Canadian Environmental Law Research Foundation

BIOTECHNOLOGY AND THE ENVIRONMENT

A REGULATORY PROPOSAL

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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 natural 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 environment 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 of the applicable technique, 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 "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 fo 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 of 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.

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 provies 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.

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, toxic, inflamamable, explosive 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 to 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

to have on hand and available such equipment and materials necessary to alleviate the effect of any contaminant of 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 or 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 course 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 fo 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 measurers 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 lead 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 biotechnical 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

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 fo the public interest and the goal of economic and industrial prosperity is sometimes a tenuous one. On 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 lays ahead will be attempting to find that middleground where the risks are minimalized without unduly or prematurely "chopping the kees 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 form 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, could 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 framewrk 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 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 makes its 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;

impacts of release to that environment. The basis of this requirements 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

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 ensue 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-in to 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 by ensuing 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 releases, 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.

In order to fulfill these goals, it would be necessary for each province to adopt legislation detailing the provisions of its scheme. No doubt in some instances, or for some aspects of its responsibilities, provinces may be able to amend some of its existing laws or expand some of its 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 licence 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 but 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 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 would 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 common however, Parliament has relied on its residual power found in section 91 of Constitution Act, 1967 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 falls within both the second and third circumstance, 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 sue 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 that all will be able to enjoy these benefits without having to unduly risk 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. Castrill 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. For eg. 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. For eg., see: P.S. Elder " Environmental Protection Through The Common Law" (1973), 12 West. Ont. L. Rev. 107.

29. For eg., see Boomer v. Atlanta 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 on 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 condition attached thereto.

37. For eg. 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 mediam (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. For eg., see the Motor Vehicle Safety Act, R.S.C. 1970 (1st Supp.), c. 26, as amended.

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

46. For eg. see the Criminal Code, R.S.C. 1970, c. C-34, as amended See: Standards 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. For eg., The Clean Air Act S.C. 1970-71-72, c. 47, as amended. The Clean Air Act, R.S.C. 1970 (1st Supp) c.5. Also see: R. v. Canada Metal Co. Ltd. 1982 7 W.C.B. 430 (Man. Prov. Ct.) 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.O. 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 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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