

In summary, if the government is interested and committed to ensuring a fair process for the regulation of biotechnology, it is imperative that a coherent, comprehensive education component be undertaken to ensure that all constituencies in Ontario are cognizant of the benefits and risks of this new industry. Unless this component is undertaken, neither the policy objectives in the Green Paper nor the commitment to a fair process can be truly achieved.

To assist in the understanding of our vision of a widespread public education campaign we have detailed our proposal for such a campaign in the next section.

4.2 Toward an Education Component for Biotechnology - A Suggested Framework

The educational component proposed can be viewed as having an institutional focal point as well as target audiences. Each of

these elements are discussed below.

(a) The Institutional Framework

The institutional framework for biotechnology would include a biotechnology resource centre and multistakeholder biotechnology roundtable.

(i) Biotechnology Resource Centre

The Biotechnology Resource Centre (BRC) will act as a central coordinating body to:

* provide an educational centre where information and material on biotechnology could be displayed, exchanged and catalogued;

* chair or facilitate the roundtable discussion outlined below;

* assist the roundtable in producing publications aimed at making all sectors of society more aware of the issues pertaining to biotechnology.

In short, the Biotechnology Resource Centre is the education arm of the Biotechnology Approval Board. They would work in conjunction with each other and share similar goals and philosophies.

(ii) Biotechnology Roundtable

The Biotechnology Roundtable will provide a forum for policy development in the area of biotechnology. The Roundtable would be comprised of all stakeholders in the biotechnology industry - government, academic institutions, the public, industry, etc. The primary task of the Roundtable would be to facilitate discussion

on important topics through the sponsoring of conferences, workshops, and seminars. The roundtable would discuss ethical issues facing the industry, socio-economic matters, and regulatory reforms. In this context, it would work with other bodies in publishing studies, reports, manuals, discussion papers on relevant topics related to current issues in biotechnology. One of its first tasks, for instance, would be the development and publication of a Biotechnology Primer, a booklet which would explain, in comprehensible terms, the ambit of issues facing biotechnology. Audio visual aids to education are also recommended, such as a video presentation.

The Roundtable would also be an advisory body to the Biotechnology Resource Centre to ensure that the educational component of biotechnology is being undertaken in an effective and efficient manner.

(b) Some Targeted Audiences

In the initial stages of the educational component, it is important that certain audiences be targeted owing to the fact that these audiences then can educate their constituencies. Eventually, the education component matures, and the nature of the audiences can expand and become more diverse.

(i) Public Interest Groups

Consideration should be given to providing opportunities for public interest groups (consumer groups, environmental groups, labour groups, among others), to produce educational material on biotechnology, undertake some research in the area, to sponsor

activities aimed at educating their members on both the benefits and risks of this industry, and generally attempt to simplify the world of biotechnology for the public to facilitate widespread understanding of the term. These groups could provide liaison with the Biotechnology Roundtable and the Biotechnology Resource Centre.

While public interest groups are part of the Biotechnology Resource Centre, it is essential that these groups also become empowered through access to information and resources to enable them to work with these issues in their own fields of interest.

(ii) Industry

It is also important that special attention be given to specific industries and industrial associations to ensure that they participate in the public dissemination of information on the industry and issues related to it. They should be encouraged to develop their own educational components pertaining to their products and the process employed in making their products.

In this context, industry then plays two roles. One is assisting in the broader dissemination of information on biotechnology and the other is the education of their own constituency to ensure that a high level of understanding of the regulatory and policy regime among the industrial group.

(iii) Educators/ Teachers

Further, concerted efforts must be made to integrate biotechnological material in the educational curriculum at all levels - materials that would explore the full range of issues

facing biotechnology (such as ethical, regulatory, economic, scientific, etc.,), to ensure that younger members of society are fully informed and aware of this industry.

Workshops should also be developed to be held by the Biotechnology Resource Centre to familiarize teachers with the new curriculum. Tools such as videos would be used in senior grade levels.

(iv) Decision-Makers

Finally, it is important that decision makers be a targeted audience so as to ensure they have an appropriate background to biotechnology. For example, a relevant pamphlet could be developed and disseminated suited to the particular needs of the decision makers.

4.3 Tools Needed to Implement the Education Component

What then are some the mechanisms needed to implement the education component? A number of these tools are as follows, including a few that have already been mentioned:

* a Biotechnology Resource Centre which would focus on the direct the education component;

* publications directed to varied audiences on a broad range of issues facing biotechnology, and in particular, a biotechnology primer;

* allotted resources to undertake a broad-based advertising campaign on the topic. This campaign would be targeted at consumers and would provide information as to the effects of consumer products.

5. SUMMARY OF RECOMMENDATIONS

In our view, Ontario is at an important point in the development of biotechnology policy. On one hand, biotechnology can be considered in the context of traditional regulatory concepts and controls with the necessary piecemeal modifications. On the other hand, there is the opportunity to take a fresh approach to this new industry in order to incorporate contemporary concepts and regulatory themes and more importantly, to overcome some of the inherent weaknesses in existing regulatory structures. We strongly favour the latter approach to ensure that past mistakes are not repeated and that this industry is based upon fair and equitable principles acceptable to all members of society.

Our main recommendations may be summarized as follows:

1. The Green Paper should incorporate a discussion of:

(a) ethical issues concerning biotechnology;

(b) long term ecological implications of biotechnology releases; and

(c) the interrelationship between sustainable development and biotechnology.

2. A comprehensive regulatory regime should be developed for biotechnology, especially with respect to open environment releases, with the following components:

(i) an agency decision-making process that includes the right to have an administrative board review of the decision in

certain circumstances;

(ii) these processes should include the features of notification and referral; full documentation; assessment and approval; and effective public participation;

(iii) provisions to deal with clean up of accidental releases and liability and compensation;

(iv) the development of a comprehensive and effective education campaign for all sectors of society.

1. This review has been begun, although there is considerable amount of work yet to do, see: Canadian Institute for Environmental Law and Policy [Formerly, the Canadian Environmental Law Research Foundation], Biotechnology Policy Development Volumes 1 and 2, June, 1988. Also see: Valiante and Muldoon, "Biotechnology and the Environment: A Regulatory Proposal" (1985), 23 Osgoode Hall Law Journal 359.

2. R.S.O. 1980, c. 141, as amended.

3. R.S.O. 1980, c. 341, as amended.

4. Green Paper, p. 17.

5. R.S.O. 1980, c. 141, as amended.

6. Paul Muldoon, "The Fight for Environmental Bill of Rights - Legislating Environmental Rights" (1988) Alternatives.

7. Valiante and Muldoon, "Biotechnology and the Environment: A Regulatory Proposal" (1985), Osgoode Hall Law Journal, vol 23, 359, at 380.

8. R.S.O. 1980, c. 141, as amended, Part IX.

9. On page 16 of the Green Paper, it was also noted that "a mechanism will be needed for sharing information between the two levels of government".